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Presidential Documents

Title 3—

The President

Proclamation 7930 of September 16, 2005

National POW/MIA Recognition Day, 2005

By the President of the United States of America

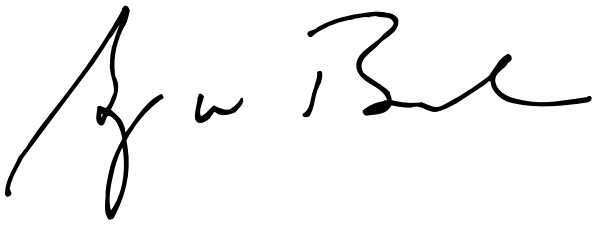
A Proclamation

In every generation, members of our Armed Forces have answered the call of service in our Nation's hour of need. These patriots have defended our freedom and way of life, triumphed over brutal enemies, and answered the prayers of millions. On National POW/MIA Recognition Day, we honor the Americans who have been prisoners of war and recognize them for enduring unimaginable hardships while serving in military conflicts around the globe. We also remember those who are still missing in action, and we renew our commitment to keep searching until we have accounted for every Soldier, Sailor, Airman, and Marine missing in the line of duty.

On National POW/MIA Recognition Day, the flag of the National League of Families of American Prisoners and Missing in Southeast Asia is flown over the White House, the Capitol, the Departments of State, Defense, and Veterans Affairs, the Selective Service System Headquarters, the National Vietnam Veterans and Korean War Veterans Memorials, U.S. Military Installations, national cemeteries, and other locations across our country. The flag is a reminder of our continued commitment to those brave patriots imprisoned while serving in conflicts around the world and of our pledge to continue to achieve the fullest possible accounting for all our men and women in uniform who are still missing. Americans are blessed with the freedom made possible by the service and sacrifice of so many. On National POW/MIA Recognition Day, our entire Nation honors and pays special tribute to our prisoners of war and those who remain missing.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Friday, September 16, 2005, as National POW/MIA Recognition Day. I call upon the people of the United States to join me in saluting all American POWs and those missing in action who valiantly served our country. I call upon Federal, State, and local government officials and private organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of September, in the year of our Lord two thousand five, and of the Independence of the United States of America the two hundred and thirtieth.



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Rules and Regulations

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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.

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AH77

List of Approved Spent Fuel Storage Casks: Standardized NUHOMS® 32PT, –24PHB, and –24PTH Revision 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations revising the Transnuclear, Inc., Standardized NUHOMS® System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 8 to Certificate of Compliance Number (CoC No.) 1004. Amendment No. 8 to the Standardized NUHOMS® System CoC will add a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and modify the NUHOMS®–32PT and –24PHB dry shielded canister designs.

DATES: The final rule is effective December 5, 2005, unless significant adverse comments are received by October 20, 2005. A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. If the rule is withdrawn, timely notice will be published in the **Federal Register**.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150–AH77) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@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. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking Web site to Carol Gallagher (301) 415–5905; e-mail *cag@nrc.gov.* Comments can also be submitted via the Federal eRulemaking Portal *http://www.regulations.gov.*

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of 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 PDR Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* An electronic copy of the proposed CoC, Technical Specifications (TS), and preliminary safety evaluation report (SER) can be found under ADAMS Accession No. ML051610554.

CoC No. 1004, the revised TS, the underlying SER for Amendment No. 8, and the Environmental Assessment (EA), are available for inspection at the NRC PDR, 11555 Rockville Pike, Rockville, MD. Single copies of these documents may be obtained from Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6219, e-mail *jmm2@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, telephone (301) 415–6219, e-mail *jmm2@nrc.gov,* of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended (NWPA), requires that ''[t]he Secretary [of the Department of Energy (DOE)] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the NWPA states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 218(a) for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the NRC approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule in 10 CFR part 72 entitled, ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L within 10 CFR part 72, entitled ''Approval of Spent Fuel Storage Casks'' containing procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on December 22, 1994 (59 FR 65898), that approved the Standardized NUHOMS® System (NUHOMS®–24P and –52B) cask designs and added them to the list of NRC-approved cask designs in

§ 72.214 as CoC No. 1004. Amendments 3, 5, and 6, respectively, added the –61BT, –32PT, and –24PHB designs to the Standardized NUHOMS® System.

Discussion

On September 19, 2003, and as supplemented on January 22, April 21, May 28, July 6, August 16, September 17, September 23, October 8, October 11, October 26, November 29, 2004, and January 14, March 15, June 10, and July 20, 2005, the certificate holder, Transnuclear, Inc. (TN), submitted an application to the NRC to amend CoC No. 1004 to add a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and to modify the NUHOMS®–32PT and –24PHB dry shielded canister (DSC) designs. The NUHOMS®–24PTH System consists of new or modified components: (1) The –24PTH DSC; (2) a new –24PTH DSC basket design; (3) a modified horizontal storage module (HSM), designated the HSM–H; and (4) a modified transfer cask (TC), designated the OS 197FC TC. The NUHOMS®–24PTH System is designed to store fuel with maximum average burnup of up to 62 gigawatts-day/metric ton of uranium (GWd/MTU); maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kilowatts (kW) per DSC. TS 1.2.18 and Table 1–1l are augmented to restrict the –24PTH DSC basket heat loading patterns to those analyzed in the Safety Analysis Report (SAR), and TS 1.2.17c is revised to delete the use of air for blowdown of the –24PTH DSC before drying operations. The changes to the –32PT and –24PHB systems include: (1) Revising the –32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the –32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the –24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12. No other changes to the Standardized NUHOMS® System cask design were requested in this application. The NRC staff performed a detailed safety evaluation of the proposed CoC amendment request and found that an acceptable safety margin is maintained. In addition, the NRC staff has determined that there continues to be reasonable assurance that public health and safety and the environment will be adequately protected.

This direct final rule revises the Standardized NUHOMS® System cask design listing in § 72.214 by adding Amendment No. 8 to CoC No. 1004. The amendment consists of changes to the TS as described above. The particular TS which are changed are identified in the NRC staff's SER for Amendment No. 8.

The amended Standardized NUHOMS® System, when used in accordance with the conditions specified in the CoC, the TS, and NRC regulations, will meet the requirements of part 72; thus, adequate protection of public health and safety will continue to be ensured.

Discussion of Amendments by Section

Section 72.214 List of Approved Spent Fuel Storage Casks

Certificate No. 1004 is revised by adding the effective date of Amendment Number 8.

Procedural Background

On May 25, 2005, a direct final rule (70 FR 29931) and companion proposed rule (70 FR 30015) were published in the **Federal Register**, to revise the cask system listing for the TN Standardized NUHOMS® System, by adding Amendment No. 8 to the list of approved spent fuel storage casks in 10 CFR 72.214. After the rules were published, staff became aware of needed changes in the TS associated with the CoC, and on July 15, 2005, the NRC withdrew the direct final rule (70 FR 40879) and the proposed rule (70 FR 40924). This direct final rule includes the original Amendment No. 8 changes, the revised TS 1.2.17c and 1.2.18, Table 1–1l, and additional changes, as discussed above. These additional changes were originally to be addressed as a subsequent amendment. However, the withdrawal of the May 25, 2005, package allowed the staff to combine this information into Amendment No. 8. This results in a more effective and efficient use of resources.

This rule is limited to the changes contained in Amendment No. 8 to CoC No. 1004 and does not include other aspects of the Standardized NUHOMS® System design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on December 5, 2005. However, if the NRC receives significant adverse comments by October 20, 2005, then the NRC will publish a document that withdraws this action and will address the comments received in response to the proposed amendments published elsewhere in this issue of the **Federal Register**. A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, in a substantive response:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the CoC or TS.

These comments will be addressed in a subsequent final rule. The NRC will not initiate a second comment period on this action.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the Standardized NUHOMS® System cask design listed in § 72.214 (List of NRC-approved spent fuel storage cask designs). This action does not constitute the establishment of a standard that establishes generally applicable requirements.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category ''NRC.'' Compatibility is not required for Category ''NRC''

regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled ''Plain Language in Government Writing,'' directed that the Government's writing be in plain language. The NRC requests comments on this direct final rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading **ADDRESSES** above.

Finding of No Significant Environmental Impact: Availability

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in subpart A of 10 CFR part 51, the NRC has determined that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The rule amends the CoC for the Standardized NUHOMS® System within the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. The amendment adds a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and modifies the NUHOMS®–32PT and –24PHB DSC designs. The NUHOMS®–24PTH System consists of new or modified components: (1) The –24PTH DSC; (2) a new –24PTH DSC basket design; (3) a modified horizontal storage module, designated the HSM–H; and (4) a modified transfer cask, designated the OS 197FC TC. The NUHOMS®–24PTH System is designed to store fuel with maximum average burnup of up to 62 GWd/MTU; maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kW per DSC. TS 1.2.18 and Table 1–1l are augmented to restrict the –24PTH DSC basket heat loading patterns to those analyzed in the SAR, and TS 1.2.17c is revised to delete the use of air for blowdown of the –24PTH DSC before drying operations. The changes to the –32PT and –24PHB systems include: (1) Revising the –32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the –32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the –24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12. The EA and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the EA and finding of no significant impact are available from Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6219, e-mail *jmm2@nrc.gov.*

Paperwork Reduction Act Statement

This direct final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150–0132.

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 OMB control number.

Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On December 22, 1994 (59 FR 65898), the NRC issued an amendment to part 72 that approved the Standardized NUHOMS® System (NUHOMS®–24P and –52B) by adding it to the list of NRC-approved cask designs in § 72.214. Amendments 3, 5, and 6, respectively, added the –61BT, –32PT, and –24PHB designs to the Standardized NUHOMS® System. On September 19, 2003, and as supplemented on January 22, April 21, May 28, July 6, August 16, September 17, September 23, October 8, October 11, October 26, November 29, 2004, and January 14, March 15, June 10, and July 20, 2005, the certificate holder, TN, submitted an application to the NRC to amend CoC No. 1004 to add a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and to modify the NUHOMS® –32PT and –24PHB DSC designs. The NUHOMS®–24PTH System consists of new or modified components: (1) The –24PTH DSC; (2) a new –24PTH DSC basket design; (3) a modified horizontal storage module, designated the HSM–H; and (4) a modified transfer cask, designated the OS 197FC TC. The NUHOMS®–24PTH System is designed to store fuel with maximum average burnup of up to 62 GWd/MTU; maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kW per DSC. TS 1.2.18 and Table 1–1l are augmented to restrict the –24PTH DSC basket heat loading patterns to those analyzed in the SAR, and TS 1.2.17c is revised to delete the use of air for blowdown of the –24PTH DSC prior to drying operations. The changes to the –32PT and –24PHB systems include: (1) Revising the –32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the –32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the –24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12.

The alternative to this action is to withhold approval of this amended cask system design and issue an exemption to each general license. This alternative would cost both the NRC and the utilities more time and money because each utility would have to pursue an exemption.

Approval of the direct final rule will eliminate this problem and is consistent with previous NRC actions. Further, the direct final rule will have no adverse effect on public health and safety. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this discussion of the benefits and impacts of the alternatives, the NRC concludes that the requirements of the direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and

security. No other available alternative is believed to be as satisfactory, and thus, this action is recommended.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only the licensing and operation of nuclear power plants, independent spent fuel storage facilities, and TN. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR part 121.

Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 50.109 or 10 CFR 72.62) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined. Therefore, a backfit analysis is not required.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

■ 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 part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 72.44(g) also issued under secs. 142(b) and 148(c),(d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c),(d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

■ 2. In § 72.214, Certificate of Compliance 1004 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1004.

Initial Certificate Effective Date: January 23, 1995.

Amendment Number 1 Effective Date: April 27, 2000.

Amendment Number 2 Effective Date: September 5, 2000.

Amendment Number 3 Effective Date: September 12, 2001.

Amendment Number 4 Effective Date: February 12, 2002.

Amendment Number 5 Effective Date: January 7, 2004.

Amendment Number 6 Effective Date: December 22, 2003.

Amendment Number 7 Effective Date: March 2, 2004.

Amendment Number 8 Effective Date: December 5, 2005.

SAR Title: Final Safety Analysis Report for the Standardized NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72–1004.

Certificate Expiration Date: January 23, 2015.

Model Number: NUHOMS®–24P, –52B, –61BT, –32PT, –24PHB, and –24PTH.

* * * * *

Dated at Rockville, Maryland, this 1st day of September 2005.

For the Nuclear Regulatory Commission.

Luis A. Reyes,

Executive Director for Operations.

[FR Doc. 05–18662 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2005N–0338]

Medical Devices; Dental Devices; Classification of Oral Rinse to Reduce the Adhesion of Dental Plaque

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the oral rinse to reduce the adhesion of dental plaque device into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective October 20, 2005. The reclassification was effective March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Robert Betz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 125.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until

the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a document in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on January 14, 2005, classifying the Decapinol Oral Rinse into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On January 24, 2005, Sinclair Pharmaceuticals submitted a petition requesting classification of the Decapinol Oral Rinse under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that Decapinol Oral Rinse can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name oral rinse to reduce the adhesion of dental plaque and is identified as a device intended to reduce the presence of bacterial plaque on teeth and oral mucosal surfaces by physical means. The device type includes those devices that act by reducing the attachment and inhibiting the growth of bacterial plaque.

FDA has identified the following risks to health associated specifically with this type of device: (1) Ineffective plaque reduction, (2) alteration of oral flora, (3) adverse tissue reaction, (4) toxicity, and (5) improper use. The class II special controls guidance document aids in mitigating potential risks by providing recommendations on material characterization; validation of performance characteristics; testing and control methods; biocompatibility testing; and labeling. Therefore, on March 28, 2005, FDA issued an order to the petitioner classifying the device into Class II. FDA is codifying this device by adding § 872.5580.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for oral rinse to reduce the adhesion of dental plaque will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the device is not exempt from premarket notification requirements. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the oral rinse to reduce the adhesion of dental plaque they intend to market.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also concludes that the special controls guidance document contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque''; the notice contains an analysis of the paperwork burden for the guidance.

V. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Sinclair Pharmaceuticals, dated January 24, 2005.

List of Subjects in 21 CFR Part 872

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.5580 is added to subpart F to read as follows:

§ 872.5580 Oral rinse to reduce the adhesion of dental plaque.

(a) *Identification.* The device is assigned the generic name oral rinse to reduce the adhesion of dental plaque and is identified as a device intended to reduce the presence of bacterial plaque on teeth and oral mucosal surfaces by physical means. The device type includes those devices that act by reducing the attachment and inhibiting the growth of bacterial plaque.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque.'' See § 872.1(e) for the availability of this guidance document.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–18656 Filed 9–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–D–7579]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified 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: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, 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.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim 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 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 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.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as shown below:

State and County	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Connecticut:					
Litchfield	Town of Harwinton.	September 6, 2005, September 13, 2005, *The Register Citizen*.	Ms. Marie Knudsen, Town of Harwinton First Selectman, Harwinton Town Hall, 100 Bentley Drive, Harwinton, Connecticut 06791.	Dec. 13, 2005	090147 B
Litchfield	Town of Litchfield	September 6, 2005, September 13, 2005, *The Register Citizen*.	Mr. Leo Paul, Town of Litchfield First Selectman, Town Offices, 74 West Street, P.O. Box 488, Litchfield, Connecticut 06759.	Dec. 13, 2005	090047 B
Litchfield	City of Torrington	September 6, 2005, September 13, 2005, *The Register Citizen*.	The Honorable Owen J. Quinn, Mayor of the City of Torrington, Municipal Building, 140 Main Street, Torrington, Connecticut 06790.	Dec. 13, 2005	095081 B
Pennsylvania:					
Chester	Township of Atglen.	August 11, 2005, August 18, 2005, *Daily Local News*.	The Honorable Wesley Vincent, Mayor of the Borough of Atglen, P.O. Box 250, Atglen, Pennsylvania 19310.	Nov. 17, 2005	420273 D
Lancaster	Township of Sadsbury.	August 11, 2005, August 18, 2005, *Parkesburg Post Ledger*.	Mr. N. Eugene Lammey, Chairman of the Township of Sadsbury Board of Supervisors, 7182 White Oak Road, Christiana, Pennsylvania 17509.	Nov. 17, 2005	421782 E
Chester	Township of West Sadsbury.	August 11, 2005, August 18, 2005, *Parkesburg Post Ledger*.	Mr. James Landis, Chairman of the Township of West Sadsbury Board of Supervisors, 6400 N. Moscow Road, Parkesburg, Pennsylvania 19365.	Nov. 17, 2005	422281 D

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: September 14, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–18729 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

ADDRESSES: The modified 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: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below of 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 Mitigation Division Director of the Emergency Preparedness and Response Directorate has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, 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 modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

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 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for Part 65 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.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community number
Alabama:					
Jefferson (FEMA Docket No. D–7571).	City of Homewood	March 21, 2005; March 28, 2005; *The Birmingham News*.	The Honorable Barry R. McCulley, Mayor of the City of Homewood, 1903 29th Avenue South, Homewood, Alabama 35209.	April 14, 2005	015006 E
Colbert (FEMA Docket No. D–7571).	City of Muscle Shoals.	March 25, 2005; April 1, 2005; *Times Daily*.	The Honorable David H. Bradford, Mayor of the City of Muscle Shoals, P.O. Box 2624, Muscle Shoals, Alabama 35662.	April 18, 2005	010047 C
Connecticut: New Haven (FEMA Docket No. D–7573).	City of Meriden	February 22, 2005; March 1, 2005; *Record-Journal*.	The Honorable Mark Benigni, Mayor of the City of Meriden, 1242 East Main Street, City Hall, Meriden, Connecticut 06450.	February 15, 2005	090081 C
Florida:					
Duval (FEMA Docket No. D–7571).	City of Jacksonville.	March 24, 2005; March 31, 2005; *The Florida Times-Union*.	The Honorable John Peyton, Mayor of the City of Jacksonville, 117 West Duval Street, Suite 400, Jacksonville, Florida 32202.	June 30, 2005	120077 E
Duval (FEMA Docket No. D–7571).	City of Jacksonville.	April 6, 2005; April 13, 2005; *The Florida Times-Union*.	The Honorable John Peyton, Mayor of the City of Jacksonville, 4th Floor, City Hall at St. James, 117 West Duval Street, Suite 400, Jacksonville, Florida 32202.	April 29, 2005	120077 E
Georiga: DeKalb (FEMA Docket No. D–7571).	City of Decatur	March 24, 2005; March 31, 2005; *The Champion*.	The Honorable Bill Floyd, Mayor of the City of Decatur, P.O. Box 220, Decatur, Georgia 30031.	March 18, 2005	135159 H
Pennsylvania:					
Northampton (FEMA Docket No. D–7571).	City of Bethlehem	April 8, 2005; April 15, 2005; *The Morning Call*.	The Honorable John B. Callahan, Mayor of the City of Bethlehem, 10 East Church Street, Bethlehem, Pennsylvania 18018.	July 15, 2005	420718 D
Lycoming (FEMA Docket No. D–7573).	Township of McIntyre.	April 22, 2005; April 29, 2005; *Williamsport Sun Gazette*.	Mr. Albert Boyer, Chairman of the Township of McIntyre Board of Supervisors, 12886 Route 14, Roaring Branch, Pennsylvania 17765.	July 29, 2005	420645 E
Adams (FEMA Docket No. D–7569).	Township of Oxford.	March 10, 2005; March 17, 2005; *The Gettysburg Times* and *The Hanover Evening Sun*.	Mr. Donald F. Poist, Supervisor of the Township of Oxford, Municipal Building, P.O. Box 86, New Oxford, Pennsylvania 17350.	June 16, 2005	420003 B

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community number
Bucks (FEMA Docket No. D–7571).	Township of Wrightstown.	April 8, 2005; April 15, 2005; *Bucks County Courtier Times*.	Mr. Chester S. Pogonowski, Chairman of the Township of Wrightstown Board of Supervisors, 738 Penns Park Road, Wrightstown, Pennsylvania 18940.	July 15, 2005	421045 F
West Virginia: Wyoming (FEMA Docket No. D–7569).	Unincorporated Areas.	February 16, 2005; February 23, 2005; *The Independent Herald*.	Mr. Herman R. Davis, President of the Wyoming County Commission, P.O. Box 309, Pineville, West Virginia 24874–0309.	May 25, 2005	540217 B

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: September 14, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–18734 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–U

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

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 on 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: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: 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 Mitigation Division Director of the Emergency Preparedness and Response Directorate, 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.

The Agency 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 rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

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 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

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:

Source of flooding and location	# Depth in feet above ground. * Elevation in feet (NGVD) • Elevation in feet (NAVD)
NORTH CAROLINA	
Duplin County (FEMA Docket Nos. D–7620 and D–7628)	
Angola Creek:	
At the confluence with Cypress Creek	•49
Approximately 0.3 mile upstream of Lightwood Bridge Road	•51
Duplin County (Unincorporated Areas)	
Back Swamp:	
At the confluence with Cypress Creek	•52
At the Duplin/Onslow County boundary	•58

Source of flooding and location	# Depth in feet above ground. * Elevation in feet (NGVD) • Elevation in feet (NAVD)
Duplin County (Unincorporated Areas)	
Back Swamp Tributary 2:	
At the confluence with Back Swamp	•59
Approximately 0.4 mile upstream of Fountaintown Road	•72
Duplin County (Unincorporated Areas)	
Back Swamp Tributary 4:	
At the confluence with Back Swamp Tributary 3	•67
Approximately 0.7 mile upstream of State Route 111	•87
Duplin County (Unincorporated Areas)	
Back Swamp Tributary 5:	
At the confluence with Back Swamp Tributary 4	•69
Approximately 0.7 mile upstream of State Route 111	•87
Duplin County (Unincorporated Areas)	
Bear Marsh Branch:	
At the confluence with Goshen Swamp	•94
Approximately 1.8 miles upstream of Beautancus Road	•137
Duplin County (Unincorporated Areas)	
Bear Swamp:	
At the confluence with Goshen Swamp	•93
Approximately 0.5 mile upstream of Warren Road	•131
Duplin County (Unincorporated Areas)	
Bear Swamp Tributary:	
At the confluence with Bear Swamp	•108
Approximately 500 feet downstream of Warren Road	•164
Duplin County (Unincorporated Areas)	
Beaverdam Branch (near Kenansville):	
At the confluence of Maple Branch	•86
Approximately 0.3 mile upstream of Doctor Williams Road	•93
Duplin County (Unincorporated Areas)	
Beaverdam Branch (near Scotts Store):	
At the confluence with Northeast Cape Fear River	•80
Approximately 100 feet downstream of White Flash Road	•100
Duplin County (Unincorporated Areas)	
Beaverdam Branch (near Gracys Crossroads):	
At the confluence with Great Branch	•95
Approximately 0.4 mile upstream of Richard Rouse Road	•108
Duplin County (Unincorporated Areas)	
Big Beaverdam Branch:	
At the confluence with Maxwell Creek	•65
Approximately 0.8 mile upstream of railroad	•98
Duplin County (Unincorporated Areas)	
Big Beaverdam Creek:	
At the confluence with Rockfish Creek	•69
Approximately 1.7 miles upstream of Old Camp Road	•97
Duplin County (Unincorporated Areas)	
Big Branch:	
At the confluence with Bear Swamp	•111
Approximately 1.8 miles upstream of the confluence with Bear Swamp	•129
Duplin County (Unincorporated Areas)	
Buck Marsh Branch:	
At the confluence with Northeast Cape Fear River	•83
At the Duplin/Wayne County boundary	•93
Duplin County (Unincorporated Areas)	
Buckhall Creek:	
At the confluence of Stewarts Creek (near Carroll)	•92
Approximately 1.3 miles upstream of Buck Hall Creek Road	•103
Duplin County (Unincorporated Areas)	
Bulltail Creek:	
At the confluence with Doctors Creek	•58
At the Duplin/Sampson County boundary	•63
Duplin County (Unincorporated Areas)	
Burn Coat Creek:	
At the confluence with Northeast Cape Fear River	•63
Approximately 0.7 mile upstream of Maxwell Mill Road	•93
Duplin County (Unincorporated Areas)	
Cabin Creek:	
At the confluence with Limestone Creek	•55
Approximately 0.9 mile upstream of State Route 111	•83
Duplin County (Unincorporated Areas)	
Camp Branch:	
At the confluence with Northeast Cape Fear River	•69
Approximately 0.8 mile upstream of Woodland Church Road	•91
Duplin County (Unincorporated Areas)	
Cow Hole Branch:	
At the confluence with Goshen Swamp	•96
Approximately 1.3 miles upstream of the confluence with Goshen Swamp	•106
Duplin County (Unincorporated Areas)	
Cowhole Branch:	
At the confluence with Burn Coat Creek	•94
Approximately 1.1 miles upstream of Jimmy Lee Road	•114
Duplin County (Unincorporated Areas)	
Cypress Creek:	
At the confluence with Northeast Cape Fear River	•33
Approximately 0.6 mile upstream of Cypress Creek Road	•51
Duplin County (Unincorporated Areas)	
Cypress Creek Tributary 1:	
At the confluence with Cypress Creek	•38
Approximately 1.6 miles upstream of Maready Road	•73
Duplin County (Unincorporated Areas)	
Cypress Creek Tributary 2:	
At the confluence with Cypress Creek Tributary 1	•44
Approximately 1.3 miles upstream of the confluence with Cypress Creek Tributary 1	•53
Duplin County (Unincorporated Areas)	
Dark Branch:	
At the confluence with Northeast Cape Fear River	•53
Approximately 1.4 miles upstream of Dark Branch Road	•86
Duplin County (Unincorporated Areas)	
Doctors Creek:	
At the confluence with Rockfish Creek	•39
At the Duplin/Sampson County boundary	•86
Duplin County (Unincorporated Areas)	
Dufis Creek:	
At the confluence with Rockfish Creek	•46
Approximately 250 feet upstream of Wellstown Road	•62
Duplin County (Unincorporated Areas)	
Elder Branch:	
At the confluence with Maxwell Creek	•58
Approximately 0.2 mile upstream of Hamilton Road	•81
Duplin County (Unincorporated Areas)	
Fussell Mill Branch:	
At the confluence with Rockfish Creek	•45
Approximately 0.9 mile upstream of Cornwallis Road	•64
Duplin County (Unincorporated Areas)	
Goshen Swamp:	
At the confluence with Northeast Cape Fear River	•59
At the Duplin/Sampson County boundary	•117

Source of flooding and location	# Depth in feet above ground. * Elevation in feet (NGVD) • Elevation in feet (NAVD)
Duplin County (Unincorporated Areas), Town of Calypso	
Great Branch:	
At the confluence with Northeast Cape Fear River	•77
Approximately 1.8 miles upstream of State Route 903	•95
Duplin County (Unincorporated Areas)	
Grove Branch:	
At the confluence with Northeast Cape Fear River	•52
Approximately 2.7 miles upstream of Abner Phillips Road	•106
Duplin County (Unincorporated Areas), Town of Kenansville	
Herring Marsh Run:	
At the confluence with Goshen Swamp	•71
Approximately 0.4 mile upstream of Kinsey Mill Road	•110
Duplin County (Unincorporated Areas)	
Island Creek:	
At the confluence with Northeast Cape Fear River	•30
Approximately 1.2 miles upstream of Rosemary Road	•52
Duplin County (Unincorporated Areas)	
Island Creek Tributary:	
At the confluence with Island Creek	•31
Approximately 1.5 miles upstream of Hanchey Road	•35
Duplin County (Unincorporated Areas)	
Juniper Branch:	
At the confluence with Matthews Creek	•91
Approximately 0.3 mile upstream of Matthews Creek	••103
Duplin County (Unincorporated Areas)	
King Branch:	
At the confluence with Nahunga Creek	•93
Approximately 0.8 mile upstream of Veachs Mill Road	•119
Duplin County (Unincorporated Areas)	
Ladds Branch:	
At the confluence with Polly Run Creek	•113
Approximately 1.2 miles upstream of Oak Ridge Avenue	•125
Duplin County (Unincorporated Areas)	
Limestone Creek:	
At the confluence with Northeast Cape Fear River	•46
Approximately 1.8 miles upstream of State Route 24	•85
Duplin County (Unincorporated Areas)	
Little Beaverdam Creek:	
At the confluence with Big Beaverdam Creek	•75
Approximately 0.1 mile upstream of Halls Pond Road	•85
Duplin County (Unincorporated Areas)	
Little Limestone Creek:	
At the confluence with Limestone Creek	•65
Approximately 0.5 mile upstream of Church Road	•97
Duplin County (Unincorporated Areas)	
Little Rockfish Creek:	
At the confluence with Rockfish Creek	•28
Approximately 0.7 mile upstream of State Route 41	•45
Duplin County (Unincorporated Areas), Town of Wallace	
Maple Branch:	
At the confluence with Goshen Swamp	•73
Approximately 0.6 mile upstream of Summerlins Crossroad Road	•85
Duplin County (Unincorporated Areas)	
Maple Creek:	
At the confluence with Limestone Creek	•46
Approximately 1.9 miles upstream of Limestone Creek	•63
Duplin County (Unincorporated Areas)	
Marsh Branch:	
At the confluence with Grove Creek	•78
Approximately 1.8 miles upstream of State Route 24/50	••94
Duplin County (Unincorporated Areas)	
Matthews Creek:	
At the confluence with Northeast Cape Fear River	•73
Approximately 3.2 miles upstream of State Route 111/903	•106
Duplin County (Unincorporated Areas)	
Maxwell Creek:	
At the confluence with Stockinghead Creek	•47
Approximately 0.6 mile upstream of I–40	•101
Duplin County (Unincorporated Areas), Town of Magnolia	
Mill Branch (near Kornegan):	
At the confluence with Burn Coat Creek	•93
Approximately 0.1 mile downstream of State Route 11	•105
Duplin County (Unincorporated Areas)	
Mill Branch (near Teachey):	
At the confluence with Little Rockfish Creek	•45
Approximately 250 feet downstream with Stallings Road	•52
Duplin County (Unincorporated Areas), Town of Wallace	
Mill Creek:	
At the confluence with Doctors Creek	•51
At the Duplin/Sampson County boundary	•55
Duplin County (Unincorporated Areas)	
Miller's Creek:	
At the confluence with Stewarts Creek (near Carroll)	•83
Approximately 1.4 miles upstream of Beasley Torrans Road	•102
Duplin County (Unincorporated Areas), Town of Magnolia	
Mire Branch:	
At the confluence with Northeast Cape Fear River	•83
Approximately 1.4 miles upstream of Garner Chapel Road	•109
Duplin County (Unincorporated Areas)	
Muddy Creek:	
At the confluence with Northeast Cape Fear River	•36
Approximately 0.7 mile upstream of Lyman Road	•64
Duplin County (Unincorporated Areas), Town of Beulaville	
Muddy Creek Tributary:	
At the confluence with Muddy Creek	•47
Approximately 3.2 miles upstream of State Route 111	•82
Duplin County (Unincorporated Areas)	
Murpheys Creek:	
At the confluence with Rockfish Creek	•72
Approximately 1.3 miles upstream of Waycross Road	•95
Duplin County (Unincorporated Areas)	
Murpheys Creek Tributary:	
At the confluence with Murpheys Creek	•81
Approximately 0.6 mile upstream of Bonham Road	•91
Duplin County (Unincorporated Areas)	
Nahunga Creek:	
At the confluence with Goshen Swamp	•78
Approximately 100 feet downstream of Revelle Road	•116
Duplin County (Unincorporated Areas)	
Northeast Cape Fear River:	
At the Duplin/Pender County boundary	•26
At the Town of Mount Olive Extraterritorial Jurisdiction limits	•126
Duplin County (Unincorporated Areas)	
Oakie Branch:	
At the confluence with Northeast Cape Fear River	•30
Approximately 0.6 mile upstream of Jack Dale Road	•50

Source of flooding and location	# Depth in feet above ground. * Elevation in feet (NGVD) • Elevation in feet (NAVD)
Duplin County (Unincorporated Areas)	
Paget Branch:	
At the confluence with Rockfish Creek	•45
Approximately 0.3 mile upstream of High School Road	•67
Duplin County (Unincorporated Areas), Town of Wallace	
Panther Branch (near Faison):	
At the confluence with Goshen Swamp	•107
Approximately 0.3 mile upstream of NC 117	•130
Duplin County (Unincorporated Areas), Town of Faison	
Panther Creek:	
At the confluence with Northeast Cape Fear River	•60
Approximately 2.8 miles upstream of Kitty Noecker Road	•101
Duplin County (Unincorporated Areas)	
Persimmon Branch:	
At the confluence with Northeast Cape Fear River	•47
Approximately 2.2 miles upstream of South Dobson Chapel Road	•76
Duplin County (Unincorporated Areas)	
Pharisee Creek:	
At the confluence with Bulltail Creek	•58
At the Duplin/Sampson County boundary	•58
Duplin County (Unincorporated Areas)	
Poley Branch:	
At the confluence with Buck Marsh Branch	•86
Approximately 1.9 miles upstream of Buck Marsh Branch	•105
Duplin County (Unincorporated Areas)	
Polly Run Creek:	
At the confluence with Northeast Cape Fear River	•107
Approximately 0.3 mile upstream of Garner Chapel Road	•113
Duplin County (Unincorporated Areas)	
Pudding Branch:	
At the confluence with Maple Branch	•86
Approximately 0.3 mile upstream of Summerlins Crossroad Road	•105
Duplin County (Unincorporated Areas)	
Rattlesnake Branch:	
At the confluence with Northeast Cape Fear River	•108
Approximately 0.2 mile downstream of State Route 403	•122
Duplin County (Unincorporated Areas)	
Reedy Branch (near Blizzards Crossroads):	
At the confluence with Mire Branch	•107
Approximately 0.3 mile upstream of the confluence with Mire Branch	•114
Duplin County (Unincorporated Areas)	
Reedy Branch (near Faison):	
At the confluence with Goshen Swamp.	
Approximately 1.3 miles upstream of Bill Clifton Road	•134
Duplin County (Unincorporated Areas), Town of Faison	
Rockfish Creek:	
At the confluence with Northeast Cape Fear River	•26
Approximately 0.9 mile upstream of Blue Newkirk Road	•93
Duplin County (Unincorporated Areas), Town of Wallace	
Sawyer Branch:	
At the confluence with Matthews Creek	•100
Approximately 0.7 mile upstream of Guy Sanderson Road	•121
Duplin County (Unincorporated Areas)	
Stewarts Creek (near Carroll):	
At the Duplin/Sampson County boundary	•83
Approximately 1.7 miles upstream of Route 117	•123
Duplin County (Unincorporated Areas), Town of Warsaw	
Stewarts Creek (near Friendship):	
At the confluence of Nahunga Creek	•84
Approximately 0.8 mile upstream of Sammy Godwin Lane	•100
Duplin County (Unincorporated Areas)	
Stocking Head Creek:	
At the confluence with Northeast Cape Fear River	•38
Approximately 700 feet upstream of South Dobson Chapel Road	•65
Duplin County (Unincorporated Areas)	
Taylor Creek:	
At the confluence with Dufis Creek	•51
Approximately 2.2 miles upstream of Brices Store Road	•87
Duplin County (Unincorporated Areas), Town of Rose Hill	
Turkey Creek:	
At the Duplin/Sampson County boundary	•117
Approximately 0.8 mile upstream of Blackmore Road	•133
Duplin County (Unincorporated Areas)	
Welch Branch:	
At the confluence with Dark Branch	•56
Approximately 2.8 miles upstream of the confluence with Dark Branch	•86
Duplin County (Unincorporated Areas)	
White Oak Branch:	
At the confluence with Panther Creek	•66
Approximately 1.6 miles upstream of the confluence of Panther Creek	•89
Duplin County (Unincorporated Areas)	
Whiteoak Branch:	
At the confluence with Goshen Swamp	•98
At the Towns of Calypso and Mount Olive Extraterritorial Jurisdiction limits	•153
Duplin County (Unincorporated Areas), Town of Calypso	
Wolfscape Branch:	
At the confluence with Polly Run Creek	•113
Approximately 0.5 mile upstream of Bethel Church Road	•129
Duplin County (Unincorporated Areas)	
Town of Beulaville	
Maps available for inspection at the Duplin County Planning Department, 224 Seminary Street, Kenansville, North Carolina.	
Town of Calypso	
Maps available for inspection at the Duplin County Planning Department, 224 Seminary Street, Kenansville, North Carolina.	
Duplin County (Unincorporated Areas)	
Maps available for inspection at the Duplin County Planning Department, 224 Seminary Street, Kenansville, North Carolina.	
Town of Kenansville	
Maps available for inspection at the Duplin County Planning Department, 224 Seminary Street, Kenansville, North Carolina.	
Town of Faison	
Maps available for inspection at the Faison Town Hall, 110 East Center Street, Faison, North Carolina.	
Town of Magnolia	
Maps available for inspection at the Duplin County Planning Department, 224 Seminary Street, Kenansville, North Carolina.	
Town of Rose Hill	

Source of flooding and location	# Depth in feet above ground. * Elevation in feet (NGVD) • Elevation in feet (NAVD)
Maps available for inspection at the Rose Hill Town Hall, 103 South Railroad Street, Rose Hill, North Carolina.	
Town of Wallace	
Maps available for inspection at the Wallace Town Hall, 311 East Murphey Street, Wallace, North Carolina.	
Town of Warsaw	
Maps available for inspection at the Warsaw Town Hall, 128 West Bay Street, Warsaw, North Carolina.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance'')

Dated: September 14, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–18733 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 70, No. 181
Tuesday, September 20, 2005

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 03–016–2]

Cut Flowers From Countries With Chrysanthemum White Rust

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of a comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the cut flowers regulations to establish specific requirements for the importation of cut flowers that are hosts of chrysanthemum white rust (CWR) from countries where the disease is known to occur. We also proposed to amend the nursery stock regulations to update lists of countries where CWR is known to occur. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on Docket No. 03–016–1 on or before October 21, 2005.

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

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate Docket No. 03–016–1.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 03–016–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–016–1.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating Docket No. 03–016–1 and submitting comments.

Reading Room: You may read any comments that we receive on Docket No. 03–016–1 in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Porsche, Import Specialist, Commodity Import Analysis and Operation, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 734–5281.

SUPPLEMENTARY INFORMATION: On July 7, 2005, we published in the **Federal Register** (70 FR 39194–39199, Docket No. 03–016–1) a proposal to amend the cut flowers regulations to establish specific requirements for the importation of cut flowers that are hosts of chrysanthemum white rust (CWR) from countries where the disease is known to occur. We also proposed to amend the nursery stock regulations to update lists of countries where CWR is known to occur.

Comments on the proposed rule were required to be received on or before September 6, 2005. We are reopening the comment period on Docket No. 03–016–1 until October 21, 2005, an additional 45 days from the original close of the comment period. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between September 7, 2005 (the day after the close of the original comment period) and the date of this notice.

Done in Washington, DC, this 13th day of September 2005.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–18604 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AH77

List of Approved Spent Fuel Storage Casks: Standardized NUHOMS®–32PT, –24PHB, and –24PTH Revision 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations revising the Transnuclear, Inc., Standardized NUHOMS® System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 8 to Certificate of Compliance Number (CoC No.) 1004. Amendment No. 8 to the Standardized NUHOMS® System CoC would add a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and modify the NUHOMS®–32PT and –24PHB dry shielded canister designs.

DATES: Comments on the proposed rule must be received on or before October 20, 2005.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150–AH77) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@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. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking Web site to Carol Gallagher (301) 415–5905; e-mail *cag@nrc.gov.* Comments can also be submitted via the Federal eRulemaking Portal *http://www.regulations.gov.*

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers at the NRC's Public Document Room (PDR), O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of 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 PDR Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* An electronic copy of the proposed CoC, Technical Specifications (TS), and preliminary safety evaluation report (SER) can be found under ADAMS Package Accession No. ML051610554.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, telephone (301) 415–6219, e-mail, *jmm2@nrc.gov* of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Procedural Background

On May 25, 2005, a direct final rule (70 FR 29931) and companion proposed rule (70 FR 30015) were published in the **Federal Register**, to revise the cask system listing for the Transnuclear, Inc. (TN) Standardized NUHOMS® System, by adding Amendment No. 8 to the list of approved spent fuel storage casks in 10 CFR 72.214. After the rules were published, staff became aware of needed changes in the TS associated with the CoC, and on July 15, 2005, the NRC withdrew the direct final rule (70 FR 40879) and the proposed rule (70 FR 40924). This rule includes the original Amendment No. 8 changes, revised TS 1.2.17c and 1.2.18, Table 1–1l, and additional changes, as discussed in the direct final rule. These additional changes were originally to be addressed as a subsequent amendment. However, the withdrawal of the May 25, 2005, package allowed the staff to combine this information into Amendment 8. This results in a more effective and efficient use of resources.

This rule is limited to the changes contained in Amendment No. 8 to CoC No. 1004 and does not include other aspects of the Standardized NUHOMS® System cask design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on December 5, 2005. However, if the NRC receives significant adverse comments by October 20, 2005, then the NRC will publish a document that withdraws the direct final rule and will subsequently address the comments received in a final rule. The NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, in a substantive response:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the CoC or TS.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

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. 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

1. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c),(d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.214, Certificate of Compliance 1004 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1004.

Initial Certificate Effective Date: January 23, 1995.

Amendment Number 1 Effective Date: April 27, 2000.

Amendment Number 2 Effective Date: September 5, 2000.

Amendment Number 3 Effective Date: September 12, 2001.

Amendment Number 4 Effective Date: February 12, 2002.

Amendment Number 5 Effective Date: January 7, 2004.

Amendment Number 6 Effective Date: December 22, 2003.

Amendment Number 7 Effective Date: March 2, 2004.

Amendment Number 8 Effective Date: December 5, 2005.

SAR Submitted by: Transnuclear, Inc.

SAR Title: Final Safety Analysis Report for the Standardized NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72–1004.

Certificate Expiration Date: January 23, 2015.

Model Number: NUHOMS®–24P, –52B, –61BT, –32PT, –24PHB, and –24PTH.

* * * * *

Dated at Rockville, Maryland, this 1st day of September, 2005.

For the Nuclear Regulatory Commission.

Luis A. Reyes,

Executive Director for Operations.

[FR Doc. 05–18663 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210, 211, and 212

[Docket No. 2004N–0439]

Current Good Manufacturing Practice for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing proposed regulations on current good manufacturing practice (CGMP) for positron emission tomography (PET) drug products. The regulations are intended to ensure that PET drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding safety, identity, strength, quality, and purity. We are proposing to establish CGMP requirements for approved PET drug products. For investigational and research PET drugs, the proposed rule states that the requirement to follow CGMP may be met by producing PET drugs in accordance with the United States Pharmacopeia (USP) general chapter on compounding PET radiopharmaceuticals. We are proposing to establish these CGMP requirements for all PET drugs under the provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).''

DATES: Submit written or electronic comments by December 19, 2005. Submit written comments on the information collection requirements by October 20, 2005. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0439, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8941.

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I. Introduction

A. Background

Positron emission tomography is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product. The majority of PET drug products are injected intravenously into patients for diagnostic purposes. Most PET drugs are produced using cyclotrons and other production equipment at locations that are close to the patients to whom the drugs are administered (e.g., in hospitals or academic institutions). Due to their short half-lives, PET drugs usually are administered to patients within a few minutes or hours of production.

Under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to ensure that the drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess. Our CGMP requirements for non-PET drug products are set forth in parts 210 and 211 (21 CFR parts 210 and 211).

B. The Modernization Act and PET Drugs

On November 21, 1997, the President signed the Modernization Act (Public Law 105–115) into law. Section 121 of the Modernization Act contains several provisions affecting the regulation of PET drugs. Section 121(d) directed us to terminate the application of the following three **Federal Register** documents:

- A notice entitled ''Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop'' (60 FR 10594, February 27, 1995). This notice stated that traditional CGMP requirements in parts 210 and 211 were applicable to PET drugs.
- A notice that announced the availability of a draft guideline on the production of PET drugs (60 FR 10593, February 27, 1995).
- A final rule authorizing us to approve exceptions or alternatives to the application of CGMP requirements to the production of PET drugs (62 FR 19493, April 22, 1997).

We terminated the application of these three documents in a notice (62 FR 66636) and final rule (62 FR 66522) published in the December 19, 1997, issue of the **Federal Register**.

Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(2) of the Modernization Act provides that FDA cannot require the submission of a new drug application (NDA) or abbreviated new drug application (ANDA) for a PET drug product until 2 years after the day we publish a final rule establishing CGMP requirements for PET drug products.

Section 121(c)(1)(B) of the Modernization Act states that, in adopting CGMP and approval requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of such drugs. We discuss the nature of PET drug production in section I.C of this document.

Section 121(c)(1)(B) of the Modernization Act also directs us, as we develop PET drug CGMP requirements and approval procedures, to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs. We have taken the following steps in developing the PET drug CGMP regulations:

- We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999.
- In accordance with §§ 10.40(f)(4) and 10.80(b)(2) (21 CFR 10.40(f)(4) and 10.80(b)(2), we announced the availability of preliminary draft regulations on PET drug CGMP requirements in the September 22, 1999, issue of the **Federal Register** (64 FR 51274).
- We held a public meeting to discuss the preliminary draft regulations on September 28, 1999.
- After considering the comments on the preliminary draft regulations, in accordance with §§ 10.40(f)(4) and 10.80(b)(2), we announced the availability of a preliminary draft proposed rule on PET drug CGMP requirements in the April 1, 2002, issue of the **Federal Register** (67 FR 15344).
- We also announced the availability of a draft guidance on ''PET Drug Products—Current Good Manufacturing Practice for Positron Emission Tomography'' on April 1, 2002 (67 FR 15404).
- We held a public meeting to discuss the preliminary draft proposed rule and draft guidance on April 21, 2002.
- After considering the comments on the preliminary draft proposed rule, we are now issuing this proposed rule on PET drug CGMP requirements. Elsewhere in this issue of the **Federal Register**, we are making available for comment a revised draft guidance on CGMP for PET drug products.

C. The Nature of PET Drug Production and Our Proposed Regulations

As directed by Congress in the Modernization Act, to aid our development of these proposed regulations, we closely examined the operations of many PET drug producers, including not-for-profit institutions and commercial manufacturers. Since the Modernization Act became law, PET drug production in the United States has significantly changed. The number of PET production facilities has increased, as has the number of facilities where PET scans are performed. The business of PET drug production has changed as well. Historically, PET drug products were produced by academicians and researchers at facilities located in universities and similar not-for-profit institutions. These academically oriented PET production facilities usually produce small amounts (a few doses per day) of a few PET drug products for onsite patient use and a larger variety of PET drug products for clinical investigation and academic research.

An increasing number of PET production facilities are now operated

by large, for-profit corporate entities that contract with academic and medical institutions (many of which have not-for-profit status) to manage the production of PET drugs at those institutions. Most of these PET drug products are administered onsite, although there is some distribution to other local or regional hospitals.

In addition, there are a growing number of independent PET production facilities that are not affiliated with any university or hospital. Typically these are for-profit, independently operated facilities, although they are often contractually managed. These facilities generally focus on producing one or two PET drug products and distribute them to significantly greater numbers of patients, sometimes hundreds of miles from the production site.

Our review of PET drug production leads us to the following conclusions:

- A PET drug producer's status as either a not-for-profit or for-profit entity does not have a significant bearing on the quality of PET drugs that it produces and distributes for administration to patients, or the methods, facilities, and controls that a PET production facility needs to ensure product quality.
- Production and CGMP differences among PET drug producers are primarily a function of the size, scope, and complexity of their production operations.
- Certain production standards and controls are necessary to ensure the production of quality PET drugs regardless of differences in the nature and scope of production among facilities.

While this proposed rule and the draft guidance primarily reflect our familiarity with the current approved PET drugs (fludeoxyglucose (FDG) F 18 injection and ammonia N 13 injection), we intend both the proposed rule and the draft guidance to apply to future PET drug products. We also recognize that the development of new PET drug products may require us to amend regulations or guidance to accommodate the new products.

This proposed rule on CGMP requirements contains the minimum standards needed for PET drug production at all types of PET production facilities. We have designed the CGMP regulations to be sufficiently flexible to accommodate not-for-profit, academically oriented institutions as well as larger commercial producers.

In consideration of the unique nature of PET drugs and PET drug production, the proposed CGMP requirements for PET drug products differ in many significant ways from the CGMP requirements for non-PET drug products found in our regulations in part 211. The proposed PET CGMP requirements include the following differences:

- Fewer required personnel with fewer organizational restrictions consistent with the scope and complexity of operations;
- Allowance for multiple operations (or storage) in the same area as long as organization and other controls are adequate;
- Streamlined requirements for aseptic processing consistent with the nature of the production process;
- Streamlined quality control requirements for components;
- Self-verification of significant steps in PET drug production consistent with the scope and complexity of operations;
- Same-person oversight of production, review of batch records, and authorization of product release consistent with the scope and complexity of operations;
- Specialized quality control requirements for PET drugs produced in multiple sub-batches; and
- Simplified labeling requirements consistent with the scope and complexity of operations.

These and other proposed PET CGMP provisions, designed to reflect the unique characteristics of PET drug production, should make it easier for PET production facilities to achieve compliance with CGMP requirements.

This proposed rule incorporates principles from Chapter <823>, ''Radiopharmaceuticals for Positron Emission Tomography—Compounding,'' of the 28th edition of the USP (2005) (USP 28). The USP contains standards that are of significant regulatory importance for PET drugs. Under section 501(a)(2)(C) of the act, a compounded PET drug is adulterated unless it is produced in compliance with the USP's PET drug compounding standards and the official monograph for the particular PET drug. Section 121(b) of the Modernization Act added this provision as a safety net while we develop this rule. Under section 121(b) of the Modernization Act, however, section 501(a)(2)(C) of the act will expire 2 years after the date on which we establish final approval procedures and CGMP requirements for PET drugs. At that time, compliance with the final version of this rule will be required. The USP 28 general chapter on PET drug compounding largely reflects the consensus views of the PET community and FDA on how to properly produce PET drug products. Consequently, we believe it is appropriate to incorporate many of the principles and concepts in the USP general chapter into these proposed CGMP requirements.

Moreover, as discussed in section II.D of this document, we believe that it is appropriate to designate the provisions of USP 28, Chapter <823> as the CGMP requirements for investigational PET drugs produced under an investigational new drug application (IND) and research PET drugs produced with the approval of a Radioactive Drug Research Committee (RDRC) under § 361.1 (21 CFR 361.1). Thus, under the proposed rule, investigational and research PET drugs produced in accordance with Chapter <823> would be deemed to meet CGMP requirements; they would not have to meet the more specific requirements in proposed part 212. Because most PET drugs currently are produced under an IND or RDRC review, adopting USP 28, Chapter <823> as the standard for CGMP for investigational PET drugs should make it easier for PET drug producers to comply with the proposed CGMP requirements.

To further assist PET production facilities in complying with the requirements in the rule, we have revised the draft guidance document entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' For many aspects of CGMP (such as resources, controls, and documentation), the draft guidance makes different recommendations depending on the size, scope, and complexity of a PET production facility's operations. The draft guidance provides practical examples of methods and procedures that different types of PET production facilities might use to comply with the CGMP requirements.

II. Description of the Proposed Rule

We are proposing to establish CGMP regulations for PET drug products by creating 21 CFR part 212. These regulations are intended to ensure that every PET drug product meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is represented to possess.

We describe our proposed CGMP regulations for PET drug production in the following sections of this document. The format of the proposed regulations, including the use of questions in section headings, is in accordance with the Presidential Memorandum of June 1, 1998, promoting the use of plain language in regulatory writing.

A. Exclusion of PET Drug Products From CGMP Regulations in Parts 210 and 211

We propose revising certain sections of parts 210 (CGMP for the manufacturing, processing, packing, or

holding of drugs) and 211 (CGMP for finished pharmaceuticals) to make clear that the regulations in those parts do not apply to PET drug products. The revisions are in § 210.1 (status of CGMP regulations), § 210.2 (applicability of CGMP regulations), and § 210.3 (definitions). We propose revising the text of each of these sections so that the provisions will only apply to parts 210, 211, 225, and 226, rather than part 210 and parts 211 through 226. The revisions would exclude part 212, which will address PET drug products, from the scope of §§ 210.1, 210.2, and 210.3. Similarly, we propose to revise § 211.1(a) (scope of CGMP for finished pharmaceuticals) to clarify that the regulations in part 211 do not apply to PET drug products.

B. Definitions

Proposed § 212.1 sets forth the meaning of several terms used in the PET drug CGMP regulations. Most of the definitions are self-explanatory and well understood by PET producers and the pharmaceutical industry. We will discuss here a few of the definitions for which added comment may help the reader better understand the provision.

• *Acceptance criteria*. We propose to define ''acceptance criteria'' as numerical limits, ranges, or other criteria for tests that are used for or in making a decision to accept or reject a unit, lot, or batch of a PET drug product. This varies slightly from the definition in part 210, which states that acceptance criteria are the ''product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).'' The proposed definition, which does not refer to sampling plans, is more appropriate for PET drug production.

• *Specifications*. We propose a separate definition of ''specifications'' to mean the tests, analytical procedures, and appropriate acceptance criteria to which a PET drug, PET drug product, component, container closure system, in-process material, or other material used in PET drug production must conform to be considered acceptable for its intended use. Conformance to specifications would mean that a PET drug, PET drug product, component, container closure system, in-process material, or other material used in PET drug production, when tested according to the described analytical procedures, meets the listed acceptance criteria.

The definitions for acceptance criteria and specifications are intended to be consistent with guidance in ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products,'' prepared under the auspices of the International Conference on Harmonisation for Registration of Pharmaceuticals for Human Use (ICH). ICH works to promote the harmonization of technical requirements (including definitions, procedures, formats, and standards) for approval of pharmaceutical products among the European Union, Japan, and the United States.

• *Active pharmaceutical ingredient*. We propose to define ''active pharmaceutical ingredient'' (API) for purposes of part 212 as a substance (excluding intermediates used in the synthesis of such substance) that is intended for incorporation into a finished PET drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis or monitoring of a disease or a manifestation of a disease in humans. For example, in the case of FDG F 18 injection drug product, 2-deoxy-2-[18F]fluoro-D-glucose is considered the API. In a commonly used production method for FDG F 18 injection, 1,3,4,6-tetra-O-acetyl-2-O-trifluoromethane sulfonyl-β-D-mannopyranose (mannose triflate) and O 18 water are considered components that yield the API but are not part of the API.

• *PET drug*. We propose to define ''PET drug'' as a radioactive drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for providing dual photon positron emission tomographic diagnostic images. The definition of PET drug includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a PET drug. This definition closely parallels the statutory definition.

• *PET drug product*. We propose to define ''PET drug product'' as a finished dosage form that contains a PET drug, whether or not in association with one or more other ingredients. In other words, a PET drug product is the finished dosage form of a PET drug, with or without an excipient such as a diluent.

• *Receiving facility*. We propose to define ''receiving facility'' as any hospital, institution, nuclear pharmacy, imaging facility, or other entity or part of an entity that accepts a PET drug product that has been given final release. A receiving facility may be in the same area as or adjacent to the production area, in a different area but located in the same building as the production area, or at a site that is completely separate from the production area.

• *Material release and final release*. We propose to define ''material release'' as the authoritative decision by a responsible person in a PET production facility to permit the use of a component, container and closure, in-process material, packaging material, or labeling in the production of a PET drug product. ''Final release,'' in contrast, is defined as the authoritative decision by a responsible person in a PET production facility to permit the use of a batch of a PET drug product in humans.

• *Strength*. We propose to define ''strength'' as the concentration of the API (radioactivity amount per volume or weight at the time of calibration). This proposed definition varies from the definition of ''strength'' in part 210 in that it specifies a radioactivity to volume (or weight) ratio rather than a weight/weight, weight/volume, or unit dose/volume ratio. The definition of strength for proposed part 212 reflects that PET drug products have radioactive APIs (quantified in units of radioactivity) and generally are produced in a solution or gas dosage form.

C. Describing CGMP Requirements for PET Drugs

Proposed § 212.2 answers the question ''What is current good manufacturing practice for PET drugs?'' Proposed § 212.2 states that CGMP for PET drug products is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality control, holding, or distribution of PET drug products intended for human use. CGMP is intended to ensure that each PET drug product meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

D. Applicability of CGMP Regulations

Proposed § 212.5 answers the question ''To what drugs do the regulations in this part apply?'' Proposed § 212.5(a) states that:

• Part 212 applies only to the production, quality control, holding, and distribution of PET drug products.

• Any human drug product that does not meet the definition of a PET drug product must be manufactured in accordance with the CGMP

requirements in parts 210 and 211 of this chapter.

• Part 212 contains CGMP requirements for all PET drug products for human use, but proposed § 212.5(b) specifies different CGMP requirements for investigational and research PET drugs.

We believe that it is appropriate to have less detailed CGMP requirements for investigational and research PET drugs to allow for more flexibility in the production of these drugs. We also recognize that many investigational PET drugs may not have commercial potential. Therefore, proposed § 212.5(b) states that the regulations in part 212 do not apply to investigational PET drugs for human use produced under an IND in accordance with part 312 and research PET drugs produced with the approval of an RDRC in accordance with § 361.1. Instead, proposed § 212.5(b) states that, for investigational and research PET drugs, the requirement under the act to follow CGMP is met by producing drugs in accordance with USP 28 Chapter <823>, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Chapter <823> sets forth requirements on several aspects of PET drug production, including control of components, materials, and supplies, verification of procedures, stability testing and expiration dating, quality control, and sterilization and sterility assurance. Because most PET drug producers are very familiar with the requirements in USP 28 Chapter <823>, adopting the Chapter <823> provisions as the CGMP requirements for investigational and research PET drugs should greatly facilitate producers' compliance with those requirements. Although the provisions in USP 28 Chapter <823>, including those on documentation, are generally less specific and explicit than the requirements in proposed part 212, we believe that they are adequate to ensure that investigational and research PET drugs are produced safely under appropriate conditions, consistent with section 501(a)(2)(B) of the act. We are interested in any comments that suggest appropriate standards, other than USP 28 Chapter <823>, for PET drugs and drug products produced under an IND or with the approval of an RDRC.

Although we propose that USP 28 Chapter <823>, rather than part 212, would constitute the minimum CGMP requirements for investigational and research PET drugs, FDA retains the authority under section 704 of the act (21 U.S.C. 374) to inspect facilities where investigational or research PET drugs are produced to verify compliance with USP 28 Chapter <823>. However, as with inspection of investigational studies of non-PET drugs, we generally would conduct inspections of facilities that produce investigational or research PET drugs only on a for-cause basis. An example of a situation that could lead to a for-cause inspection would be when we become aware of a potential safety concern related to the production of an investigational or research PET drug.

E. Adequate Personnel and Resources

Proposed § 212.10 answers the question ''What personnel and resources must I have?'' The proposal would require:

• A sufficient number of personnel with the necessary education, background, training, and experience to enable those personnel to perform their assigned functions, and

• Adequate resources, including facilities and equipment, to enable personnel to perform their functions.

What constitutes ''adequate'' personnel and resources will depend in part on the size and complexity of the PET drug producer's operations. A PET production facility having a simple operation that produces only one or two doses each day (or week) of a single PET drug would need fewer personnel and other resources than a facility having a more complex operation that produces multiple PET drug products or a facility producing larger amounts of a PET drug product.

F. Quality Assurance

Proposed § 212.20 answers the question ''What activities must I perform to ensure product quality?'' Under proposed § 212.20, PET drug product producers would be required to:

• Oversee production operations to ensure that each PET drug product meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have (proposed § 212.20(a)). Each PET drug producer will determine what personnel should perform the quality assurance function; at some PET production facilities, it may be reasonable for the same personnel to be involved in both production and quality assurance.

• Examine and approve or reject components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms to ensure compliance with procedures and specifications affecting the identity, strength, quality, or purity of a PET drug product (proposed § 212.20(b)).

• Approve or reject, before implementation, any initial specifications, methods, processes, or procedures, and any proposed changes to existing specifications, methods, processes, or procedures, to ensure that they maintain the identity, strength, quality, and purity of the PET drug product when they are implemented. PET drug producers must demonstrate that any change does not adversely affect the identity, strength, quality, or purity of any PET drug product (proposed § 212.20(c)).

• Review production records to determine whether errors have occurred. If errors have occurred or a production batch or any of its components fails to meet any of its specifications, the producer must determine the need for an investigation, conduct investigations when necessary, and take appropriate corrective action (proposed § 212.20(d)). Possible errors include miscalculating yield, omitting a production step, or transcription mistakes.

• Establish and follow written quality assurance procedures to ensure that quality assurance responsibilities are known to all personnel involved in PET drug product production (proposed § 212.20(e)).

G. Facilities and Equipment

Proposed § 212.30 answers the question ''What requirements must my facilities and equipment meet?'' Under proposed § 212.30, a PET drug producer would be required to:

• Provide adequate facilities to ensure the orderly handling of materials and equipment, the prevention of mixups, and the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality (proposed § 212.30(a)).

• Implement procedures to ensure that all equipment that could reasonably be expected to adversely affect the strength, quality, or purity of a PET drug product (such as a laminar airflow workbench or sterilizing filters) or give erroneous or invalid test results when improperly used or maintained (such as high pressure liquid chromatography (HPLC) devices) is clean, suitable for its intended purposes, properly installed, maintained, and capable of repeatedly producing valid results. PET production facilities must document their activities in accordance with these procedures (proposed § 212.30(b)).

• Ensure that equipment is constructed and maintained so that surfaces that contact components, in process materials, or PET drug products are not reactive, additive, or absorptive

so as to alter the quality of PET drug products (proposed § 212.30(c)).

H. Control of Components, Containers, and Closures

Proposed § 212.40 answers the question ''How must I control the components I use to produce PET drugs and the containers and closures I package them in?'' Under proposed § 212.40, PET drug producers would be required to:

• Establish, maintain, and follow written procedures describing the receipt, login, identification, storage, handling, testing, approval, and rejection of components and drug product containers and closures. The procedures must be adequate to ensure that the components, containers, and closures are suitable for their intended use (proposed § 212.40(a)).

• Establish appropriate written specifications for the identity, quality, and purity of components and for the identity and quality of drug product containers and closures (proposed § 212.40(b)).

Proposed § 212.40(c) specifies that:

• Upon receipt, each lot of components and containers and closures must be uniquely identified and tested or examined to determine whether it complies with the PET production facility's specifications.

• Any lot that does not meet its specifications, including any expiration date if applicable, or that has not yet received its material release, must not be used in PET drug production.

• Any incoming lot must be appropriately designated as either quarantined, accepted, or rejected.

• PET drug producers must use a reliable supplier as a source of each lot of each component, container, and closure.

We are proposing to establish different requirements for examination and testing of components required under proposed § 212.40(c) depending on whether a PET drug producer conducts finished-product testing that includes testing to ensure that the correct components have been used:

• When the finished-product testing of a PET drug product includes testing to ensure that the correct components have been used, the PET drug producer need only determine that each lot of incoming components complies with written specifications by examining a certificate of analysis provided by the supplier (proposed § 212.40(c)(1)(i)). We believe that the use of this type of finished-product testing makes specific identity testing of components redundant and unnecessary. For example, when identity of the F 18 radionuclide is established as part of the finished-product testing and the method of production used is well-documented and understood (e.g., as in the ^{18}O (p,n) ^{18}F nuclear reaction), it can be reasonably argued that the component that yields this radionuclide is likely to be O 18 water. In this case, a specific identity test for O 18 water is not necessary before the lot is used in production. Similarly, a specific identity test before using a lot of mannose triflate may be redundant and unnecessary when: (1) A well-understood method of synthesis of FDG F 18 is used, (2) a test to confirm the radiochemical identity is performed in the finished drug product, and (3) the mannose triflate was obtained from a reliable supplier with whom a relationship has been previously established.

• If the finished-product testing of a PET drug product does not include testing to ensure that the correct components have been used, the following provisions (proposed § 212.40(c)(1)(ii)) would apply:

—The PET drug producer would be required to conduct identity testing, using a test that is specific to the component, on each lot of a component that yields an active ingredient and each lot of an inactive ingredient.

—For any other component, such as solvents or reagents, the PET drug producer would determine that each lot complies with written specifications by examining a certificate of analysis provided by the supplier.

—If the PET drug producer prepares an inactive ingredient on site, the producer would be required to perform an identity test on the components used to make the inactive ingredient before those components could be released for use.

However, if the PET drug producer uses as an inactive ingredient a product that is marketed as a finished drug product intended for intravenous administration, the producer would not need to perform a specific identity test on that ingredient.

We are also proposing that PET drug producers would be required to do the following:

• Examine a representative sample of each lot of containers and closures for conformity to its written specifications (proposed § 212.40(c)(2)).

• Perform at least a visual identification of each lot of containers and closures (proposed § 212.40(c)(2)).

• Handle and store components, containers, and closures in a manner that prevents contamination, mixups, and deterioration and ensures that these items are and remain suitable for their intended use (proposed § 212.40(d)).

• Keep a record of each shipment of each lot of components, containers, and closures they receive (proposed § 212.40(e)), including the following information:

—Identity and quantity of each shipment,

—Supplier's name and lot number,

—Date of receipt,

—Results of any testing performed,

—Disposition of rejected material, and

—Expiration date, where applicable. (Some components may not have expiration dates.)

I. Production and Process Controls

Proposed § 212.50 answers the question ''What production and process controls must I have?'' Proposed § 212.50 states that PET drug producers must have adequate production and process controls to ensure the consistent production of a PET drug product that meets the applicable standards of identity, strength, quality, and purity. Proposed § 212.50 would require PET drug producers to have the following controls:

• Written production and process control procedures,

• Master production and control records,

• Batch and production control records,

• Production area and equipment checks,

• In-process materials controls, and

• Depending on finished-product testing, process verification.

The proposed written production and process control procedures would ensure and document that all key process parameters are controlled and that any deviations from the procedures are justified (proposed § 212.50(a)).

The proposed master production and control records would document all steps in the PET drug product production and would include the following information (proposed § 212.50(b)):

• The name and strength of the PET drug product;

• If applicable, the name and radioactivity or other measurement of each API and each inactive ingredient per batch or per unit of radioactivity or other measurement of the drug product, and a statement of the total radioactivity or other measurement of any dosage unit;

• A complete list of components designated by names and codes sufficiently specific to indicate any special quality characteristic;

• Identification of all major pieces of equipment used in production;

• An accurate statement of the weight or measurement of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component (with reasonable variations permitted in the amount of component necessary if specified in the master production and control records);

• A statement of acceptance criteria on radiochemical yield, i.e., the minimum percentage of yield beyond which investigation and corrective action are required;

• Complete production and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed; and

• A description of the PET drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling.

The creation of a unique batch and production control record would be required each time a batch of a PET drug product is produced (proposed § 212.50(c)), including the following information:

• The name and strength of the PET drug product,

• An identification number or other unique identifier of the specific batch that was produced,

• The name and radioactivity or other measure of each API and each inactive ingredient per batch or per unit of radioactivity or other measurement of the drug product,

• Each major production step (obtained from the approved appropriate master production and control record),

• Weights and identification codes of components,

• Dates and time of production steps,

• Identification of major pieces of equipment used in production of the batch,

• Testing results,

• Labeling,

• Initials or signatures of persons performing or checking each significant step in the operation, and

• Results of any investigations conducted.

Proposed § 212.50(d) would require production area and equipment checks to ensure cleanliness and suitability immediately before use, and a record of the checks.

Proposed § 212.50(e) specifies that process controls for PET production facilities include control of in-process materials to ensure that the materials are controlled until required tests or other verification activities have been completed or necessary approvals are received and documented.

Proposed § 212.50(f) would establish different requirements for process verification depending on whether a PET drug producer conducts full finished-product testing on a particular PET drug product:

• Proposed § 212.50(f)(1) would exempt a PET drug product from these process verification requirements if each batch of that PET drug product, prior to human administration, undergoes full finished-product testing to ensure that the product meets all specifications. For example, process verification under proposed § 212.50(f)(2) would not be required for the production of FDG F 18 where: (1) The entire batch is made in a single vial, (2) a sample from the vial is withdrawn for full finished-product testing, and (3) the finished product passes all established specifications (except for sterility) prior to human administration.

• When the results of the production of an entire batch of a PET drug product are not fully verified through finished-product testing or when only the initial sub-batch in a series is tested, process verification would be required. The PET drug producer would be required to demonstrate that the process for producing the PET drug product is reproducible and is capable of producing a drug product that meets the predetermined acceptance criteria (proposed § 212.50(f)(2)). While currently most, if not all, batches of PET drug products are fully verified through finished-product testing, future PET drug products may not be suitable for finished-product testing of an entire batch due to the short half-life of the radionuclide, and process verification would be required.

• When process verification activities are conducted, the PET drug producer would be required to document activities and results, including the date and signature of the individual(s) performing the verification, the monitoring and control methods and data, and the major equipment qualified (proposed § 212.50(f)(2)).

For a PET facility that has an established history of producing a particular PET drug product, verification of that production process may be conducted retrospectively provided that the process has not changed and has not resulted in process-related failures. However, when a PET drug product is not fully verified through finished-product testing or when only the initial sub-batch in a series is tested, process verification would be required for any new production process and after any significant change to a qualified process.

J. Laboratory Testing Requirements

Proposed § 212.60 answers the question ''What requirements apply to the laboratories where I test components, in process materials, and finished PET drug products?'' Under proposed § 212.60, the following requirements would apply to laboratories used to conduct testing of components, in process materials, and finished PET drug products:

• Each laboratory must have and follow written procedures for the conduct of each test and for the documentation of the results (proposed § 212.60(a)).

• Each laboratory must have sampling and testing procedures designed to ensure that components, in process materials, and PET drug products conform to appropriate standards, including established standards of identity, strength, quality, and purity (proposed § 212.60(b)).

• Laboratory analytical methods must be suitable for their intended use and must be sufficiently sensitive, specific, accurate, and reproducible (proposed § 212.60(c)).

If a compendial test is used, the testing laboratory should verify that the method works under the actual conditions of use and that the drug product as formulated can be analyzed using the compendial method. This verification is recommended because many compendial methods for PET drug products lack specific information (for example, they do not describe specific equipment used), the method may not have been developed in the context of the production method actually being used, and the PET production facility may not be using the same equipment that was used in the compendial method.

• The identity, purity, and quality of reagents, solutions, and supplies used in testing must be adequately controlled, and all solutions prepared by the PET production facility must be labeled with their identity and expiration date (proposed § 212.60(d)).

• All testing equipment must be suitable for its intended purposes and capable of producing valid results (proposed § 212.60(e)).

• Each laboratory must have and follow written procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, and these activities must be documented (proposed § 212.60(f)).

• Each laboratory performing tests related to the production of a PET drug product must keep complete records of all tests performed to ensure compliance with established specifications and

standards, including examinations and assays (proposed § 212.60(g)).

The records required under proposed § 212.60(g) would include the following:

• A description of the sample received for testing, including its source, the quantity, the batch or lot number, the date (and time, if appropriate) the sample was taken, and the date (and time, if appropriate) the sample was received for testing;

• A description of each method used in the testing of the sample, a record of all calculations performed in connection with each test, and a statement of the weight or measurement of the sample used for each test;

• A complete record of all data obtained in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or drug product for each lot tested;

• A statement of the results of tests and how the results compare with established acceptance criteria; and

• The initials or signature of the person performing the test and the date on which the test was performed.

K. Stability

Proposed § 212.61 answers the question ''What must I do to ensure the stability of my PET drug products through expiry?'' Proposed § 212.61 would provide the following requirements to ensure the stability of PET drug products:

• PET production facilities must establish, follow, and maintain a written testing program to assess the stability characteristics of their PET drug products (proposed § 212.61(a)).

• Test methods must be reliable, meaningful, and specific (i.e., they must be capable of determining the stability characteristics of the PET drug product) (proposed § 212.61(a)).

• Samples tested for stability must be representative of the lot or batch from which they were obtained and must be stored under suitable conditions (proposed § 212.61(a)).

• Results of the stability testing must be documented and used in determining appropriate storage conditions and expiration dates and times for each PET drug product (proposed § 212.61(b)).

L. Controls and Acceptance Criteria for Finished Products

Proposed § 212.70 answers the question ''What controls and acceptance criteria must I have for my finished PET drug products?'' These controls and acceptance criteria are the requirements that must be met before a PET production facility may give final release to a finished PET drug product. We propose to establish the following requirements regarding controls and acceptance criteria:

• PET production facilities would be required to establish specifications for each batch of a PET drug product, including criteria for identity, strength, quality, purity, and, if appropriate, sterility and pyrogenicity (proposed § 212.70(a)). Most, but not all, PET drugs are sterile injectable products, and such products would be required to have specifications for sterility and pyrogenicity.

• Before a PET drug producer implements a test procedure in a specification, the producer would be required to establish and document the accuracy, sensitivity, specificity, and reproducibility of the procedure (proposed § 212.70(b)).

• If the PET drug producer uses an established compendial test procedure in a specification, the producer would be required to first verify and document that the test works under the conditions of actual use (proposed § 212.70(b)).

• PET drug producers would be required to conduct laboratory testing of a representative sample of each batch of a PET drug product before final release to ensure that the batch conforms to its specifications, except for sterility. For a PET drug product produced in sub-batches (e.g., ammonia N 13 injection), at least each initial sub-batch that is representative of the entire batch must conform to specifications, except for sterility, before final release (proposed § 212.70(c)).

• Under proposed § 212.70(d), producers would be required to establish and follow procedures to ensure that a PET drug product is not given final release until:

—Appropriate laboratory testing under paragraph (a) of this section is completed,

—Associated laboratory data and documentation are reviewed (review may be performed by a second person or self-verified in a one-person operation) and they demonstrate that the PET drug product meets specifications, except for sterility, and

—A designated qualified individual authorizes final release by dated signature.

In many cases, the short half-life of a PET radionuclide precludes the completion and review of all laboratory testing before release of the PET drug product for distribution to a receiving facility. In such cases, release for distribution in accordance with previously established and documented procedures is acceptable as long as all testing and review, except for sterility, is completed before final release of the drug product. The PET production facility should document the communication of this authoritative decision to the receiving facility.

We are proposing special requirements for sterility testing because of the short half-lives of PET radionuclides. Proposed § 212.70(e) provides that:

• Sterility testing need not be completed before final release but must be performed within 30 hours after completion of production. Sterility testing should normally be started within 24 hours after production. We propose the additional 6 hours in response to the concerns of some PET drug producers that a 24-hour test initiation period would coincide with the peak activity for PET production the following day. Proposed § 212.70(e) would allow the 30-hour period to be exceeded in certain cases, such as weekends or holidays, provided it is shown that the extended period will not affect the stability or viability of the contaminants in the product or otherwise yield a potentially inaccurate result.

• Product samples must be tested individually and must not be pooled.

• If the product fails the sterility test, all receiving facilities must be notified of the results immediately.

• The notification must include any appropriate recommendations and must be documented.

We are also including in this proposal a provision to allow the conditional final release of PET drug products under certain conditions. At the September 28, 1999, public meeting on PET drug product CGMP, some comments stated that the regulations should allow PET drug producers to release a PET drug product if they experience an unanticipated, temporary failure of analytical equipment that prevents them from completing final release testing. The comments maintained that having duplicative equipment was difficult for smaller PET production facilities. They stated that having to cancel scheduled PET scans because of analytical equipment failure would inconvenience physicians and patients, some of whom may have traveled long distances to undergo the diagnostic procedure.

In our preliminary draft proposed rule, we requested comments on whether the regulations should allow the conditional final release of PET drug products in case of equipment breakdown and, if so, what conditions should apply to such release. Nearly all the comments that we received on this matter requested that conditional final release be permitted. After

consideration of the comments, we propose to allow the conditional final release of PET drug products under certain conditions.

Under proposed § 212.70(f), a PET drug producer that cannot complete one of the required finished product tests for a PET drug product because of a breakdown of analytical equipment may approve the conditional final release of the product if the conditions in proposed § 212.70(f)(1) through (f)(7) are met. These conditions would require the PET drug producer to do the following:

• Have data to document that preceding consecutive batches, produced using the same method of production as the conditionally released batch, demonstrate that the conditionally released batch will likely meet the established specifications,

• Determine that all other acceptance criteria are met,

• Notify the receiving facility of the incomplete testing,

• Retain a reserve sample of the conditionally released batch of drug product,

• Complete the omitted test using the reserve sample after the analytical equipment is repaired and document that reasonable efforts have been made to ensure that the problem does not recur,

• Immediately notify the receiving facility if an out-of-specification result is obtained when testing the reserve sample, and

• Document all actions regarding the conditional final release of the drug product, including the justification for the release, all followup actions, results of completed testing, all notifications, and corrective actions to ensure that the equipment breakdown does not recur.

Conditional final release should be a rare occurrence. In general, we believe that a PET drug producer should be prepared for equipment failures. Conditional final release would not be permissible when certain types of equipment fail. If a PET drug producer could not perform a radiochemical identity/purity test on the API of a PET drug product, conditional final release of a PET drug product would not be allowed. There are, however, certain tests, such as the gas chromatography (GC)-based residual solvent determination in FDG F 18, where an equipment failure could result in the authorization of a conditional final release if all the criteria in proposed § 212.70(f) were met. Conditional final release would not generally be appropriate for certain tests where it is difficult to envision equipment failing or where equipment should be very easy to replace (for example, in the case of FDG F 18, the hydrogen-ion concentration (pH) test, test for kryptofix, thin layer chromatography based radiochemical identity and purity tests). Alternate test methods can be developed and used when these problems occur, so conditional final release should not be necessary except in very rare circumstances. Repeated conditional final releases based on the unavailability of equipment that is difficult to envision failing or that is easily replaced could be considered to be a failure to take ''reasonable efforts * * * to ensure that the problem does not recur'' and could lead to FDA taking enforcement action.

M. Actions To Be Taken if Product Does Not Conform to Specifications

Proposed § 212.71 answers the question ''What actions must I take if a batch of PET drug product does not conform to specifications?'' Proposed § 212.71(a) states that:

• If a batch of a PET drug product does not conform to specifications, the PET drug producer must reject it.

• The producer must identify and segregate the nonconforming product to avoid mixups.

• The producer must have and follow procedures to investigate the causes of the nonconforming product.

• The investigation must include examination of processes, operations, records, complaints, and other relevant sources of information concerning the nonconforming product.

Under the proposal, PET drug producers also would be required to:

• Document the investigation of a PET drug product that does not conform to specifications, including the results of the investigation and what happened to the rejected PET drug product (proposed § 212.71(b)), and

• Take action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem (proposed § 212.71(c)).

PET drug producers would be permitted, if appropriate, to reprocess a batch of a PET drug product that does not conform to specifications (proposed § 212.71(d)). To reprocess material that does not meet acceptance criteria:

• The producer must follow preestablished procedures (set forth in production and process controls) and

• The finished product must conform to specifications, except for sterility, before final release.

Examples of reprocessing could include a second passage through a purification column to remove an impurity or a second passage through a filter if the original filter failed the integrity test.

N. Labeling and Packaging

Proposed § 212.80 answers the question ''What are the requirements associated with labeling and packaging PET drug products?'' Under proposed § 212.80, the following requirements would apply:

• PET drug products must be suitably labeled and packaged to protect the product from alteration, contamination, and damage during the established conditions of shipping, distribution, handling and use (proposed § 212.80(a)).

• Labels must be legible and applied so they will remain legible and affixed during the established conditions of processing, storage, handling, distribution, and use (proposed § 212.80(b)).

• Information stated on each label must also be contained in each batch production record (proposed § 212.80(c)).

• Labeling and packaging operations must be controlled to prevent product and labeling mixups (proposed § 212.80(d)).

O. Distribution Controls

Proposed § 212.90 answers the question ''What actions must I take to control the distribution of PET drug products?'' This section would primarily apply to PET production facilities that distribute PET drug products beyond the immediate vicinity of the production site. Under proposed § 212.90, PET drug producers would be required to:

• Establish, maintain, and follow written procedures for the control of distribution of PET drug products shipped from the PET production facility to ensure that shipping will not adversely affect the identity, purity, or quality of the PET drug product (proposed § 212.90(a)).

• Maintain distribution records for each PET drug product (proposed § 212.90(b)), including the following information:

—Name, address, and telephone number of the receiving facility that received each batch of a PET drug product,

—Name and quantity of the PET drug product shipped,

—Lot number, control number, or batch number for the PET drug product shipped, and

—Date and time the PET drug product was shipped.

P. Complaint Handling

Proposed § 212.100 answers the question ''What do I do if I receive a complaint about a PET drug product produced at my facility?'' We propose

the following requirements regarding complaints:

• PET drug producers must develop and follow written procedures for the receipt and handling of all complaints concerning a PET drug product (proposed § 212.100(a)).

• The procedures must include review by a designated person of any complaint involving the possible failure of a PET drug product to meet any of its specifications and an investigation to determine the cause of the failure (proposed § 212.100(b)).

• Producers must maintain a written record of each complaint in a file designated for PET drug product complaints (proposed § 212.100(c)), including the following information:

—Name and strength of the PET drug product,

—Batch number,

—Name of the complainant,

—Date the complaint was received,

—Nature of the complaint,

—Response to the complaint, and

—Findings of any investigation and followup.

• PET drug products that are returned because of a complaint may not be reprocessed and must be destroyed in accordance with applicable Federal and State law (proposed § 212.100(d)).

Q. Records

Proposed § 212.110 answers the question ''How must I maintain records of my production of PET drug products?'' Proposed § 212.110 would require that:

• PET drug producers maintain all records at the PET production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections (proposed § 212.110(a)). A reasonably accessible location is one that would enable the PET center to make requested records available to us in a reasonable period of time.

• All records, including those not stored at the inspected establishment, be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees (proposed § 212.110(b)).

• PET drug producers maintain all records and documentation referenced in part 212 for at least 1 year after the final release or conditional final release of a PET drug product (proposed § 212.110(c)).

III. Analysis of Economic Impacts

We have considered the potential economic impact of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize the benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The agency has determined that this proposed rule is not an economically significant rule as described in the Executive order because annual impacts on the economy are substantially below $100 million. Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant economic impact of a rule on small entities. We project that the rule may have a significant effect on a substantial number of small entities. A regulatory flexibility analysis explaining this finding is presented in the following paragraphs.

A. Regulatory Benefits

The Modernization Act requires us to establish appropriate good manufacturing practices for PET drugs. Without minimum manufacturing standards, unintentionally inferior PET drug products may be produced for human use. The short half-life characteristic of PET drug products often limits extensive and complete finished product testing prior to administration to humans. Moreover, recalls are usually impossible due to this short half-life, which can range from minutes to hours. Most PET drug products are marketed without FDA approval, and we have not received any official reports of adverse events. Official reports that can be relied upon to demonstrate or project the actual number of adverse events related to these products therefore do not exist. Tracing infections possibly caused by contaminated PET drugs to patients is difficult since there are a multitude of other factors that can cause infections in hospitalized patients, as well as a time delay before infection presents itself. Lacking this information, we are unable to quantify this proposal's reduction of risk of adverse events associated with PET drug products and the accompanying increase in public health benefits.

This proposed rule would create minimum manufacturing standards to ensure the safety, identity, strength, quality, and purity of PET drug products. Although, as discussed in section III.B of this document, all PET drug producers have adopted some level of good manufacturing practices or SOPs, not all producers currently are fully compliant with all USP standards. Therefore, compliance with the provisions of the proposed rule would ensure that all producers establish and implement adequate SOPs for production and quality control, including internal procedures for product quality audits, resulting in consistent production of quality products. Building quality into the production process would permit early detection and correction of problems and promote continuous improvement. Activities such as developing specifications may result in increased reliability and uniformity of PET drug products to patients. Ultimately, this rule would be expected to result in a reduction in adverse reactions to PET drug products and an increase in overall benefit to the public health.

B. Regulatory Costs

All PET drug producers have already adopted some level of good manufacturing practices or SOPs, although the specificity of the written documents may vary. The Modernization Act requires that compounded PET drugs conform to USP compounding standards and official monographs for PET drugs until CGMP regulations are established for PET drugs. For producers already following required USP standards, we would expect average compliance costs associated with this proposal to be small.

The proposed CGMP rule is expected to affect all PET drug producers, especially those affiliated with hospitals and academic medical centers, as well as the small number of unaffiliated regional producers that produce FDG F 18. Most of the large corporate PET drug

producers and hospital PET drug producers associated with these corporate entities are expected to already comply to a great degree with the proposed CGMP rule. Based on our contacts with industry, we have made a general assessment of the current operational status of PET drug producers.

For this cost analysis, we consulted with the PET community, including PET drug producers and professional associations, through direct contact as well as via public comments at public meetings and previously published preliminary proposed rules (for a full description of our interactions with the PET community regarding this proposed rule, see section I.B of this document). We visited six PET drug producers affiliated with academic medical centers and four commercial (corporate or regional) operations. Using the knowledge gained from these site visits, public meeting comments from industry members including the Academy of Molecular Imaging (AMI) (a primary professional organization for PET), and agency employee expertise in PET drug manufacturing procedures, we estimated the average level of effort needed to bring each of the different types of PET drug producer into compliance with this proposed rule. Compliance costs (labor costs) were then calculated using these estimated levels of effort. In effect, we projected compliance costs based on the expected additional labor above implicit baseline levels (based on information acquired through the site visits by FDA officials).

The estimated number of U.S. establishments producing PET drug products was created by combining an AMI-prepared list of PET centers with cyclotrons with a list of PET manufacturing facilities from the Society of Nuclear Imaging in Drug Development (which has since merged with the AMI), and adding additional facilities that we identified. This resulted in the projection that the proposed rule would affect 51 producers of PET drugs, operating 101 establishments. Fifteen of these producers own or operate 65 commercial establishments (16 of which are associated with academic hospitals). Of these 15 producers, 11 are regional or local unaffiliated producers that have begun to produce PET drug products in recent years. The other four commercial producers are corporations, each of which has multiple establishments. In total, these 4 corporate producers operate 48 establishments. The remaining 36 producers are part of academic or hospital institutions (see table 1 of this document).

TABLE 1.—PET DRUG PRODUCERS

Producer Type	No. of Producers	No. of Establishments
Hospital/Academic[1]	36	36
Commercial-Regional	11	17
Commercial-Corporate[2]	4	48
Total	51	101

[1] Sixteen hospital producers operated by commercial firms are counted under Commercial-Corporate.
[2] One producer may not be a corporation but is included here due to its multiple sites and longer history of PET drug production.

C. Compliance Requirements

The proposed CGMP rule would impose compliance requirements resulting in two types of costs. From the date of publication of the final rule until the effective date, PET drug producers would incur one-time costs as each producer is brought into compliance. In succeeding years, each producer would be expected to incur only annual costs related to maintaining compliance.

The following proposed sections contain the general requirements of the rule:

- Section 212.10: Require qualified and trained personnel.
- Section 212.20: Establish SOPs to define quality assurance.
- Section 212.30: Establish SOPs and prepare documents related to installation, cleaning, qualification, and maintenance of facilities and equipment.
- Section 212.40: Establish SOPs and prepare documents on the receipt, identification, storage, handling, testing, and approval of components and drug product containers and closures. Establish specifications for the components, containers, and closures.
- Section 212.50: Establish written production and process control procedures (including in-process parameters) for production of a PET drug. Prepare master production record and batch record.
- Section 212.60: Establish written procedures and schedules for the calibration, cleaning, and maintenance of laboratory testing equipment. Establish testing procedures for components, in-process materials and finished PET drug products.
- Section 212.61: Establish written procedures to assess the stability characteristics of PET drug products.
- Section 212.70: Establish acceptance criteria and written procedures to control the release of products. Prepare SOPs to establish system suitability of each test. Prepare documents to record tests performed on the PET drug product for final release.
- Section 212.71: Establish procedures to investigate the reason for product nonconformance.
- Section 212.80: Establish templates for labeling.
- Section 212.90: Establish procedures and documents for the distribution of PET drugs.
- Section 212.100: Establish procedures for the receipt and handling of complaints regarding a PET drug product.

We expect some variation in the exact SOPs that would need to be created or revised to comply with the proposal. We expect that the various types of producers already comply with the proposed rule to different extents. The hospital PET drug producers and the independent regional commercial producers would likely require more time and effort to comply than would the group of corporate producers. Because of this, we estimated average compliance efforts for two separate groups based on expected current compliance levels—the corporate

producers and the hospital and regional commercial producers.

1. Costs to Establish SOPs

All PET drug producers are expected to incur some costs associated with interpreting the rule, determining the manner of compliance, and implementing the compliance method. These costs would be included in the efforts of a designated individual or individuals who would be primarily responsible for bringing each center into compliance. In this case, we have included any general administrative efforts in the time required to establish and write the SOPs for the previously listed requirements and to prepare templates for CGMP documentation.

The document entitled ''Sample Formats for Chemistry, Manufacturing, and Controls Sections''[1] provides guidance that may be helpful in preparing master production records, finished-product release testing records, and in-coming component tracking and testing records. PET drug producers would have the option of choosing their own format (and the amount of detail) as long as essential information required by the CGMPs is included. We believe that the CGMP guidance will aid PET drug producers that have little or no experience in creating these documents, helping to reduce compliance costs.

We estimate that all hospital and regional commercial producers will need from 3 to 5 months to establish and write detailed SOPs that comply with this rule, even with the guidance provided and the understanding that these establishments currently operate under less-detailed SOPs. We assume that the employee responsible for writing the SOPs would be in a management position, either in quality assurance or elsewhere, with a salary of up to $100,000 per year. Including an additional 35 percent for employee benefits, the cost of an average 4-month effort would amount to $45,000 for each hospital and regional commercial PET drug producer.[2]

Although most corporate PET drug producers are believed to have a complete set of SOPs, we believe each would expend some time to verify its compliance with this proposal and make minor adjustments to their SOPs. We estimate that it would take, on average, 1 month for an individual to complete the same undertaking due to the current high compliance rates expected at the corporate establishments.[3] This would result in a cost of approximately $11,250 per corporate PET drug producer, again using an estimated salary of $100,000 per year plus benefits. We assume that corporate producers with multiple manufacturing sites would amend a single set of SOPs to cover all of their production sites. Since there are currently four corporate producers of PET drug products, the cost of the SOP revisions is estimated at $45,000 (4 times $11,250).

The SOP establishment or revision work could be performed by company personnel or an outside consultant or contractor. Although we predict that the use of an outside consultant or contractor would be more likely at the hospital and regional commercial PET drug producers, we would not expect the total cost of this compliance effort to vary considerably.

Producers would also be expected to provide some additional training to at least one person on revisions made to current procedures to comply with the CGMP rule. While we do not think extensive training would be necessary at most establishments, our experience with PET drug production procedures and our 10 producer site visits leads us to believe that one person at each establishment could need up to 1 week of additional training. The cost of this additional training would amount to about $262,000 (101 establishments times 1 week at $135,000 per year).

The total cost for initial compliance associated with writing the SOPs and creating document forms amounts to approximately $2.42 million. The 47 hospital and regional commercial producers would incur a total of about $2.25 million (47 producers times $45,000 plus 53 establishments times $2,600). The 4 corporate producers would incur a total of about $170,000 (4 producers times $11,250 plus 48 establishments times $2,600). Annualizing the total one-time cost over 5 years at a 7-percent discount rate results in annualized costs of about $591,000 (at a 3-percent discount rate, the costs are estimated to be about $529,000).

Once procedures are established and documents are in place to record PET drug production and events associated with routine production of PET drugs, we would expect there to be some additional costs for the day-to-day implementation of the CGMP provisions. Periodic audits conducted by company personnel to ensure compliance with current procedures would have to be expanded to include any provisions with which the company was not already in compliance (for example, tracking and recordkeeping of incoming components, proper documentation of production and laboratory testing, tracking, investigation and documentation of products not meeting specifications). Additional time would also be spent updating the SOPs as the equipment and procedures used in the manufacture of PET drugs are upgraded and refined.

We project the day-to-day implementation of the CGMP rules would require, at most, 1 to 2 additional hours per day for an individual at each hospital or regional commercial producer. Using the midpoint of this range would result in 2.25 additional months of labor each year. Using the same estimated annual salary ($100,000 plus benefits), 2.25 months of labor equates to about $25,300 in annual costs to each PET drug production establishment, or about $1.34 million for all 53 hospital and regional commercial producer establishments. Our assessment of corporate PET drug producers is that they comply substantially with the proposed rule. For these producers, we project that 1 production individual may expend an additional 1 month of effort over the course of each year (about 3 hours per week) in order to comply with the proposed rule. This month would result in each corporate PET center incurring about $11,250 in additional annual costs, totaling $540,000 for the 48 corporate PET drug production establishments. Some producers would probably opt to use an outside consultant to manage the implementation of the new rules in the first year. Although we do not know how many producers would hire a consultant, we would not expect this to affect the total cost considerably, as the cost of the consultant would replace the cost of the company employee. Total annual costs for day-to-day implementation are estimated at $1.88 million.

Producers would also be expected to provide some additional training in future years on SOPs that were amended to comply with this CGMP rule. We would expect that this training (review for current employees as well as new employees) would be incorporated into

[1] The document is an attachment to the guidance for industry entitled ''PET Drug Applications—Content and Format for NDAs and ANDAs: Fludeoxyglucose F 18 Injection, Ammonia N 13 Injection, Sodium Fluoride F 18 Injection'' (available on the Internet at *http://www.fda.gov/cder/guidance*).

[2] Salary represents upper range of estimate (intended to not underestimate costs) provided at FDA site visit to a commercial PET drug producer on October 2, 2001. Although there is uncertainty concerning salaries paid by academic/hospital producers, we assume they would pay a salary similar to those of corporate producers.

[3] Labor hour estimate from FDA site visit to a PET drug producer on October 2, 2001.

current training programs and therefore be less burdensome to producers. Nevertheless, we have included the cost for annual training for one person per establishment for one-half week. The cost of this additional training would amount to about $131,000 (101 establishments times one-half week at $135,000 per year).

Total annual costs associated with daily implementation and training amount to $2.01 million. The 53 hospital and regional commercial establishments would incur a total of about $1.41 million (53 establishments times ($25,300 plus $1,300)). The average cost per facility for these provisions is $26,600. The 48 corporate production establishments would incur a total of about $602,000 (48 establishments times ($11,250 plus $1,300)). The average cost per facility for these provisions is $12,600.

TABLE 2.—CGMP COSTS

Rule Requirement	No. of Estab.	Labor (Months)	Wage (Yr. Sal) [1]	Cost [2]
One-Time Costs				
Establish/Write SOPs				
Academic PET Producers	47	3	$135,000	$2,115,000
Commercial PET Producers	4	1	$135,000	$45,000
Training on SOPs				
Academic PET Producers	53	0.23	$135,000	$138,000
Commercial PET Producers	48	0.23	$135,000	$125,000
Total One-Time Costs				$2,422,000
Annual Costs				
Rule Requirement				
Daily Implementation, Audits, Updates				
Academic PET Products	53	2.25	$135,000	$1,342,000
Commercial PET Products	48	1.0	$135,000	$540,000
Training				
Academic PET Products	53	0.11	$135,000	$69,000
Commercial PET Products	48	0.11	$135,000	$62,000
Total Annual Costs				$2,013,000

[1] Salary includes 35 percent increase for benefits.
[2] Cost totals may not sum to rounding.

2. Equipment Costs

Based on at least 10 site visits to PET drug production facilities (both commercial and academic) by FDA personnel, we believe that the current laboratory facilities and equipment comply with the requirements of the proposed rule. Therefore, additional costs for laboratory space or equipment would not be incurred in complying with this regulation. Further, we believe that the qualification procedures for all current production equipment already occur as a matter of current business practice, and further equipment qualification procedures would not be required.

3. Process Verification Costs

In response to public comments to the preliminary draft proposed rule, modifications have been made to the process verification requirements. For this proposed rule, all PET drug product batches that undergo full finished-product testing to ensure that the product meets specifications would not be required to verify the production process. Currently, all NDA-approved PET drug products undergo finished-product testing. We believe that all PET drug products that will receive NDA approval in the foreseeable future will undergo finished-product testing. This is because it would be difficult, using current PET drug technology, to commercialize a PET drug product with a half-life of only minutes (which would prevent finished-product testing before release). Therefore, the proposed finished-product testing requirement would not be expected to impose any additional burden in the near term. In the future, however, it is possible that some small percentage of PET drugs products with NDA approval may submit only the initial sub-batch to finished-product testing before release. In such cases, producers would have to document their process verification procedures. Since we do not know how many, if any, PET drug products such as this would be approved in the future, we are unable to estimate any additional burden to the industry from process verification requirements. Nevertheless, we believe current business practice includes process verification, so any burden to producers would result from the need to document and organize the verification activities.

4. Total Costs

Total one-time costs are estimated at about $2.42 million (annualized at $591,000 over 5 years at 7 percent, and at $529,000 at 3 percent), and annual costs at about $2.01 million (see table 3

of this document). The 53 hospital and regional commercial PET drug production establishments would incur about $2.25 million in one-time costs and $1.41 million in annual costs. The annualized (annualized one-time costs plus annual costs) cost per facility is estimated at about $35,700 at a 7-percent discount rate (and at $34,600 at 3 percent). The 48 corporate PET production facilities would incur about $170,000 and $602,000 in one-time and annual costs, respectively. Total annualized (annualized one-time costs plus annual costs) costs per corporate establishment are estimated at about $13,400 at a 7-percent discount rate (and at $13,300 at 3 percent). Total annualized costs for all producers are estimated at $2,603,000 at a 7-percent discount rate (and at $2,541,000 at 3 percent).

TABLE 3.—PET DRUG PRODUCERS' COMPLIANCE COSTS

	One-Time Cost	Annual Cost
Hospital and Regional Commercial Establishments (53)	$2,250,000	$1,410,000
Corporate Establishments (48)	$170,000	$602,000
Total Cost [1]	$2,420,000	$2,010,000
Total Annualized Cost [2]		2,600,000

[1] Sum of costs may not equal total cost due to rounding.
[2] Total annualized cost equal to total one-time cost discounted at 7-percent over 5 years plus total annual cost. Using a 3-percent discount rate reduces annualized costs by about $60,000.

D. Growth of the PET Industry

Although we do not have reliable estimates of the annual number of PET scans, the number has increased dramatically over the last 10 years, due at least in part to the increased numbers of disease conditions for which both public and private insurers have extended coverage. The number of establishments producing PET drug products, and FDG F 18 in particular, has also increased over this time period. As mentioned previously in this document, the majority of this growth in establishments reflects commercial operations that focus mainly or solely on FDG F 18 production.

As demand for PET scan services and, therefore, PET drug products is expected to continue to increase, we have projected compliance costs over the next 10 years. We cannot confidently predict the number of additional PET drug production runs to meet the additional demand for PET services because of unknown factors. We do not know the number of additional diseases for which PET will be used and be reimbursable in the future or possible increases in size of production batches of PET drugs. Because PET drug producers are not currently producing to capacity, we believe that increased demand would be partially met by increasing production runs and batch sizes at existing establishments rather than proportional increases in the number of PET production establishments. We have therefore tentatively projected that average annual PET drug production establishment increases would range from 3 to 7 percent. Assuming this growth occurs evenly across producer types, this growth rate implies an increase in annualized costs from $2.60 million currently to $3.40 to $4.79 million in year ten (with a present value of $3.37 million at a 7-percent discount rate, and $3.64 million at a 3-percent discount rate). The PET drug risk reduction resulting from this rule would also apply to the additional volume of PET drug dosages implied by the 3 to 7 percent annual growth rate in PET drug establishments. We request public comment and data on the annual number of PET scans and the expected future growth rate of PET drug products and production establishments subject to this proposed rule.

E. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities if that rule may have a significant impact on a substantial number of small entities.

1. Objective of the Rule

The implementation of this proposed rule, in accordance with the Modernization Act, would help ensure the safety, identity, strength, quality, and purity of PET drugs by establishing CGMP. The objective of the proposal is to reduce the risk to public health from adverse events that would be more likely to occur in the absence of adherence to CGMP for PET drug products.

2. Definition of Small Entities

A regulatory flexibility analysis (RFA) is required to estimate the number of small entities to which the proposed rule would apply. Under the Regulatory Flexibility Act (as amended), the definition of a small entity would include a small business as defined under the Small Business Administration (SBA) Act, nonprofit organizations, and small governmental jurisdictions.

This rule would affect producers of PET drug products. These include certain hospitals, clinics, colleges and universities, and producers of in vivo diagnostic substances. According to the SBA, pharmaceutical preparation manufacturers with 750 or fewer employees, electromedical and electrotherapeutic apparatus manufacturers with 500 or fewer employees, drugs and druggists' sundries wholesalers with 100 or fewer employees, and for-profit hospitals, clinics, colleges, and universities with $29 million or less in revenue are considered small businesses or entities. As stated earlier in this analysis, we identified 101 establishments operated by 51 PET drug producers. In over one-third of the cases, the PET drug product is produced by a hospital. In other instances, a corporate producer manages production under contract at one or more hospitals with cyclotrons. PET drug products are also produced at independent establishments by corporate producers or small regional producers. Total producer numbers continue to increase as the current corporate producers expand their

number of establishments and more independent regional producers enter the market.

Using information from the American Hospital Association (AHA), we characterized 28 of the hospital producers as one of the following establishment types:

- Government, non-Federal;
- Government, Federal;
- Non-Government not-for-profit; and
- Investor-owned (for-profit).[4]

The AHA data did not include information for eight hospitals associated with large colleges or universities, but for this analysis, these were assumed to be not-for-profit because approximately 93 percent of all 4-year higher education institutions are public or nonprofit institutions.[5] Census data reports indicate that private hospitals (with more than 100 employees) average gross revenues of about $36.8 million in 1997. This figure inflates to about $46.0 million using the Consumer Price Index (CPI) for medical care from 1997 to 2003. Considering that hospitals producing PET drug products would probably be larger than the average private hospital, we consider it very likely that the two private hospitals producing PET drugs have annual revenues over $29 million and would therefore not be considered small entities.[6] In instances where PET drug producer information is not available, this analysis assumes that the PET drug producer is owned by the hospital in which it is located.

Two of the three domestic corporate PET drug producers exceed the SBA employee limits within their respective business classifications to qualify as small businesses. Employee data were not available for the other domestic corporation or any of the 11 regional commercial producers, and we therefore assume that these may be small businesses.

In total, the 51 identified producers of PET drug products are classified as follows: 6 Federal, 6 State, 34 small entities, and 5 large entities. Most of those that were considered small entities were classified as such because they are not-for-profit organizations, not because they met the employee or revenue limits for small businesses. It should be noted that an entity's identification as small or large in this analysis does not necessarily indicate the volume of PET drug products it produces or the share of the market it holds.

3. Impact on Small Entities

Another requirement of an RFA is that we estimate the reporting, recordkeeping, and other compliance requirements on small entities. These requirements are detailed in the regulatory cost section of this preamble. Most, if not all, of the PET drug producers currently employ individuals who possess skills necessary to establish written procedures and prepare documentation as required by this rule. Some may choose, as mentioned above, to contract with an outside consultant to manage their compliance with the rule.

At most, a single-establishment PET drug producer may incur one-time and annual costs of approximately $42,500 and $25,300 per operating facility, respectively. The hospital and regional commercial producers would incur these higher per-facility costs because these establishments are expected to require more time to fully comply with the written procedure and recordkeeping requirements. The total of the maximum one-time and annual costs per producer equates to significantly less than 1 percent of the $88 million ($70.8 million inflated by the CPI for medical care from 1997 until 2003) average annual gross revenue per nonprofit hospital. In addition, most of the hospitals that would be affected by this rule are affiliated with large universities whose total revenues are expected to be much higher than the $88 million figure cited. The estimated compliance cost would represent an even smaller portion of a percent of the entire university's revenues. Revenue data were not available for the one possibly small corporate producer. This company would incur annual costs of approximately $62,700 and one-time costs of about $24,000. The 11 regional commercial producers are expected to incur one-time and annual costs of approximately $42,500 per producer and $25,300 per operating facility, respectively. We lack sufficient data to estimate the expected compliance costs as a percent of revenues for the regional commercial producers. Accordingly, it is possible that this proposed rule might have a significant effect on these small entities. We request comment on the extent of the effect that this rule will have on small entities, as well as additional data to profile PET drug producers.

4. Other Federal Rules

We are not aware of any relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule. We request any information that may show otherwise.

5. Description of Alternatives

Several alternative provisions were considered but not adopted during the formulation of this rule.

Traditional CGMP. We considered requiring PET drug producers to follow traditional CGMP (parts 210 and 211), but because these requirements would not allow the flexibility of PET drug CGMP detailed in this rule, the compliance costs would have been much greater under this alternative. The increased flexibility provided by this proposal is believed to be more appropriate because of the special characteristics of PET drugs, including their short half-life, small-scale manufacturing, and limited distribution environment.

Specific identity testing of PET drug components. We were also interested in preventing contamination of PET drugs with components that may present a threat to public health. We therefore considered an alternative that would have required specific identity testing of PET drug components. In the May 2002 preliminary proposed rule, we proposed that PET drug producers perform identity testing on raw materials that yield a drug substance and each inactive ingredient that is not a finished drug product. For FDG F 18 production, this would have required that mannose triflate be tested using either infrared spectroscopy (IR) or nuclear magnetic spectroscopy (NMR). We were unable to estimate the current level of compliance with this provision and therefore assumed the level to be zero, although it is possible that some PET drug producers currently perform this testing. Contact with PET drug producers indicated that the most probable method of compliance would have been to use a private laboratory to perform these tests under contract to the PET drug producers. Although some producers, especially hospital producers, may have IR testing equipment or could at least acquire these services from other departments at their institutions, we assumed they would also use the services of private laboratories.

We estimated that producers receive from two to six lots of mannose triflate annually, and we believe the average number is around three. We have estimated the costs of the identity testing alternative assuming the use of NMR. Since testing could be done using

[4] "AHA Guide to the Health Care Field, 1997–98 Edition." Healthcare Infosource, Inc., a subsidiary of the American Hospital Association.

[5] "The Nation: Colleges and Universities," *The Chronicle of Higher Education, 1999–2000, Almanac Issue*, volume XVI, no. 1, p. 7, August 27, 1999.)

[6] "Hospital Statistics," table 3, pp. 8–9, Health Forum, An American Hospital Association Company, 1999.

either IR or NMR, with IR being somewhat less expensive, our estimates may overstate actual costs. Sample testing using the NMR is expected to cost up to $400 including the additional consultation and interpretation of the results with the technical staff. Testing three lots per year would result in a cost of $1,200 to each PET drug producer. We estimate that the total annual cost of identity testing the mannose triflate would have been about $121,000 for all PET drug producers.

Identity testing of O 18 water would be performed through the cyclotron production run and is believed to be current practice. Therefore, no additional compliance costs would have been added for identity testing of the O 18 water.

Many of the hospital PET producers make a small number of additional PET drug products and may use other inactive ingredients. Almost all excipients and other components are marketed as finished drug products and would not have required identification testing under this alternative policy. We do not have enough data to estimate confidently the average number of additional PET drug products made by each establishment, but we conservatively project that two components would require identity testing at each of the 36 hospital PET producers as well as the 16 hospital producers operated by corporate producers. Identity testing of these additional components would have added an additional $2,400 per PET drug producer (2 components times $400 per test times 3 lots per year), resulting in a total of about $125,000 in costs to the industry ($2,400 times 36 academic and hospital producers plus 16 hospital producers operated by industry). The total cost of identity testing of components would have amounted to about $246,000 ($121,000 for mannose triflate and $125,000 for the other components). The regional commercial PET drug producers and the corporate producers (excluding hospital producers operated by corporate entities) are believed to produce only FDG F 18. These producers would have incurred no additional costs under this alternative.

PET drug producers commented that this alternative requirement would still be unnecessary and unduly burdensome because components and contaminants would be identified in finished-product testing and a certificate of analysis is provided by the supplier. We are in substantial agreement with these comments and have removed the component identity testing requirement from the proposed rule.

Verification of the certificate of analysis. A related alternative, also proposed in the preliminary draft proposed rule of May 2002, would have required producers to verify the component specifications as written on the certificate of analysis. We believe that certificate of analysis verification would also be completed by independently testing the first three lots of each component received. We estimate that this would require contract testing of about three components for the hospital and regional commercial producers and about two components for the corporate producers. The total cost associated with verifying the reliability of the component suppliers would be a one-time cost of about $306,000. This would include $3,600 (3 lots times 3 components times $400) for each hospital and regional commercial producer establishment for a total of $191,000, and about $2,400 (3 lots times 2 components times $400) for corporate producer establishments for a total of about $115,000. Using a discount rate of 7 percent over 5 years, the annualized cost would have amounted to about $75,000.

Several PET drug producers commented that a requirement for verification of the supplier's certificate of analysis would also be unnecessary and unduly burdensome. They stated that an established track record with a supplier showing no problems in finished-product test results should adequately establish the reliability of a supplier. As with the component identity testing alternative, we are in substantial agreement with PET drug producer comments and have not included the certificate of analysis verification requirement in the proposed rule.

Validation of production and process controls. We also considered a requirement that production and process controls in every PET drug production process be validated according to established procedures. This provision was included in the preliminary draft proposed rule. It would have provided for retrospective validation in most cases, which would have relied on a review of historical data to show that each process is sufficiently capable of yielding batches meeting specifications. PET drug producers commented that this provision would be unnecessarily burdensome for those producers without written validation protocols, and finished-product testing would alleviate the safety concerns. After considering these comments, we decided not to include this provision in the proposed rule. While we did not calculate a separate cost for this provision, we believe it could have been burdensome for some producers.

Audit trail capabilities. Another alternative would have been to require audit trail capabilities for all computer-operated systems to ensure the security of all production and nonproduction records. For nonproduction systems, software is available with audit trail capabilities and can be run alongside a widely used spreadsheet software program. This additional software system would provide PET producers with audit trail capabilities for tracking the receipt of drug components and in-process materials, the distribution of finished products, batch records, complaint files, personnel training, and equipment maintenance. Prices for this software, including its base price, a validation package, and annual maintenance and support, are available on the Internet. The entire package would amount to about $7,000 in first year costs for a PET drug producer. A short training course provided by the software vendor would increase first year costs by about $1,600 for each producer. In order to account for some uncertainty and regional price differences for this or similar software programs, we increased the estimated costs about 50 percent. Compliance costs would therefore be expected to total about $12,900 for each PET drug producer ($10,400 for the base license, validation package, and first year maintenance and support plus about $2,400 for a short training program). We believe there is very little use of software providing secure audit trail capabilities. Therefore, we assumed that to comply with this provision, all PET drug producers would have had to purchase software providing secure audit trail capabilities. The total first year cost of this software would have been about $1,303,000 for the 101 PET drug production establishments. We further assumed that 50 percent of the producers would need to purchase the spreadsheet software at a cost of about $150 each, adding $7,600 to the software costs. Total one-time software costs for non-production equipment would have been about $1,310,000.

The manufacturers of the audit-trail capable software would also have been expected to provide on-site maintenance and support of their systems, as mentioned above. PET drug producers would have been expected to purchase these maintenance and support systems. Based on our contact with one such software manufacturer, we estimated that the annual cost of such a system would be about $1,000 per year. In order to account for the uncertainty in using

only a single software application in estimating costs, we increased this amount to about $1,500 for each PET drug producer for this analysis. The estimated total cost for all 101 producers would have been about $152,000 annually.

We also considered requiring the radiochemical synthesis apparatus, as well as the HPLC and GC equipment, to have secure audit trail software systems with electronic signature capabilities. We believe that most of this equipment and programming software currently provides date, time, and employee identification capabilities. However, for at least some producers we believe that a software update would be required to provide, at a minimum, file deletion prevention capabilities. While software packages are updated regularly in the industry, we did not have enough information to estimate the incremental cost of updating all types of production equipment software to include audit trail capabilities. Information on electronic recordkeeping, which would apply to electronic audit trails, may be found in 21 CFR part 11; Electronic Records; Electronic Signatures and the draft guidance document entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' We invite public comment and data on the scope and cost of creating electronic audit trail capability, including data on current audit trail capabilities within the industry.

The electronic audit trail requirements we have described were excluded from the proposed rule because we could not determine if the additional level of quality assurance would justify the additional compliance costs. We request public comment and data concerning the need for electronic audit trail requirements as part of the CGMPs for PET drug products.

IV. Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice for Positron Emission Tomography Drugs

Description: In accordance with the Modernization Act, the proposed rule would establish CGMP requirements for PET drugs. The proposed CGMP requirements are designed to take into account the unique characteristics of PET drugs, including their short half-lives and the fact that most PET drugs are produced at locations that are very close to the patients to whom the drugs are administered. The estimate is based on there being 51 PET drug producers operating 36 hospital or academic facilities and 65 commercial facilities for a total of 101 PET drug production facilities.

The proposed regulations are intended to ensure that approved PET drug products meet the requirements of the act as to safety, identity, strength, quality, and purity. The proposed regulations address the following matters: Personnel and resources; quality control; facilities and equipment; control of components, in-process materials, and finished products; production and process controls; laboratory controls; acceptance criteria; labeling and packaging controls; distribution controls; complaint handling; and recordkeeping.

The proposed CGMP regulations would establish several recordkeeping requirements for the production of PET drugs. In making our estimates of the time spent in complying with these proposed requirements, we relied on communications we have had with PET producers, visits by our staff to PET facilities, and our familiarity with both PET and general pharmaceutical manufacturing practices.

Description of Respondents: Academic institutions, hospitals, commercial manufacturers, and other entities that produce PET drug products.

Burden Estimate: Table 4 of this document provides an estimate of the annual recordkeeping burdens associated with the proposed rule. We are not proposing any reporting requirements. All of our recordkeeping burden estimates are based on there being 101 PET production facilities, with each of the 36 academic or hospital facilities producing 3 different PET drug products and each of the 65 commercial facilities producing 1 PET drug product, resulting in an estimated 173 total PET drug products. Our estimates are also based on a 250-day work year with an average yearly production of 500 batches for each facility. We have also taken into account that time spent on recording procedures, processes, and specifications may be somewhat higher in the year in which these records are first established and correspondingly lower in subsequent years, when only updates and revisions would be required.

A. Investigational and Research PET Drug Products

Proposed § 212.5(b)(2) provides that for investigational PET drugs or drug products produced under an IND and research PET drugs or drug products produced with approval of an RDRC, the requirement under the act to follow current good manufacturing practice is met by complying with USP 28 Chapter <823>. We believe that PET production facilities producing drugs under INDs and RDRCs are currently substantially complying with the recordkeeping requirements of USP 28 Chapter <823> (see section 121(b) of the Modernization Act), and accordingly, we have not estimated any recordkeeping burden for this provision of this proposed rule.

B. Batch Production and Control Records

Proposed §§ 212.20(c) through (e), 212.50(a) through (c), and 212.80(c) set out requirements for batch and production records as well as written control records. We estimate that it would take 20 hours annually for each PET production facility to prepare and maintain written production and control procedures and to create and maintain master batch records for each PET drug product produced. We also estimate that there will be a total of 173 PET drug products produced, with a total estimated recordkeeping burden of 3,460 hours. We estimate that it would

take a PET production facility an average of 30 minutes to complete a batch record for each of 500 batches. Our estimated burden for completing batch records is 25,250 hours.

C. Equipment and Facilities Records

Proposed §§ 212.20(c), 212.30(b), 212.50(d), and 212.60(f) contain requirements for records dealing with equipment and physical facilities. We estimate that it would take 1 hour to establish and maintain these records for each piece of equipment in each PET production facility. We estimate that the total burden for establishing procedures for these records would be 1,515 hours. We estimate that recording maintenance and cleaning information would take 5 minutes a day for each piece of equipment, with a total recordkeeping burden of 31,436 hours.

D. Records of Components, Containers, and Closures

Proposed §§ 212.20(c), 212.40(a) through (b) and (e) contain requirements on records regarding receiving and testing of components, containers, and closures. We estimate that the annual burden for establishing these records would be 202 hours. We estimate that each facility would receive 36 shipments annually and would spend 10 minutes per shipment entering records. The annual burden for maintaining these records would be 604 hours.

E. Process Verification

Proposed § 212.50(f)(2) would require that any process verification activities and results be recorded. Because process verification would only be required when results of the production of an entire batch are not fully verified through finished-product testing, we believe that process verification will be a very rare occurrence, and we have not estimated any recordkeeping burden for documenting process verification.

F. Laboratory Testing Records

Proposed §§ 212.20(c), 212.60(a) through (b) and (g), 212.61(a) through (b), and 212.70(a) through (b) and (d) set out requirements for documenting laboratory testing and specifications referred to in laboratory testing, including final release testing and stability testing. We estimate that each commercial PET production facility will need to establish procedures and create forms for 20 different tests for the 1 product they produce. Each hospital and academic PET drug production facility will need to establish procedures and create forms for a total of 34 different tests for the 3 products they produce. We estimate that it will take each facility an average of 1 hour to establish procedures and create forms for one test. The estimated annual burden for establishing procedures and creating forms for these records would be 2,525 hours, and the annual burden for recording laboratory test results would be 8,383 hours.

G. Sterility Test Failure Notices

Proposed § 212.70(e) would require PET drug producers to notify all receiving facilities if a batch fails sterility tests. We also believe that sterility test failures will be a very rare occurrence, and we have estimated no recordkeeping burden for the notices. If such an event were to occur, we believe that PET drug producers would use e-mail and facsimile transmission to notify the receiving facilities of the test failure. Providing notice should take less than 1 hour per failure.

H. Conditional Final Releases

Proposed § 212.70(f) would require PET drug producers to document any conditional final releases of a product. We believe that conditional final releases would be fairly uncommon, but for purposes of the PRA, we have estimated that each PET production facility would have one conditional final release a year and would spend 1 hour documenting the release and notifying receiving facilities.

I. Out-of-Specification Investigations

Proposed §§ 212.20(c) and 212.71(a) and (b) would require PET drug producers to establish procedures for investigating products that do not conform to specifications and conduct these investigations as needed. We estimate that it would take 1 hour annually to record and update these procedures for each PET production facility. We also estimate, for purposes of the PRA, that one out-of-specification investigation would be conducted at each facility each year and that it would take 1 hour to document the investigation.

J. Reprocessing Procedures

Proposed §§ 212.20(c) and 212.71(d) would require PET drug producers to establish and document procedures for reprocessing PET drug products. We estimate that it would take 1 hour a year to document these procedures for each PET production facility. We have not estimated a separate burden for recording the actual reprocessing, both because we believe it would be an uncommon event and because the recordkeeping burden has been included in our estimate for batch production and control records.

K. Distribution Records

Proposed §§ 212.20(c) and 212.90(a) would require that written procedures regarding distribution of PET drug products be established and maintained. We estimate that it would take 1 hour annually to establish and maintain records of these procedures for each PET production facility. Proposed § 212.90(b) would require that distribution records be maintained. We estimate that it would take 15 minutes to create an actual distribution record for each batch of PET drug products, with a total burden of 1,375 hours for all PET producers.

L. Complaints

Proposed §§ 212.20(c) and 212.100 would require that PET drug producers establish written procedures for dealing with complaints, as well as document how each complaint is handled. We estimate that establishing and maintaining written procedures for complaints would take 1 hour annually for each PET production facility and that each facility would receive one complaint a year and would spend 30 minutes recording how the complaint was dealt with.

We invite comments on this analysis of information collection burdens.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
212.20(c) and (e), 212.50(a) and (b)	101	1.71	173	20	3,460

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
212.20(d) and (e), 212.50(c), 212.80(c)	101	500	50,500	.5	25,250
212.20(c), 212.30(b), 212.50(d), 212.60(f)	101	15	1,515	1	1,515
212.30(b), 212.50(d), 212.60(f)	101	3,750	378,750	.083	31,436
212.20(c), 212.40(a) and (b)	101	2	202	1	202
212.40(e)	101	36	3,636	.166	604
212.20(c), 212.60(a) and (b), 212.61(a), 212.70(a), (b), and (d)	101	25	2,525	1	2,525
212.60(g), 212.61(b), 212.70(d)(2) and (d)(3)	101	500	50,500	.166	8,383
212.70(f)	101	1	101	1	101
212.20(c), 212.71(a)	101	1	101	1	101
212.71(b)	101	1	101	1	101
212.20(c), 212.71(d)	101	1	101	1	101
212.20(c), 212.90(a)	101	1	101	1	101
212.90(b)	101	500	50,500	.25	12,625
212.20(c), 212.100(a)	101	1	101	1	101
212.100(b) and (c)	101	1	101	.5	50
Total					86,656

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the PRA, we have submitted the information collection requirements of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB.

Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB. OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have tentatively determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Consequently, we do not currently plan to prepare a federalism summary impact statement for this rulemaking procedure. We invite comments on the federalism implications of this proposed rule.

VII. Proposed Effective Date

In accordance with section 121 of the Modernization Act, we propose that any final rule that may issue based on this proposal become effective 2 years after the date on which we issue the final rule.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 210

Drugs, Packaging and containers.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 212

Current good manufacturing practice, Drugs, Incorporation by reference, Labeling, Laboratories, Packaging and containers, Positron emission tomography drugs, Prescription drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Modernization Act of 1997, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 210.1 [Amended]

2. Amend § 210.1(a), (b), and (c) by removing the phrase ''211 through 226'' each time it appears and by adding in its place the phrase ''211, 225, and 226''.

§ 210.2 [Amended]

3. Amend § 210.2(a) and (b) by removing the phrase ''211 through 226'' both times it appears and by adding in its place the phrase ''211, 225, and 226''.

§ 210.3 [Amended]

4. Amend § 210.3 in paragraphs (a) and (b) introductory text by removing the phrase ''211 through 226'' and adding in its place the phrase ''211, 225, and 226''.

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

5. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

6. Amend § 211.1 by revising paragraph (a) to read as follows:

§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drug products) for administration to humans or animals.

* * * * *

7. Add part 212 to read as follows:

PART 212—CURRENT GOOD MANUFACTURING PRACTICE FOR POSITRON EMISSION TOMOGRAPHY DRUGS

Subpart A—General Provisions

Sec.

212.1 What are the meanings of the technical terms used in these regulations?

212.2 What is current good manufacturing practice for PET drugs?

212.5 To what drugs do the regulations in this part apply?

Subpart B—Personnel and Resources

212.10 What personnel and resources must I have?

Subpart C—Quality Assurance

212.20 What activities must I perform to ensure product quality?

Subpart D—Facilities and Equipment

212.30 What requirements must my facilities and equipment meet?

Subpart E—Control of Components, Containers, and Closures

212.40 How must I control the components I use to produce PET drugs and the containers and closures I package them in?

Subpart F—Production and Process Controls

212.50 What production and process controls must I have?

Subpart G—Laboratory Controls

212.60 What requirements apply to the laboratories where I test components, in-process materials, and finished PET drug products?

212.61 What must I do to ensure the stability of my PET drug products through expiry?

Subpart H—Finished Drug Product Controls and Acceptance Criteria

212.70 What controls and acceptance criteria must I have for my finished PET drug products?

212.71 What actions must I take if a batch of PET drug product does not conform to specifications?

Subpart I—Packaging and Labeling

212.80 What are the requirements associated with labeling and packaging PET drug products?

Subpart J—Distribution

212.90 What actions must I take to control the distribution of PET drug products?

Subpart K—Complaint Handling

212.100 What do I do if I receive a complaint about a PET drug product produced at my facility?

Subpart L—Records

212.110 How must I maintain records of my production of PET drug products?

Authority: 21 U.S.C. 321, 351, 352, 355, 371, 374; Sec. 121, Pub. L. 105–115, 111 Stat. 2296.

Subpart A—General Provisions

§ 212.1 What are the meanings of the technical terms used in these regulations?

The following definitions apply to words and phrases as they are used in this part. Other definitions of these words may apply when they are used in other parts of this chapter.

Acceptance criteria means numerical limits, ranges, or other criteria for tests that are used for or in making a decision to accept or reject a unit, lot, or batch of a PET drug product.

Act means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321 *et seq.*).

Active pharmaceutical ingredient means a substance that is intended for incorporation into a finished PET drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis or monitoring of a disease or a manifestation of a disease in humans, but does not include intermediates used in the synthesis of such substance.

Batch means a specific quantity of PET drug product intended to have uniform character and quality, within specified limits, that is produced according to a single production order during the same cycle of production.

Batch production and control record means a unique record that references an accepted master production and control record and documents specific details on production, labeling, and quality control for a single batch of a PET drug product.

Component means any ingredient intended for use in the production of a

PET drug product, including any ingredients that may not appear in the final PET drug product.

Conditional final release means a final release made prior to completion of a required finished product test because of a breakdown of analytical equipment.

Final release means the authoritative decision by a responsible person in a PET production facility to permit the use of a batch of a PET drug product in humans.

Inactive ingredient means any intended component of the PET drug product other than the active pharmaceutical ingredient.

In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and is used in, the preparation of a PET drug product.

Lot means a batch, or a specifically identified portion of a batch, having uniform character and quality within specified limits. In the case of a PET drug product produced by continuous process, a lot is a specifically identified amount produced in a unit of time or quantity in a manner that ensures its having uniform character and quality within specified limits.

*Lot number, control number, or batch number*means any distinctive combination of letters, numbers, or symbols from which the complete history of the production, processing, packing, holding, and distribution of a batch or lot of a PET drug product can be determined.

Master production and control record means a compilation of records containing the procedures and specifications for the production of a PET drug product.

Material release means the authoritative decision by a responsible person in a PET production facility to permit the use of a component, container and closure, in-process material, packaging material, or labeling in the production of a PET drug product.

PET means positron emission tomography.

PET drug means a radioactive drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for providing dual photon positron emission tomographic diagnostic images. The definition includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a PET drug.

PET drug product means a finished dosage form that contains a PET drug, whether or not in association with one or more other ingredients.

PET production facility means a facility that is engaged in the production of a PET drug product.

*Production*means the manufacturing, compounding, processing, packaging, labeling, reprocessing, repacking, relabeling, and testing of a PET drug product.

Quality control means a system for maintaining the quality of active ingredients, PET drug products, intermediates, components that yield an active pharmaceutical ingredient, analytical supplies, and other components, including container-closure systems and in-process materials, through procedures, tests, analytical methods, and acceptance criteria.

Receiving facility means any hospital, institution, nuclear pharmacy, imaging facility, or other entity or part of an entity that accepts a PET drug product that has been given final release, but does not include a common or contract carrier that transports a PET drug product from a PET production facility to a receiving facility.

Specifications means the tests, analytical procedures, and appropriate acceptance criteria to which a PET drug, PET drug product, component, container closure system, in-process material, or other material used in PET drug production must conform to be considered acceptable for its intended use. Conformance to specifications means that a PET drug, PET drug product, component, container closure system, in-process material, or other material used in PET drug production, when tested according to the described analytical procedures, meets the listed acceptance criteria.

Strength means the concentration of the active pharmaceutical ingredient (radioactivity amount per volume or weight at the time of calibration).

Verification means confirmation that an established method, process, or system meets predetermined acceptance criteria.

§ 212.2 What is current good manufacturing practice for PET drugs?

Current good manufacturing practice for PET drug products is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality control, holding, or distribution of PET drug products intended for human use. Current good manufacturing practice is intended to ensure that each PET drug product meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

§ 212.5 To what drugs do the regulations in this part apply?

(a) *Application solely to PET drug products.* The regulations in this part apply only to the production, quality control, holding, and distribution of PET drug products. Any human drug product that does not meet the definition of a PET drug product must be manufactured in accordance with the current good manufacturing practice requirements in parts 210 and 211 of this chapter. The regulations in this part apply to all PET drug products for human use except for investigational and research PET drugs as described in paragraph (b) of this section.

(b) *Investigational and research PET drugs.* The regulations in this part do not apply to investigational PET drugs or drug products for human use produced under an investigational new drug application in accordance with part 312 of this chapter and PET drugs or drug products produced with the approval of a Radioactive Drug Research Committee in accordance with part 361 of this chapter. For such investigational and research PET drugs or drug products, the requirement under the act to follow current good manufacturing practice is met by producing PET drugs or drug products in accordance with Chapter 823, ''Radiopharmaceuticals for Positron Emission Tomography—Compounding,'' of the 28th edition of the United States Pharmacopeia (2005), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or you may examine a copy at the Center for Drug Evaluation and Research's Division of Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Subpart B—Personnel and Resources

§ 212.10 What personnel and resources must I have?

You must have a sufficient number of personnel with the necessary education,

background, training, and experience to perform their assigned functions. You must have adequate resources, including facilities and equipment, to enable your personnel to perform their functions.

Subpart C—Quality Assurance

§ 212.20 What activities must I perform to ensure product quality?

(a) *Production operations*. You must oversee production operations to ensure that each PET drug product meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

(b) *Materials*. You must examine and approve or reject components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms to ensure compliance with procedures and specifications affecting the identity, strength, quality, or purity of a PET drug product.

(c) *Specifications and processes*. You must approve or reject, before implementation, any initial specifications, methods, processes, or procedures, and any proposed changes to existing specifications, methods, processes, or procedures, to ensure that they maintain the identity, strength, quality, and purity of a PET drug. You must demonstrate that any change does not adversely affect the identity, strength, quality, or purity of any PET drug product.

(d) *Production records*. You must review production records to determine whether errors have occurred. If errors have occurred, or a production batch or any component of the batch fails to meet any of its specifications, you must determine the need for an investigation, conduct investigations when necessary, and take appropriate corrective actions.

(e) *Quality assurance*. You must establish and follow written quality assurance procedures.

Subpart D—Facilities and Equipment

§ 212.30 What requirements must my facilities and equipment meet?

(a) *Facilities*. You must provide adequate facilities to ensure the orderly handling of materials and equipment, the prevention of mixups, and the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality.

(b) *Equipment procedures*. You must implement procedures to ensure that all equipment that could reasonably be expected to adversely affect the identity, strength, quality, or purity of a PET drug product, or give erroneous or invalid test results when improperly used or maintained, is clean, suitable for its intended purposes, properly installed, maintained, and capable of repeatedly producing valid results. You must document your activities in accordance with these procedures.

(c) *Equipment construction and maintenance*. Equipment must be constructed and maintained so that surfaces that contact components, in-process materials, or PET drug products are not reactive, additive, or absorptive so as to alter the quality of PET drug products.

Subpart E—Control of Components, Containers, and Closures

§ 212.40 How must I control the components I use to produce PET drugs and the containers and closures I package them in?

(a) *Written procedures*. You must establish, maintain, and follow written procedures describing the receipt, login, identification, storage, handling, testing, and acceptance and/or rejection of components and drug product containers and closures. The procedures must be adequate to ensure that the components, containers, and closures are suitable for their intended use.

(b) *Written specifications*. You must establish appropriate written specifications for the identity, quality, and purity of components and for the identity and quality of drug product containers and closures.

(c) *Examination and testing*. Upon receipt, each lot of components and containers and closures must be uniquely identified and tested or examined to determine whether the lot complies with your specifications. You must not use in PET drug product production any lot that does not meet its specifications, including any expiration date if applicable, or that has not yet received its material release. Any incoming lot must be appropriately designated as either quarantined, accepted, or rejected. You must use a reliable supplier as a source of each lot of each component, container, and closure.

(1)(i) If you conduct finished-product testing of a PET drug product that includes testing to ensure that the correct components have been used, you must determine that each lot of incoming components used in that PET drug product complies with written specifications by examining a certificate of analysis provided by the supplier. You are not required to perform a specific identity test on any of those components.

(ii) If you do not conduct finished-product testing of a PET drug product that ensures that the correct components have been used, you must conduct identity testing on each lot of a component that yields an active ingredient and each lot of an inactive ingredient used in that PET drug product. This testing must be conducted using tests that are specific to each component that yields an active ingredient and each inactive ingredient. For any other component, such as a solvent or reagent, that is not the subject of finished-product testing, you must determine that each lot complies with written specifications by examining a certificate of analysis provided by the supplier; if you use such a component to prepare an inactive ingredient on site, you must perform an identity test on the components used to make the inactive ingredient before the components are released for use. However, if you use as an inactive ingredient a product that is approved under section 505 of the act (21 U.S.C. 355) and is marketed as a finished drug product intended for intravenous administration, you need not perform a specific identity test on that ingredient.

(2) You must examine a representative sample of each lot of containers and closures for conformity to its written specifications. You must perform at least a visual identification of each lot of containers and closures.

(d) *Handling and storage*. You must handle and store components, containers, and closures in a manner that prevents contamination, mixups, and deterioration and ensures that they are and remain suitable for their intended use.

(e) *Records*. You must keep a record for each shipment of each lot of components, containers, and closures that you receive. The record must include the identity and quantity of each shipment, the supplier's name and lot number, the date of receipt, the results of any testing performed, the disposition of rejected material, and the expiration date (where applicable).

Subpart F—Production and Process Controls

§ 212.50 What production and process controls must I have?

You must have adequate production and process controls to ensure the consistent production of a PET drug product that meets the applicable standards of identity, strength, quality, and purity.

(a) *Written control procedures*. You must have written production and process control procedures to ensure and document that all key process parameters are controlled and that any deviations from the procedures are justified.

(b) *Master production and control records*. You must have master production and control records that document all steps in the PET drug product production process. The master production and control records must include the following information:

(1) The name and strength of the PET drug product;

(2) If applicable, the name and radioactivity or other measurement of each active pharmaceutical ingredient and each inactive ingredient per batch or per unit of radioactivity or other measurement of the drug product, and a statement of the total radioactivity or other measurement of any dosage unit;

(3) A complete list of components designated by names and codes sufficiently specific to indicate any special quality characteristic;

(4) Identification of all major pieces of equipment used in production;

(5) An accurate statement of the weight or measurement of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations are permitted in the amount of component necessary if they are specified in the master production and control records;

(6) A statement of acceptance criteria on radiochemical yield, i.e., the minimum percentage of yield beyond which investigation and corrective action are required;

(7) Complete production and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed; and

(8) A description of the PET drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling.

(c) *Batch production and control records*. Each time a batch of a PET drug product is produced, a unique batch production and control record must be created. The batch production record must include the following information:

(1) Name and strength of the PET drug product;

(2) Identification number or other unique identifier of the specific batch that was produced;

(3) The name and radioactivity or other measure of each active pharmaceutical ingredient and each inactive ingredient per batch or per unit of radioactivity or other measurement of the drug product;

(4) Each major production step (obtained from the approved appropriate master production and control record);

(5) Weights (or other measure of quantity) and identification codes of components;

(6) Dates and time of production steps;

(7) Identification of major pieces of equipment used in production of the batch;

(8) Testing results;

(9) Labeling;

(10) Initials or signatures of persons performing or checking each significant step in the operation; and

(11) Results of any investigations conducted.

(d) *Area and equipment checks*. The production area and all equipment in the production area must be checked to ensure cleanliness and suitability immediately before use. A record of these checks must be kept.

(e) *In-process materials controls*. Process controls must include control of in-process materials to ensure that the materials are controlled until required tests or other verification activities have been completed or necessary approvals are received and documented.

(f) *Process verification*. (1) For a PET drug product for which each entire batch undergoes full finished-product testing to ensure that the product meets all specifications, process verification, as described in paragraph (f)(2) of this section, is not required.

(2) When the results of the production of an entire batch of a PET drug product are not fully verified through finished-product testing or when only the initial sub-batch in a series is tested, the PET drug producer must demonstrate that the process for producing the PET drug product is reproducible and is capable of producing a drug product that meets the predetermined acceptance criteria. Process verification activities and results must be documented. Documentation must include the date and signature of the individual(s) performing the verification, the monitoring and control methods and data, and the major equipment qualified.

Subpart G—Laboratory Controls

§ 212.60 What requirements apply to the laboratories where I test components, in-process materials, and finished PET drug products?

(a) *Testing procedures*. Each laboratory used to conduct testing of components, in-process materials, and finished PET drug products must have and follow written procedures for the conduct of each test and for the documentation of the results.

(b) *Specifications and standards*. Each laboratory must have sampling and testing procedures designed to ensure that components, in-process materials, and PET drug products conform to appropriate standards, including established standards of identity, strength, quality, and purity.

(c) *Analytical methods*. Laboratory analytical methods must be suitable for their intended use and must be sufficiently sensitive, specific, accurate, and reproducible.

(d) *Materials*. The identity, purity, and quality of reagents, solutions, and supplies used in testing procedures must be adequately controlled. All solutions that you prepare must be properly labeled to show their identity and expiration date.

(e) *Equipment*. All equipment used to perform the testing must be suitable for its intended purposes and capable of producing valid results.

(f) *Equipment maintenance*. Each laboratory must have and follow written procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, and that these activities are documented.

(g) *Test records*. Each laboratory performing tests related to the production of a PET drug product must keep complete records of all tests performed to ensure compliance with established specifications and standards, including examinations and assays, as follows:

(1) A description of the sample received for testing, including its source, the quantity, the batch or lot number, the date (and time, if appropriate) the sample was taken, and the date (and time, if appropriate) the sample was received for testing.

(2) A description of each method used in the testing of the sample, a record of all calculations performed in connection with each test, and a statement of the weight or measurement of the sample used for each test.

(3) A complete record of all data obtained in the course of each test, including the date and time the test was conducted, all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or drug product for each lot tested.

(4) A statement of the results of tests and how the results compare with established acceptance criteria.

(5) The initials or signature of the person performing the test and the date on which the test was performed.

§ 212.61 What must I do to ensure the stability of my PET drug products through expiry?

(a) *Stability testing program.* You must establish, follow, and maintain a written testing program to assess the stability characteristics of your PET drug products. The test methods must be reliable, meaningful, and specific. The samples tested for stability must be representative of the lot or batch from which they were obtained and must be stored under suitable conditions.

(b) *Storage conditions and expiration dates.* The results of such stability testing must be documented and used in determining appropriate storage conditions and expiration dates and times for each PET drug product you produce.

Subpart H—Finished Drug Product Controls and Acceptance Criteria

§ 212.70 What controls and acceptance criteria must I have for my finished PET drug products?

(a) *Specifications.* You must establish specifications for each batch of a PET drug product, including criteria for determining identity, strength, quality, purity, and, if appropriate, sterility and pyrogenicity.

(b) *Test procedures.* Before you implement a new test procedure in a specification, you must establish and document the accuracy, sensitivity, specificity, and reproducibility of the procedure. If you use an established compendial test procedure in a specification, you must first verify and document that the test works under the conditions of actual use.

(c) *Conformance to specifications.* Before final release, you must conduct laboratory testing of a representative sample of each batch of a PET drug product to ensure that the product conforms to specifications, except for sterility. For a PET drug product produced in sub-batches, at least each initial sub-batch that is representative of the entire batch must conform to specifications, except for sterility, before final release.

(d) *Final release procedures.* You must establish and follow procedures to ensure that a PET drug product is not given final release until the following is done:

(1) Appropriate laboratory testing under paragraph (a) of this section is completed;

(2) Associated laboratory data and documentation are reviewed and they demonstrate that the PET drug product meets specifications, except for sterility; and

(3) A designated qualified individual authorizes final release by dated signature.

(e) *Sterility testing.* Sterility testing need not be completed before final release but must be started within 30 hours after completion of production. The 30-hour requirement may be exceeded due to a weekend or holiday. If the sample for sterility testing is held longer than indicated, you must demonstrate that the longer period does not adversely affect the sample and the test results obtained will be equivalent to test results that would have been obtained if the test had been started within the 30-hour time period. Product samples must be tested individually and must not be pooled. If the product fails the sterility test, all receiving facilities must be notified of the results immediately. The notification must include any appropriate recommendations. The notification must be documented.

(f) *Conditional final release.* (1) If you cannot complete one of the required finished product tests for a PET drug product because of a breakdown of analytical equipment, you may approve the conditional final release of the product if you meet the following conditions:

(i) You have data documenting that preceding consecutive batches, produced using the same methods used for the conditionally released batch, demonstrate that the conditionally released batch will likely meet the established specifications;

(ii) You determine that all other acceptance criteria are met;

(iii) You immediately notify the receiving facility of the incomplete testing;

(iv) You retain a reserve sample of the conditionally released batch of drug product;

(v) You complete the omitted test using the reserve sample after the analytical equipment is repaired and you document that reasonable efforts have been made to ensure that the problem does not recur;

(vi) If you obtain an out-of-specification result when testing the reserve sample, you immediately notify the receiving facility; and

(vii) You document all actions regarding the conditional final release of the drug product, including the justification for the release, all followup actions, results of completed testing, all notifications, and corrective actions to ensure that the equipment breakdown does not recur.

(2) Even if the criteria in paragraph (f)(1) of this section are met, you may not approve the conditional final release of the product if the breakdown in analytical equipment prevents the performance of a radiochemical identity/purity test.

§ 212.71 What actions must I take if a batch of PET drug product does not conform to specifications?

(a) *Rejection of a nonconforming product.* You must reject a batch of a PET drug product that does not conform to specifications. You must have and follow procedures to identify and segregate the product to avoid mixups. You must have and follow procedures to investigate the cause(s) of the nonconforming product. The investigation must include, but is not limited to, examination of processes, operations, records, complaints, and any other relevant sources of information concerning the nonconforming product.

(b) *Investigation.* You must document the investigation of a PET drug product that does not meet specifications, including the results of the investigation and what happened to the rejected PET drug product.

(c) *Correction of problems.* You must take action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem.

(d) *Reprocessing.* If appropriate, you may reprocess a batch of a PET drug product that does not conform to specifications. If material that does not meet acceptance criteria is reprocessed, you must follow preestablished procedures (set forth in production and process controls) and the finished product must conform to specifications, except for sterility, before final release.

Subpart I—Packaging and Labeling

§ 212.80 What are the requirements associated with labeling and packaging PET drug products?

(a) A PET drug product must be suitably labeled and packaged to protect the product from alteration, contamination, and damage during the established conditions of shipping, distribution, handling, and use.

(b) Labels must be legible and applied so as to remain legible and affixed during the established conditions of processing, storage, handling, distribution, and use.

(c) All information stated on each label must also be contained in each batch production record.

(d) Labeling and packaging operations must be controlled to prevent labeling and product mixups.

Subpart J—Distribution

§ 212.90 What actions must I take to control the distribution of PET drug products?

(a) *Written distribution procedures.* You must establish, maintain, and follow written procedures for the control of distribution of PET drug products shipped from the PET production facility to ensure that the method of shipping chosen will not adversely affect the identity, purity, or quality of the PET drug product.

(b) *Distribution records.* You must maintain distribution records for each PET drug product that include or refer to the following:

(1) The name, address, and telephone number of the receiving facility that received each batch of a PET drug product;

(2) The name and quantity of the PET drug product shipped;

(3) The lot number, control number, or batch number for the PET drug product shipped; and

(4) The date and time you shipped the PET drug product.

Subpart K—Complaint Handling

§ 212.100 What do I do if I receive a complaint about a PET drug product produced at my facility?

(a) *Written complaint procedures.* You must develop and follow written procedures for the receipt and handling of all complaints concerning a PET drug product.

(b) *Complaint review.* The procedures must include review by a designated person of any complaint involving the possible failure of a PET drug product to meet any of its specifications and an investigation to determine the cause of the failure.

(c) *Complaint records.* A written record of each complaint must be maintained in a file designated for PET drug product complaints. The record must include the name and strength of the PET drug product, the batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup.

(d) *Returned products.* A PET drug product that is returned because of a complaint may not be reprocessed and must be destroyed in accordance with applicable Federal and State law.

Subpart L—Records

§ 212.110 How must I maintain records of my production of PET drug products?

(a) *Record availability.* Records must be maintained at the PET production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections.

(b) *Record quality.* All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees.

(c) *Record retention period.* You must maintain all records and documentation referenced in other parts of this regulation for a period of at least 1 year from the date of final release, including conditional final release, of a PET drug product.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18510 Filed 9–15–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2005–WI–0003; FRL–7970–7]

Approval and Promulgation of Implementation Plans; Wisconsin; General and Registration Permit Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Wisconsin State Implementation Plan (SIP) submitted by the State of Wisconsin on July 28, 2005. These revisions include General and Registration permit programs that provide for the issuance of general and registration permits as part of the State's construction permit and operation permit programs. In addition, these permit programs may include the regulation of hazardous air pollutants (HAPs) which may be regulated under section 112 of the Clean Air Act (the Act). Thus, EPA is also proposing approval of Wisconsin's general and registration permit program under section 112(l) of the Act.

These SIP revisions also contain changes to definitions related to Wisconsin's air permit program, as well as a minor technical change to provide correct references to the recently updated chapter NR 445, which was inadvertently omitted in the processing of that rule package. Additionally, these revisions clarify an existing construction permit exemption and operation permit exemption for certain grain storage and drying operations. This clarification is necessary to ensure that column dryers and rack dryers are included in the exemption criteria.

DATES: Written comments must be received on or before October 20, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2005–WI–0003, by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Agency Web site: *http://docket.epa.gov/rmepub/.* RME, EPA's electronic public docket and comments system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: *blakley.pamela@epa.gov.*

Fax: (312) 886–5824.

Mail: You may send written comments to: Pamela Blakley, Chief, Air Permit Section, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand Delivery or Courier: Deliver your comments to: Pamela Blakley, Chief, Air Permit Section, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05–OAR–2005–WI–0003. 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://docket.epa.gov/rmepub/,* 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 RME, regulations.gov, or e-mail. The EPA RME website and the federal regulations.gov Web site are ''anonymous access'' systems, 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 RME or

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 RME index at *http://docket.epa.gov/rmepub/*. 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 RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. We recommend that you telephone Susan Siepkowski, Environmental Engineer, at (312) 353–2654 before visiting the Region 5 office. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Susan Siepkowski, Environmental Engineer, Air Permit Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–2654, *siepkowski.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Does This Action Apply to Me?
II. What Has Wisconsin Submitted?
A. General Permit Rule
B. Registration Permit Rule
C. Clarification to Grain Elevator Exemption
D. Changes to Definitions, References, and Numbering
III. Do These Rules Comply With Federal Requirements?
A. Evaluation of the General Permit Rule
B. Evaluation of the Registration Permit Rule
C. Evaluation of the Clarification to Grain Elevator Exemption
D. Evaluation of the Changes to Definitions, References, and Numbering
IV. What Action Is EPA Taking Today?
V. Statutory and Executive Order Reviews

I. Does This Action Apply to Me?

This rule provides certain owners and operators in Wisconsin with alternatives to traditional construction and operation air permits. Wisconsin has created new permitting programs to provide registration and general air permits as an alternative to individual source permits. The rule sets certain standards for developing the permits and criteria under which sources would qualify for coverage under the permits. Specific terms and conditions will be established during the development of each permit, which will then be standard for all sources that are covered under the permit. Sources may apply for coverage under these permits by submitting an application to the Wisconsin Department of Natural Resources (WDNR), who will determine whether the source is eligible for the permit.

Under the registration permit rule, registration construction and registration operation permits will be developed for sources with low actual or potential emissions of air pollutants. The rule provides that a registration construction permit will be issued to a facility for the construction, reconstruction, replacement, relocation or modification of stationary sources whose actual emissions do not exceed 25% of any major source threshold. The rule also provides that a registration operation permit must be issued to facilities whose actual emissions do not exceed 25% of major source thresholds.

The second revision to the Wisconsin SIP permitting program is the general permit rule. This rule establishes that general construction and general operation permits will be developed for categories of sources with the same or similar emissions, operations, control systems, and regulatory requirements. Categories of sources that are or could be eligible for general permits include nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses and hospital sterilization equipment. If an eligible owner or operator elects to comply with the rule, a generic permit that requires operation in compliance with the applicable sections of the Wisconsin rules will be issued to the source.

II. What Has Wisconsin Submitted?

On July 28, 2005, Wisconsin submitted the following revisions to its SIP: To repeal NR 406.04(1)(c) and 407.03(1)(c); to renumber NR 406.02(1) to (4); to amend NR 406.04(1)(ce), (cm) and (m)(intro.), 406.11(1)(intro.) and (c), 407.03(1)(ce) and (cm), 407.05(7), 407.15(intro.) and (3), 410.03(1)(a)(5), and 484.05(1); to repeal and recreate NR 407.02(3) and 407.10; and to create NR 400.02(73m) and (131m), 406.02(1) and (2), 406.04(2m), 406.11(3), 406.16, 406.17, 406.18, 407.02(3m), 407.105, 407.107, 407.14 Note, 407.14(4)(c) and 410.03(1)(a)(6) and (7). These rules, as discussed in more detail below, establish general and registration permit programs, clarify an exemption for grain elevators under the State's construction and operation permit programs, define terms related to the State's permitting programs, and correct a reference in Wisconsin's regulations.

The WDNR held a second public comment period on this rule because it made significant changes to the proposed rule to address comments received during the first comment period. The first comment period ran during October and November 2004, and the second through February and March 2005. WDNR held public hearings during both comment periods. As a result of the public comments, WDNR made more specific the criteria for developing the permits and the criteria under which sources would be eligible for coverage.

In April 2005, WDNR proposed this rule revision to the Wisconsin Natural Resources Board for adoption, and the Board approved the rule on April 27, 2005. WDNR submitted its request that EPA approve the rules as a SIP revision to EPA on July 28, 2005, and EPA determined on August 11, 2005 that the submittal was complete.

A. General Permit Rule

On February 5, 2004, Wisconsin enacted Act 118, which gave WDNR the authority to develop a general construction permit program. The State has existing authority to issue general operation permits under its operation permit program. Act 118 required WDNR to establish the general permit program to provide industry and the WDNR with a streamlined approach for permitting sources that have similar operations and air emissions levels. The general construction and operation permit provisions are codified at NR 406.16 and NR 407.10 of the Wisconsin Administrative Code, respectively. A definition for ''general permit'' is codified at NR 400.02(73m) of the Wisconsin Administrative Code.

Under the general permit program, WDNR must develop construction and operation permits for categories of

sources with the same or similar emissions, operations, control systems and regulatory requirements, as described at NR 407.16(1) and NR 407.10(1) of the Wisconsin Administrative Code. Categories of sources that are, or could be, eligible for general permits include: Nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses, and hospital sterilization equipment. The procedure for establishing general construction or operation permits includes the preparation of an air quality analysis and preliminary determination, and the distribution of a notice of the opportunity for public and EPA comment and of the opportunity to request a public hearing. Once WDNR has established a general permit, individual sources may apply for coverage.

Pursuant to NR 406.16(2) and NR 407.10(2), sources that are not eligible for coverage under general permits include: Municipal solid waste combustion sources; projects that require a Prevention of Significant Deterioration (PSD) or New Source Review (NSR) permit or emission units that may cause or exacerbate, a violation of an ambient air quality standard or air increment. Further, NR 406.11(1)(g) and NR 407.15(8) provide the methodologies that WDNR will use to determine for general construction and general operation permits, respectively, whether a source covered under a general permit has emissions that may cause or exacerbate a violation of an ambient air quality standard or air increment.

The process for determining coverage under a general construction or operation permit is described under NR 406.16(3) and NR 407.10(3), respectively. This process requires the source to submit an application to the WDNR, who will then determine whether the source is eligible for coverage.

NR 406.16(4) of the Wisconsin Administrative Code requires that the general construction permit be incorporated into the facility operation permit. NR 407.10(4) of the Wisconsin Administrative Code creates an exemption from the requirement to obtain a construction permit for sources covered under a general operation permit as long as, among other things, the modification does not result in a violation of the terms and conditions of the general operation permit. NR 406.04(2m) creates a similar exemption for sources that are covered under either a registration or general operation permit.

NR 406.16(5) and NR 407.10(5) describe the process by which sources covered under a general construction or operation permit may apply for and request a different type of permit. In addition, NR 407.10(6) provides that sources covered under a general operation permit which are later determined not to qualify would be subject to legal action.

The rule also creates NR 406.18 and NR 407.107, both of which describe the procedures for a party to petition WDNR to develop a general permit for other categories of stationary sources, and describe the factors that WDNR will use in setting its priorities for general permit development.

In addition to criteria pollutants, Wisconsin's general permit program applies to HAPs. Certain HAPs are, or will be, regulated under sections 111 and 112 of the Act. Thus, EPA is also approving Wisconsin's general permit program under section 112(l) of the Act for the purpose of creating federally enforceable limitations on the potential to emit HAPs regulated under section 112.

B. Registration Permit Rule

Wisconsin Act 118 also provided WDNR with the authority to develop a registration permit program for construction and operation permits. The registration permit program is designed to provide industry and the WDNR with a streamlined approach for permitting sources with low actual or potential emissions. The registration permit program is also a mechanism to permit small sources that may otherwise be subject to the Federally Enforceable State Operating Permit (FESOP) program and require an individual source permit. This program thereby reduces the permitting burden on both sources and the WDNR. Registration construction permit provisions are codified at NR 406.17, and the registration operation permit provisions are codified at NR 407.105. A definition was created for ''registration permit'' at NR 400.02(131m).

NR 406.17(1) and NR 407.105(1) allow the WDNR to issue registration permits to sources which meet specific criteria. The process for issuing these permits includes the preparation of an air quality analysis and preliminary determination, and the distribution of a notice of the opportunity for public and EPA comment and of the opportunity to request a public hearing. Once WDNR has issued the registration permit, individual sources may apply for coverage. The registration permit will essentially cap, or limit, the facility, or unit emissions to a specified level.

NR 406.17(2) establishes the criteria for issuance of a registration construction permit. It provides that a registration construction permit shall be issued to a facility for the construction, reconstruction, replacement, relocation or modification of stationary sources whose actual emissions do not exceed 25% of any major source threshold. NR 407.105(2) establishes the criteria for issuance of a registration operation permit. A source is eligible for coverage under a registration operation permit if its actual emissions do not exceed 25% of any major source threshold. This section also establishes physical design and air dispersion modeling criteria.

Sources that are not eligible for coverage under a registration permit are described at NR 406.17(3) and NR 407.105(3), and include: Municipal solid waste combustion sources; projects that require a PSD or NSR major source permit (NR 406.16); emission units subject to section 111 or 112 of the Act other than those deemed by WDNR not to preclude eligibility for the registration operation permit; or emission units that may cause or exacerbate, a violation of an ambient air quality standard or air increment. NR 406.11(1) and NR 407.15(8) authorize WDNR, among other things, to withdraw a source from coverage of the general or registration permits, and provide the methodologies that WDNR must use to determine if a source covered under a registration permit has emissions that may cause or exacerbate a violation of an ambient air quality standard or air increment.

NR 406.17(4) and NR 407.105(4) describe the process for determining coverage under a registration construction or operation permit, respectively. This process requires the source to submit an application to the WDNR, who will then determine whether the source is eligible for coverage.

NR 406.17(5) requires that the terms of a registration construction permit be incorporated into the facility's registration operation permit. NR 407.105(5) exempts sources with a registration operation permit from obtaining a construction permit for construction activities that will not violate the terms or conditions of the registration operation permit. NR 406.04(2m) also creates this exemption for sources that are covered under a registration or general operation permit.

NR 406.17(6) and NR 407.105(6) describe the process by which a source with a registration construction or operation permit can apply for a different type of permit. NR 407.105(7) describes the criteria WDNR will use for

determining whether a facility under the registration operation permit is in compliance with all applicable requirements.

The rule also creates provisions NR 406.18 and NR 407.107, which describe the procedures for a person to petition WDNR to develop a general or registration construction or operation permit for a category of stationary sources, and describes the factors that WDNR will consider in determining whether to grant or deny the petition.

Wisconsin's registration permit program not only applies to criteria pollutants, but also to hazardous air pollutants (HAPs). Certain HAPs are, or will be, regulated under sections 111 and 112 of the Act. Thus, EPA is also approving under section 112(l) of the Act Wisconsin's registration permit program for the purposes of creating federally enforceable limitations on the potential to emit HAPs regulated under section 112 of the Act.

C. Clarification to Grain Elevator Exemption

This rule amends provisions of Wisconsin's construction and operation permit programs, NR 406.04(1) and NR 407.03(1), respectively, relating to an existing exemption for certain grain storage and processing facilities from needing to obtain a construction or operation permit. This clarification is necessary to ensure that facilities with column dryers and rack dryers that remain below the major source threshold for air permit programs are included in the exemption. This exemption does not apply to sources subject to New Source Performance Standards (NSPS), Standards of Performance for Grain Elevators, (40 CFR part 60, subpart DD) or subject to part 70 (40 CFR part 70).

D. Changes to Definitions, References, and Numbering

Several other changes are being made to Wisconsin's construction and operation permit program rules, NR 406 and NR 407. Several sections are renumbered because of the addition of new provisions and definitions. Additional changes are being made to NR 410, Wisconsin's air permit fee rules. NR 410.03(1)(a)(5), related to the fees for a construction permit revision, is amended to exempt the fee if the requested revision is to make the source eligible for a registration operation permit. NR 410.03(1)(a)(6) and (7) provide that sources subject to Part 70 pay fees for coverage under a general or registration construction permit.

III. Do These Rules Comply With Federal Requirements?

EPA reviewed Wisconsin's July 28, 2005, SIP revision submittal to determine completeness, in accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). We found the submittal to be complete, and sent a letter dated August 11, 2005, to the WDNR Bureau of Air Management Director indicating the completeness of the submittal.

The next step in the review process was EPA's analysis of the State's submittal. EPA evaluated Wisconsin's general and registration permit programs with respect to the SIP approval criteria established in EPA's June 28, 1989, rulemaking ''Requirements for the Preparation, Adoption, and Submittal of Implementation Plans,'' (EPA's 1989 rulemaking); Approval and Promulgation of Implementation Plans, 54 FR 27274. In addition, EPA has evaluated portions of Wisconsin's rule with respect to relevant EPA guidance documents, as discussed in more detail below.

The EPA's 1989 rulemaking criteria are as follows:

1. The state operating permit program (*i.e.*, the regulations or other administrative framework describing how such permits are issued) is submitted and approved by EPA into the SIP.

2. The SIP imposes a legal obligation that operating permit holders adhere to the terms and limitations of such permits (or subsequent revisions of the permit made in accordance with the approved operating permit program.)

3. The State operating permit program requires that all emissions, limitations, controls and other requirements imposed by such permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP, and that the program may not issue permits that waive, or make less stringent, any limitation or requirement contained in or issued pursuant to the SIP, or that are otherwise 'federally enforceable' (*e.g.*, standards established under sections 111 and 112 of the Act).

4. The limitations, controls, and requirements in the operating permits are permanent, quantifiable and otherwise enforceable as a practical matter.

5. The permits are issued subject to public participation.

A. Evaluation of the General Permit Rule

The general permit rule establishes the fundamental framework for the general permits to be issued by setting certain criteria for developing the permits, and criteria under which sources would qualify for coverage under the permits. WDNR will establish specific terms and conditions during the development of each general permit, which then will be standard for all sources that are covered under the permit.

In the past, Wisconsin has issued general operation permits for certain source categories, such as rock crushers. WDNR now is establishing standard general construction permits with this rule, and revising its general operation permit program. EPA has the authority to enforce these types of permits if the permit program establishing them is approved into the SIP. EPA acknowledged in our July 10, 1995 memorandum, ''White Paper for Streamlined Development of Part 70 Permit Applications,'' as well as in various other policy and guidance documents related to permitting, the development of general permits as a mechanism for streamlining.

For example, EPA's April 14, 1998, memorandum ''Potential to Emit (PTE) Guidance for Specific Source Categories'' discusses approaches that permitting authorities can use to establish enforceable emission limits, such as general permits. Generally appropriate for less complex sources, states create a standard set of terms and conditions for many similar sources at the same time. Sources wishing to be subject to the general permit must provide a notification to the permitting agency, and must comply with the standard terms and conditions. This EPA memorandum also states that ''[i]n making any change to a minor NSR program, the State or local agency needs to address air quality impact considerations in addition to those discussed here.'' Additionally, Section 110 of the Act specifies that permit programs must ensure that the National Ambient Air Quality Standards (NAAQS) are protected.

Wisconsin's submittal satisfies this requirement. Rules NR 406.16(2)(c) and NR 407.10(2)(b), for general construction and general operation permits, respectively, state that a source is ineligible for coverage under a general permit if the emissions unit or units cause or exacerbate, or may cause or exacerbate, a violation of any ambient air quality standard or ambient air

increment, as determined by the WDNR through an air quality assessment.

Another guidance document, EPA's January 25, 1995 memorandum ''Guidance an Enforceability Requirements for Limiting Potential to Emit through SIP and section 112 Rules and General Permits'' (sic) (EPA's 1995 guidance) discusses general permit rule requirements. This guidance states that ''[a]lthough this concept [of general permits] is generally thought of as an element of Title V permit programs there in no reason that a state or local agency could not submit a general permit program as a SIP submittal aimed at creating synthetic minor sources.'' This guidance document further states that, although general permit programs can be separate from Title V permit programs, the issuance of general permits under the general permit program should comply with Title V procedures. Therefore, EPA will evaluate Wisconsin's general permit program with these procedures. That is, all general permits must meet certain legal and practical federal requirements. The guidance states ''[w]ith respect to legal sufficiency, the operating permit regulations provide that once the general permit has been issued, after opportunity for public participation and, EPA and affected State review, the permitting authority may grant or deny a sources request to be covered by a general permit without further public participation or EPA or affected State review.'' *Id.* at 4. Wisconsin's general construction permit rule provides for public participation at NR 406.16(1)(c), which states that WDNR shall use the applicable procedures in Wisconsin Statutes s. 285.61 and s. 285.63 to issue a general construction permit. The general operation permit rule at NR 407.10(1)(c) states that WDNR shall use the applicable procedures in Statutes s. 285.62 to issue the general operation permit. Both of these statutes require that the WDNR distribute a notice of the availability of the proposed general permit and of the WDNR's analysis and preliminary determination, a notice of the opportunity for public comment and a notice of the opportunity to request a public hearing.

The general permit rule also provides that the WDNR may grant or deny a source's request to be covered by a general permit. NR 406.16(1)(c) and NR 407.10(1)(c), for general construction and operation permits, respectively, require the WDNR to prepare an air quality analysis and a preliminary determination on the approvability of the proposed general permit. Both NR 406.16(3)(c) and NR 407.10(3)(c) state that WNDR must provide the applicant notice of WDNR's determination that the source is covered under the general permit; a description of any information that is missing from the application for the general permit; or notice of WDNR's determination that the source does not qualify for coverage and the reasons for that determination.

EPA's 1995 guidance also specifies that the rule establishing the general permit program must require that: ''(1) General permits apply to a specific and narrow category of sources; (2) sources electing coverage under general permits where coverage is not mandatory, provide notice or reporting to the permitting authority; (3) general permits provide specific and technically accurate (verifiable) limits that restrict the potential to emit; (4) general permits contain specific compliance requirements; (5) limits in general permits are established based on practicably enforceable averaging times; and, (6) violations of the permit are considered violations of the state and federal requirements and result in the source being subject to major source requirements.'' Id. at 6.

With respect to the first requirement above, NR 406.16(1)(b) and NR 407.10(1)(b) contain criteria to define the types of sources for which WDNR can issue general construction and operation permits. These criteria serve to describe and narrow the sources for which WDNR may establish general permits.

Regarding compliance with the second requirement of the 1995 guidance, sources electing to be covered by Wisconsin's non-mandatory general construction or operation permits must submit applications to the WDNR, upon which the agency must act.

Wisconsin's general permit program satisfies requirements 3 to 5 of the 1995 guidance regarding emission limits, compliance requirements, and averaging times. NR 406.16(1)(d) and NR 407.10(1)(d) require that the general construction and operation permits contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the stationary source category.

Regarding the sixth requirement, that violations of the permit should be considered violations of the applicable requirement that result in the source becoming subject to major source requirements, both NR 406.16(1)(d) and NR 407.10(1)(d) state that the general construction and operation permit include terms and conditions required to comply with the Act and required to assure compliance with applicable provisions in Wisconsin's statutes and regulations. In addition, NR 406.10, which is an existing provision of the Wisconsin SIP that addresses violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statute s. 285.65 (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act) shall be considered in violation of Wisconsin statute 285.60. Wisconsin statute s. 285.60 requires air pollution control permits for new or modified sources, specifically a construction permit for commencing construction, reconstruction, replacement or modification of a stationary source, and an operation permit before any person can operate a new source or a modified source. Further, NR 407.09(1)(f), operation permit content, requires that permits include the following provision: The permittee must comply with all conditions of the permit and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. The WDNR also retains the discretion to determine whether violations of a registration or general permit result in the source becoming subject to major source permitting requirements.

With respect to EPA's 1989 rulemaking criteria discussed above, EPA has determined that Wisconsin's general permit program meets these criteria, as outlined below.

1. Wisconsin submitted the regulations and administrative framework for the general permit rule, under NR 400, NR 406, NR 407, and NR 410, as a revision to its SIP on July 28, 2005. EPA's approval of this section would provide legal support for these permit programs and, would satisfy the first criterion.

2. Wisconsin's rule imposes a legal obligation that permit holders adhere to the terms and limitations of the permits. NR 406.10, violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statute s. 285.65, (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act,) shall be considered in violation of Wisconsin statute s. 285.60, (which requires the air pollution control permit.) Also, NR 407.09(1)(f), an existing SIP provision that addresses operation permit content,

requires that permits include the following provision: The permittee must comply with all conditions of the permit and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. This satisfies the second approval criterion that the permittee must comply with the permit conditions.

3. The permit program requires that all emissions, limitations, controls and other requirements imposed by permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP. NR 406.16(1)(d) and NR 407.10(1)(d) both require that the general permit contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the source category; and, that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's rules (ch. 285, Stats., and chs. NR 400 to 499.) This provision satisfies the third criterion.

4. The limitations, controls, and requirements in the permits will be permanent, quantifiable and otherwise enforceable as a practical matter. As discussed above, Wisconsin's general permit rule requires that WDNR provide a 30-day public comment on the proposed general permit, and it specifies that the general permit will contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the source category. During the comment period, EPA has the opportunity to review the permit to ensure that the limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. Additionally, the general construction permits do not expire. For general operation permits, NR 407.10(1)(e) states that a general operation permit issued to a part 70 source category may not exceed 5 years, and that general operation permits issued to a non-part 70 source category shall only expire if an expiration date is requested by the source owner or operator, or if the WDNR finds that expiring coverage would significantly improve the likelihood of continuing compliance with applicable requirements, compared to coverage that does not expire. Although the general operation permits can expire, the expiration ends the source's right to operate unless the permittee has submitted a timely and complete renewal application or WDNR has issued a renewed operation permit. Based on the reasons above, the fourth criterion is met.

5. As discussed previously, Wisconsin's rule requires that the general permits are issued subject to public participation under NR 406.16(1)(c) and NR 407.10(1)(c), for construction and operation permits, respectively. EPA has determined that, in cases where standardized permits have been adopted, EPA and the public need not be involved in their application to individual sources as long as the standard permits themselves have been subject to notice and opportunity to comment. EPA's 1995 guidance, on page 10. Specifically, EPA's 1995 guidance states that ''since the rule establishing the program does not provide the specific standards to be met by the source, each general permit, but not each application under each general permit, must be issued pursuant to public and EPA notice and comment.'' *Id.* Wisconsin's general permit rule satisfies this criterion.

Sources of HAPs may also be eligible for coverage under Wisconsin's general permit rule. NR 406.16(2) and NR 407.10(2), which describe the sources which are ineligible for coverage under a general construction or general operation permit, do not include sources of HAPS. Therefore, EPA is evaluating Wisconsin's general permit program under section 112(l) of the Act for the purposes of creating federally enforceable limitations on the potential to emit HAPs.

Several EPA guidance documents address this issue, including EPA's November 3, 1993, guidance document, ''Approaches to Creating Federally Enforceable Emissions Limits,'' which states on page 2 that a state permit program could be extended to create federally enforceable limits for emissions of HAPs if the program were approved pursuant to section 112(l) of the Act. Also, EPA's 1995 guidance states on page 4 that a mechanism available to limit potential to emit is a general permit program approved into the SIP or under Section 112(1). Wisconsin's general permit program may limit HAP emissions in permits and therefore must also be evaluated with the approval criteria for programs limiting potential to emit of HAPs under 40 CFR part 63, subpart E, the regulations promulgated to implement section 112(l) of the Act. 40 CFR 63.91(a)(5) states, ''[t]he Administrator may, under the authority of section 112(l) and this subpart, also approve a State program designed to establish limits on the potential to emit hazardous air pollutants listed pursuant to section 112 of the Act.''

Section 112(l) allows EPA to approve a state's permit program only if it meets the following statutory criteria for approval under section 112(l)(5): (1) It contains adequate authority to assure compliance with any section 112 standards, regulations, or requirements established under section 112, (2) it provides for adequate authority and resources to implement the program, (3) it provides for an expeditious schedule for assuring compliance with section 112 requirements, and, (4) it is otherwise in compliance with Agency guidance and is likely to satisfy the objectives of the Act.

EPA has determined that Wisconsin's general permit program meets these 112(l) criteria as outlined below:

First, Wisconsin's general permit program contains adequate authority to assure compliance with section 112 standards or requirements. Both NR 406.16(1)(d) and NR 407.10(1)(d) state that the general construction or operation permit shall contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's regulations.

Furthermore, Wisconsin Statutes s. 285 provides the authority for Wisconsin to administer and enforce all of its permit programs. Section 285.11 specifies that the WDNR shall: ''(1) Promulgate rules implementing and consistent with this chapter and statute 299.15; * * * (18) Adopt and apply objective performance measurements, for the subunit of the department that administers this chapter, relating to the issuance of permits under subchapter VII and to overall performance of the subunit.'' In addition, section 285.13 specifies WDNR's powers, including ''* * * (2) Issue orders to effectuate the purposes of this chapter and statute 299.15 and enforce the same by all appropriate administrative and judicial proceedings.''

For criterion 2, regarding adequate resources, NR 410.03(1)(a)(6) requires WDNR to collect fees from sources subject to 40 CFR Part 70 that are

covered under the general construction permit. The general operation permit program also requires fees to be collected, as described in the July 26, 2005, State budget. The State anticipates that its new fee structure, adopted in this budget, will provide sufficient resources to administer the general permit program. WDNR has submitted this revised fee structure along with a fee sufficiency demonstration to EPA for review. EPA will monitor the State's implementation of the permit program to assure that adequate resources continue to be available.

Wisconsin's general permit program also meets the third requirement for an expeditious schedule to assure compliance. Nothing in this program would allow a source to avoid or delay compliance with federal HAPs requirements if it fails to obtain the appropriate federally enforceable limit by the relevant deadline.

Fourth, Wisconsin's general permit program is consistent with the objectives of the section 112 program, since its purpose is to enable sources to obtain federally enforceable limits on potential to emit. This is also consistent with the intent of the guidance documents discussed above.

Based on the discussion above, EPA has determined that Wisconsin's general permit program is approvable under section 112(l). By approving Wisconsin's general permit program, EPA recognizes it as a federally enforceable method of limiting a source's potential to emit HAPs.

B. Evaluation of the Registration Permit Rule

The registration permit rule establishes the general framework for the registration permits by setting certain criteria for developing the permits and criteria under which sources would qualify for coverage under the permits. Specific terms and conditions will be established during the development of each registration permit, which will then be standard for all sources that are covered under the permit.

In the past, Wisconsin has placed federally enforceable synthetic minor limitations on sources through individual permits issued pursuant to a federally approved program. WDNR is now establishing standardized federally enforceable synthetic minor permits. EPA has the authority to enforce the terms of these permits if the permit program under which they are issued is approved into the SIP. EPA has acknowledged this approach for creating emission limitations and discussed various criteria that must be considered for approval in several policy and guidance documents related to creating federally enforceable emissions limits and approval of SIPs.

As discussed above, various regulatory options exist for the creation of federally enforceable limits on potential to emit. Several guidance documents, including EPA's November 3, 1993, memorandum, ''Approaches to Creating Federally Enforceable Emission Limits,'' summarize these options. Major NSR permits, minor NSR permits (if EPA has approved the NSR program into the SIP and the program meets certain procedural requirements), and operating permits based on programs approved into the SIP pursuant to the criteria in the June 28, 1989 **Federal Register** (54 FR 27274), are available regulatory mechanisms.

EPA's April 14, 1998, memorandum ''Potential to Emit (PTE) Guidance for Specific Source Categories'' also discusses on page 2 approaches that permitting authorities can use to establish enforceable emission limits which ensure that a source's potential emissions are below the major source threshold, such as using a general permit. Under its registration permit program, Wisconsin establishes permits which, like general permits, contain standardized conditions that will cap or limit source or unit emissions below a certain threshold. The guidance states that sources wishing to be subject to the standard permit must provide a notification to the permitting agency, and must comply with the standard terms and conditions. Wisconsin's registration permit program specifically requires sources to apply for coverage under NR 406.17(4) and NR 407.105(4), for registration construction and operation permits, respectively.

EPA's April 14, 1998 memorandum states that, ''[i]n making any change to a minor NSR program, the State or local agency needs to address air quality impact considerations in addition to those discussed here.'' Id. at 6. Additionally, Section 110 of the Act specifies that permit programs must ensure that the NAAQS are protected.

NR 406.17(3)(c) and NR 407.105(3)(c) for registration construction and operation permits, respectively, state that a source is ineligible for coverage under a registration permit if the emissions unit or units cause or exacerbate, or may cause or exacerbate, a violation of any ambient air quality standard or ambient air increment, as determined by the WDNR through an air quality assessment.

EPA's 1995 guidance, as discussed in Section A, above, outlines general permit rule requirements. Again, this guidance states on page 3 that ''[a]lthough this concept [of general permits] is generally thought of as an element of Title V permit programs there is no reason that a state or local agency could not submit a general permit program as a SIP submittal aimed at creating synthetic minor sources.'' The guidance further states on page 4 that ''[a]nother mechanism available to limit potential to emit is a general permit program approved into the SIP or under section 112(1).''

This guidance document further states that, although general permit programs can be separate from Title V permit programs, the issuance of general permits should comply with Title V procedures. That is, all general permits must meet certain legal and practical requirements for federal enforceability. The guidance states on page 4 ''[w]ith respect to legal sufficiency, the operating permit regulations provide that once the general permit has been issued, after opportunity for public participation and, EPA and affected State review, the permitting authority may grant or deny a sources request to be covered by a general permit without further public participation or EPA or affected State review.'' Because Wisconsin's registration permit program is essentially a general permit that will contain standardized emissions limitations, we have evaluated it using the criteria from EPA's 1995 guidance discussed above. Wisconsin's registration construction permit rule provides for public participation at NR 406.17(1)(b), which states that WDNR shall use the applicable procedures in Wisconsin Statutes s. 285.61 to issue registration construction permits. NR 407.105(1)(b) states that WDNR shall use the applicable procedures in Statutes s. 285.62 to issue registration operation permits. Both of these statutes require that the WDNR distribute a notice of the availability of the proposed registration permit and of the WDNR's analysis and preliminary determination, a notice of the opportunity for public comment and a notice of the opportunity to request a public hearing.

Wisconsin's registration permit rules also provides that the WDNR may grant or deny a source's request to be covered by a registration permit. Both the registration construction and operation permit rules, at NR 406.17(1)(b) and NR 407.105(1)(b), respectively, state that the WDNR shall prepare an air quality analysis and a preliminary determination on the approvability of the proposed registration permit. NR 406.17(2) and NR 407.105(2) establish the criteria that the WDNR will use to determine if a facility is eligible for

coverage under a registration permit. Additionally, NR 406.17(4)(c) and NR 407.105(4)(c) require that WDNR provide notice of its determination that the source is covered under the registration permit; a description of any information that is missing from the application for coverage under the registration permit; or a notice of its determination that the source does not qualify for coverage, and the reasons for that determination.

EPA's 1995 guidance specifies that the rule establishing the general permit program must require that: ''(1) General permits apply to a specific and narrow category of sources; (2) sources electing coverage under general permits where coverage is not mandatory, provide notice or reporting to the permitting authority; (3) general permits provide specific and technically accurate (verifiable) limits that restrict the potential to emit; (4) general permits contain specific compliance requirements; (5) limits in general permits are established based on practicably enforceable averaging times; and (6) violations of the permit are considered violations of the state and federal requirements and result in the source being subject to major source requirements.'' For the reasons explained previously, EPA will evaluate Wisconsin's registration permit program based upon these general permit program criteria with respect to establishing emissions limits.

For the first criterion, registration permits will be available to types of sources that have low actual emissions and that meet other criteria. These types of sources may elect to limit their emissions to specified levels.

Because coverage under Wisconsin's registration permit program is not mandatory, and sources electing to be covered by a general permit must submit an application to the WDNR which the agency must act on, the registration permit program complies with the second requirement.

For requirements 3 to 5, regarding emission limits, compliance requirements, and averaging times, both NR 406.17(1)(c) and NR 407.105(1)(c) require the registration construction or operation permit to contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions.

Regarding criterion 6, that violations of the permit should be considered violations of the applicable requirement, both NR 406.17(1)(c) and NR 407.105(1)(c) state that the permit must include terms and conditions required to comply with the Act and required to assure compliance with applicable provisions in Wisconsin's statutes and regulations. In addition, NR 406.10, which governs violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statutes. 285.65 (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act) will be considered in violation of Wisconsin statutes. 285.60, (which requires the air pollution control permit.) Also, NR 407.09(1)(f), operation permit content, requires permits to provide that the permittee must comply with all conditions of the permit and that any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. Therefore, EPA concludes that the portion of the Wisconsin's SIP which deals with registration permits complies with the 1995 guidance.

With respect to EPA's 1989 rulemaking criteria, discussed above, EPA has determined that Wisconsin's registration permit program meets these criteria as outlined below:

1. Wisconsin submitted the regulations and administrative framework for the registration permit rule, under NR 400, NR 406, NR 407, and NR 410, as a revision to its SIP on July 28, 2005. EPA's approval of this section would provide legal support for these permit programs and, would satisfy the first criterion.

2. Wisconsin's rule imposes a legal obligation that permit holders adhere to the terms and limitations of the permits. Existing SIP provision NR 406.10, violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statutes. 285.65, (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act), shall be considered in violation of Wisconsin statutes. 285.60, (which requires the air pollution control permit.) Also, existing SIP provision NR 407.09(1)(f), operation permit content, requires that permits provide that the permittee must comply with all conditions of the permit, and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. This satisfies the second approval criterion which requires that permit holders abide by the permit conditions.

3. The registration permit program requires that all emissions, limitations, controls, and other requirements imposed by permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP. NR 406.17(1)(c) and NR 407.105(1)(c) require that the registration construction and operation permits contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and, that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's rules (ch. 285, Stats., and chs. NR 400 to 499.) This provision satisfies the third criterion.

4. This criterion provides that limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. As discussed above, Wisconsin's registration rule requires that a 30-day public comment period be held on the proposed registration permit, and it specifies that the registration permit will contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions. During the comment period, EPA has the opportunity to review the permits to ensure that the limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. Additionally, the registration permits do not expire. The registration permit program meets the fourth criterion for permit program approval.

5. As discussed previously, Wisconsin's rule requires that the registration construction and registration operation permits are issued subject to public participation under NR 406.17(1)(b) and NR 407.105(1)(b), respectively. EPA has determined that, in cases where standardized permits have been adopted, EPA and the public need not be involved in their application to individual sources as long as the standard permits themselves have been subject to notice and opportunity to comment. Specifically, EPA's 1995 guidance states on page 10, ''since the rule establishing the program does not provide the specific standards

to be met by the source, each general permit, but not each application under each general permit, must be issued pursuant to public and EPA notice and comment.''

Sources of HAPs also may be eligible for coverage under Wisconsin's registration permit rule. NR 406.17(2)(a)(1) and NR 407.105(2)(a)(1), the criteria for issuance of registration construction and operation permits, respectively, specify that the actual emissions from sources will not exceed 25% of any major source threshold in NR 407.02(4). NR 407.02(4) includes sources that emit HAPs listed under section 112(b) of the Act. NR 406.17(3) and 407.105(3), which describe types of sources which are ineligible for coverage under registration construction and operation permits, does not include sources of HAPS. Furthermore, NR 406.17(3)(d) states that sources ineligible for registration construction permits include an emission unit or units subject to a standard or regulation under section 111 or 112 of the Act, other than those contained in the registration construction permit or those determined by WDNR not to preclude eligibility for the registration construction permit. Therefore, EPA is evaluating Wisconsin's registration permit program under section 112(l) of the Act for the purposes of creating federally enforceable limitations on the potential to emit HAPs.

As discussed above, several EPA guidance documents address the creation of limitations on the potential to emit HAPs, including EPA's November 3, 1993, guidance document, ''Approaches to Creating Federally Enforceable Emissions Limits.'' This guidance states on page 2 that a state permit program could be extended to create federally enforceable limits for emissions of HAPs if the program were approved pursuant to section 112(l) of the Act. Also, EPA's 1995 guidance on page 4 states that a mechanism available to limit potential to emit is a general permit program approved into the SIP or under Section 112(1). Wisconsin may establish a registration permit to cap or limit HAP emissions in permits and, therefore, is eligible under the 1995 guidance for evaluation under 40 CFR part 63, subpart E, the regulations promulgated to implement section 112(l) of the Act, as a program that the state can use to limit a source's potential to emit HAPs. 40 CFR 63.91(a)(5) states that ''[t]he Administrator may, under the authority of section 112(l) and this subpart, also approve a State program designed to establish limits on the potential to emit hazardous air pollutants listed pursuant to section 112 of the Act.''

As discussed above, section 112(l) allows EPA to approve a state's permit program only if it meets the following the statutory criteria for approval under section 112(l)(5): (1) It contains adequate authority to assure compliance with any section 112 standards or requirements, (2) it provides for adequate resources, (3) it provides for an expeditious schedule for assuring compliance with section 112 requirements, and, (4) it is otherwise likely to satisfy the objectives of the Act. EPA has determined that Wisconsin's registration permit program meets these 112(l) criteria as outlined below.

First, Wisconsin's registration permit program contains adequate authority to assure compliance with section 112 standards or requirements. NR 406.17(1)(c) and NR 407.105(1)(c) both state that a registration construction or operation permit must contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's regulations.

Furthermore, Wisconsin Statutes s. 285 provides the authority for Wisconsin to administer and enforce all of its permit programs. Section 285.11 specifies that the WDNR shall: ''(1) Promulgate rules implementing and consistent with this chapter and statute 299.15; * * * (18) Adopt and apply objective performance measurements, for the subunit of the department that administers this chapter, relating to the issuance of permits under subchapter VII and to overall performance of the subunit.'' In addition, section 285.13 specifies WDNR's powers, including ''* * * (2) Issue orders to effectuate the purposes of this chapter and statute 299.15 and enforce the same by all appropriate administrative and judicial proceedings.''

For criterion 2, regarding adequate resources, NR 410.03(1)(a)(7) provides that sources subject to 40 CFR part 70 must pay fees for coverage under a registration construction permit. The registration operation permit also requires fees to be collected, as described in the July 26, 2005, state budget. The State anticipates that its new fee structure, adopted in this budget, will provide sufficient resources to administer the registration permit program. WDNR has submitted this revised fee structure along with a fee sufficiency demonstration to EPA for review. EPA will monitor the State's implementation of the permit program to assure that adequate resources continue to be available.

Regarding the third requirement, Wisconsin's registration permit program provides for an expeditious schedule for assuring compliance. Nothing in this program would allow a source to avoid or delay compliance with the Federal requirement if it fails to obtain the appropriate federally enforceable limit by the relevant deadline.

Fourth, Wisconsin's registration permit program is consistent with the objectives of the section 112 program, since its purpose is to enable sources to obtain federally enforceable limits on potential to emit. This also is consistent with the intent of the guidance documents discussed above.

Based on the discussion above, EPA has determined that Wisconsin's registration permit program is approvable under section 112(l). By approving Wisconsin's registration permit program, EPA recognizes the program as a federally enforceable method of limiting a source's potential to emit HAPs.

C. Evaluation of the Clarification to Grain Elevator Exemption

EPA reviewed Wisconsin's permit exemption with regard to its potential emissions and with respect to relevant EPA guidance, such as EPA's November 14, 1995, memorandum, ''Calculating the Potential to Emit (PTE) for Grain Handling Facilities.'' The WDNR provided EPA with additional documentation regarding its grain storage and grain handling facilities exemption in a May 31, 2005, internal memorandum which contains its PTE calculations for these permit exemptions. This document demonstrates and clarifies the following: Only non-part 70 sources are eligible for the air operation permit exemptions; only non-NSPS sources are eligible for the air construction and operation permit exemptions; air emission calculations for the ''worst case'' facility exempt from operation permit requirements demonstrate that the Particulate Matter (PM–10) emission rate is 29.6 tons per year, which is below the 100 tons per year part 70 major source threshold level; air emission calculations for the ''worst case'' facility exempt from construction permit requirements demonstrate that the PM–10 emission rate is 8.8 tons per year; and sources subject to PSD are excluded from the construction permit exemptions in ch. NR 406, Wis. Adm.

Code. Based on this information, EPA is proposing to approve these exemptions.

D. Evaluation of the Changes to Definitions, References, and Numbering

Several definitions were created or amended due to the creation of the general and registration permit programs. In addition, several regulatory citations were revised as well as other administrative changes related to the registration and general permit programs. All of the changes, as described in Part I, Section D, ''Changes to Definitions, References, and Numbering'', are consistent with Wisconsin's statutes and the Act.

IV. What Action Is EPA Taking Today?

EPA is proposing to approve revisions to Wisconsin SIP rules NR 400, 406, 407, and 410 submitted by the State on July 28, 2005. EPA also is soliciting comment on this proposed approval.

V. Statutory and Executive Order Reviews

Executive Order 12866; Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' this action also is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

Regulatory Flexibility Act

This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this action proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This proposed action 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).

Executive Order 13132 Federalism

This proposed action 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 proposes to approve a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act.

Executive Order 13045 Protection of Children From Environmental Health and Safety Risks

This proposed approval 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 is not a significant regulatory action under executive order 12866.

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTA), 15 U.S.C. 272, requires federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impracticable. In reviewing program submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a program submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Act. Therefore, the requirements of section 12(d) of the NTTA do not apply.

Civil Justice Reform

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

Governmental Interference With Constitutionally Protected Property Rights

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order, and has determined that the rule's requirements do not constitute a taking.

Paperwork Reduction Act

This proposed 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.*).

List of Subjects in 40 CFR Part 52

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

Dated: September 12, 2005.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 05–18722 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–D–7638]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs are the basis for the floodplain management measures that the 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 comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed 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: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: 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 base flood elevations 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 are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification. This proposed 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 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

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	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)	
				Existing	Modified
Pago Pago	Territory of American Samoa.	South Pacfic Ocean (Aunuu Island).	Approximately 1,000 feet northwest of the center of Aunuu Village.	*2	*10
			Approximately 3,500 feet northeast of the center of Aunuu Village.	*2	*18
		South Pacific Ocean (Ofu Island).	Approxiamtely 400 feet northwest of Nuupule Rock.	None	*12
			Approximately 550 feet northeast of Tuumuai Point.	None	*21
		South Pacific Ocean (Olosega Island).	Approxiamtely 1,300 feet northwest of Pouono Point.	None	*9
			Approximately 770 feet southeast of Pouono Point.	None	*20
		South Pacific Ocean (Tau Island).	Approximately 1,000 feet northwest of the center of Faleasao Village.	None	*14
			Approximately 1,450 feet northeast of the center of Faleasao Village.	None	*24
		South Pacific Ocean (Tutuila Island).	Approximately 300 feet southeast of the intersection of Highway 1 and Rainmaker Hotel Drive.	*4	*5
			Approximately 330 feet southeast of the center of Fagneanea Village.	*3	*42

Maps available for inspection at the American Samoa Department of Public Works, American Samoa Government Center, Pago Pago, American Samoa.

Send comments to Mr. Taeaotui P. Tilei, American Samoa Department of Public Works Director, Public Works Department, Pago Pago, American Samoa 96799.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: September 14, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–18730 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–D–7636]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs are the basis for the floodplain management measures that the 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 comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed 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: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: 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 base flood elevations 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 are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act

This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to establish and maintain community eligibility in the NFIP. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification

This proposed 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 12612, Federalism

This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This proposed rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

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:

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
FLORIDA Alachua County				
Little Hatchet Creek	Approximately 0.59 mile upstream of the entrance to Gum Root Swamp.	•86	•85	Alachua County (Unincorporated Areas).
	Approximately 4,400 feet upstream of the entrance to Gum Root Swamp.	•94	•89	
Little Monteocha Creek ..	At the confluence with Monteocha Creek	None	•102	Alachua County (Unincorporated Areas).
	Approximately 100 feet upstream of County Route 340.	None	135	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Monteocha Creek	Approximately 1,700 feet upstream of the confluence with Sante Fe River.	•95	•96	Alachua County (Unincorporated Areas).
	Approximately 2.48 miles upstream of County Route 340.	None	•160	
Rhoda Branch	At the confluence with Sunshine Lake	None	•91	Alachua County (Unincorporated Areas).
	Approximately 440 feet upstream of County Route 231.	None	•136	
Rocky Creek	Approximately 1,220 feet upstream of the Santa Fe River.	•84	•85	Alachua County (Unincorporated Areas).
	Approximately 1.74 miles upstream of County Route 329.	None	•174	
Rocky Creek Tributary	At the confluence with Rocky Creek	None	•114	Alachua County (Unincorporated Areas).
	Approximately 1.48 miles upstream of the confluence with Rocky Creek.	None	•139	
Grass Prairie		None	•64	Alachua County (Unincorporated Areas).
Ledwith Lake		None	•69	Alachua County (Unincorporated Areas).
Levy Lake East		None	•65	Alachua County (Unincorporated Areas).
Lochloosa Lake		None	•61	Alachua County (Unincorporated Areas).
Mud Pond		None	•71	Alachua County (Unincorporated Areas).
Orange Lake		None	•61	Alachua County (Unincorporated Areas).
Sunshine Lake		None	•89	Alachua County (Unincorporated Areas).
Unnamed Lake West of Sunshine Lake.	Approximately 1,500 feet south of the intersection of State Highway 235 and State Highway 329.	None	•95	
Kanapaha Prairie		None	•64	Alachua County (Unincorporated Areas).
Little Manteocha Creek Diversion.	At the confluence with Little Manteocha Creek	None	•107	Alachua County (Unincorporated Areas).
	Divergence from Little Manteocha Creek	None	•122	
Little Manteocha Creek Diversion Tributary.	At the confluence with Little Manteocha Creek Diversion.	None	•108	Alachua County (Unincorporated Areas).
	Approximately 100 feet upstream of County Road 31A.	None	•110	
Levy Lake-West		None	•65	Alachua County (Unincorporated Areas).
Levy Lake-North		None	•65	Alachua County (Unincorporated Areas).
Kanapaha Sink		None	•64	Alachua County (Unincorporated Areas).
Unnamed flooding area between Levy Lake and Zedwith Lake.	Connecting channel between Levy Lake-East and Ledwith Lake.	None	#1	Alachua County (Unincorporated Areas).
Unnamed Pond West of Ledwith Lake.	Approximately 0.96 mile west of Lake Ledwith on the Marion County boundary.	None	•76	Alachua County (Unincorporated Areas).
Unnamed Pond North of Mud Pond.	Approximately 1,400 feet north of Mud Pond	None	•67	Alachua County (Unincorporated Areas).
Unnamed Ponding Area No. 1 South Levy Lake West.	Approximately 1,000 feet south of Levy Lake-West.	None	•65	Alachua County (Unincorporated Areas).
Unnamed Ponding Area No. 2 South of Levy Lake-West.	Approximately 2,000 feet south of Levy Lake-West.	None	•66	Alachua County (Unincorporated Areas).
Hogtown Creek Tributary 1.	Approximately 400 feet downstream of Northwest 53rd Avenue.	None	•155	City of Gainesville.
	Approximately 300 feet upstream of Northwest 53rd Avenue.	None	•167	

Alachua County (Unincorporated Areas)

Maps available for inspection at the Alachua County Department of Public Works, 5620 Northwest 120th Lane, Gainesville, Florida.

Send comments to Mr. Randall H. Reid, Alachua County Manager, P.O. Box 2877, 12 Southeast 1st Street, Gainesville, Florida 32602–2877.

City of Gainesville

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Maps available for inspection at the City of Gainesville Department of Public Works, 306 Northeast 6th Avenue, Gainesville, Florida.				
Send comments to The Honorable Pegeen Hanrahan, Mayor of the City of Gainesville, 200 East University Avenue, P.O. Box 490, Gainesville, Florida 32602.				
NEW HAMPSHIRE Cheshire County				
Connecticut River	Approximately 1.2 miles downstream of Boston and Maine Railroad.	•228	•229	Towns of Hinsdale, Chesterfield, Walpole, and Westmoreland.
	At the upstream county boundary	•300	•301	
Sprague Brook	At the confluence with Connecticut River	•226	•227	Town of Hinsdale.
	Approximately 5 feet downstream of State Route 19.	•226	•227	
Blaneherd Brook	At the confluence with Connecticut River	•249	•253	Town of Walpole.
	Approximately 200 feet upstream of State Route 12 and 123.	•252	•253	
Ashuelot River	At the downstream Town of Sullivan corporate limit, approximately 1,480 feet downstream of State Route 10.	None	•846	Town of Sullivan.
	At the upstream Town of Sullivan corporate limits, approximately 145 feet downstream of State Route 10.	None	•862	
Town of Chesterfield				
Maps available for inspection at the Town of Chesterfield Selectmen's Office, 504 Route 63, Chesterfield, New Hampshire.				
Send comments to Mr. Chester Greenwood, Chairman of the Town of Chesterfield Board of Selectmen, Chesterfield Town Office, P.O. Box 175, Chesterfield, New Hampshire 03443–0175.				
Town of Hinsdale				
Maps available for inspection at the Hinsdale Town Hall, 11 Main Street, Hinsdale, New Hampshire.				
Send comments to Mr. William Nebelski, Chairman of the Town of Hinsdale Board of Selectmen, Hinsdale Town Office, P.O. Box 13, Hinsdale, New Hampshire 03451–0013.				
Town of Sullivan				
Maps available for inspection at the Town of Sullivan Selectmen's Office, 452 Centre Street, Sullivan, New Hampshire.				
Send comments to Mr. Richard Hotchkiss, Chairman of the Town of Sullivan Board of Selectmen, P.O. Box 110, Sullivan, New Hampshire 03445.				
Town of Walpole				
Maps available for inspection at the Walpole Town Hall, 34 Elm Street, Walpole, New Hampshire.				
Send comments to Mr. Sheldon Sawyer, Chairman of the Walpole Board of Selectmen, P.O. Box 729, Walpole, New Hampshire 03608–0729.				
Town of Westmoreland				
Maps available for inspection at the Town of Westmoreland Selectmen's Office, 780 Route 63, Westmoreland, New Hampshire.				
Send comments to Mr. David Putnam, Chairman of the Town of Westmoreland Board of Selectmen, P.O. Box 55, Westmoreland, New Hampshire 03467.				
NEW HAMPSHIRE Sullivan County				
Connecticut River	Approximately 0.5 mile upstream of the downstream County boundary.	•301	•300	Towns of Charlestown, Cornish, Plainfield, and City of Claremont.
	At County boundary	•354	•344	
Beaver Brook No. 1	At the confluence with Connecticut River	•306	•308	Town of Charlestown.
	Approximately 1.3 miles upstream of the confluence.	•307	•308	
Little Sugar River	At the confluence with Connecticut River	•307	•310	Town of Charlestown.
	Approximately 1,625 feet upstream of the confluence with Connecticut River.	•309	•310	
Ox Brook	At the confluence with Connecticut River	•307	•311	Town of Charlestown.
	Approximately 1,420 feet upstream of the confluence.	•310	311	
Blow-Me-Down Brook	At the confluence with Connecticut River	•333	•330	Town of Cornish.
	Approximately 1.2 miles upstream of the confluence.	•333	•320	
Sugar River	At the confluence with Connecticut River	•318	•320	City of Claremont.
	Approximately 1.2 miles upstream of the confluence with Connecticut River.	•319	•320	
North Branch Sugar River.	Approximately 540 feet downstream of corporate limits.	•513	•514	Town of Croydon.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 60 feet downstream of corporate limits.	•513	•515	

Town of Charlestown

Maps available for inspection at the Charlestown Town Hall, 26 Railroad Street, Charlestown, New Hampshire.

Send comments to Ms. Brenda Ferland, Chairman of the Town of Charlestown Board of Selectmen, P.O. Box 385, Charlestown, New Hampshire 03603.

City of Claremont

Maps available for inspection at the City of Claremont Planning and Development Office, 14 North Street, Claremont, New Hampshire.

Send comments to Mr. Guy Santagate, Claremont City Manager, Claremont City Hall, 58 Opera House Square, Claremont, New Hampshire 03743–7014.

Town of Cornish

Maps available for inspection at the Cornish Town Offices, 488 Townhouse Road, Cornish, New Hampshire.

Send comments to Mr. William Gallagher, Chairman of the Town of Cornish Board of Selectmen, 488 Townhouse Road, Cornish, New Hampshire 03745.

Town of Croydon

Maps available for inspection at the Croydon Town Office, 879 New Hampshire Route 10, Croydon, New Hampshire.

Send comments to Mr. James Harding, Chairman of the Town of Croydon Board of Selectmen, Croydon Town Office, 879 New Hampshire Route 10, Croydon, New Hampshire 03733.

NORTH CAROLINA
Bladen County

Bakers Creek	At the confluence with Cape Fear River	None	•54	Unincorporated Areas of Bladen County.
	Approximately 2.1 miles upstream of Owen Hill Road.	None	•79	
Black River	At the Bladen/Pender County boundary	None	•16	Unincorporated Areas of Bladen County.
	At the confluence with South River	None	•26	
Browns Creek	At the confluence with Cape Fear River	None	•48	Unincorporated Areas of Bladen County, Town of Elizabethtown.
	Approximately 2.2 miles upstream of Peanut Plant Road.	None	•101	
Browns Creek Tributary	At the confluence with Browns Creek	None	•96	Unincorporated Areas of Bladen County, Town of Elizabethtown.
	Approximately 0.9 mile upstream of Cromartie Road.	None	•120	
Cape Fear River	At the Bladen/Pender County boundary	None	•18	Unincorporated Areas of Bladen County, Town of Elizabethtown.
	Approximately 190 feet downstream of the Bladen/Cumberland County boundary.	None	•70	
Carvers Creek	At the confluence with Cape Fear River	None	•31	Unincorporated Areas of Bladen County.
	Approximately 1.6 miles upstream of Doctor Robinson Road.	None	•61	
Colly Creek	At the Bladen/Pender County boundary	None	•18	Unincorporated Areas of Bladen County, Town of White Lake.
	Approximately 1,600 feet upstream of Susie Sand Hill Road.	None	•85	
Cypress Creek	At the confluence with South River	None	•62	Unincorporated Areas of Bladen County.
	Approximately 0.5 mile upstream of NC 210	None	•76	
Donoho Creek	At the confluence with Cape Fear River	None	•35	Unincorporated Areas of Bladen County.
	Approximately 800 feet upstream of NC Highway 87.	None	•69	
Ellis Creek	At the confluence with Cape Fear River	None	•54	Unincorporated Areas of Bladen County.
	Approximately 3.0 miles upstream of Dowd Dairy Road.	None	•75	
Georgia Branch	At the confluence with Cape Fear River	None	•68	Unincorporated Areas of Bladen County.
	Approximately 1.6 miles upstream of Glengerry Hill Road.	None	•128	
Hammond Creek	At the confluence with Cape Fear River	None	•43	Unincorporated Areas of Bladen County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 400 feet miles upstream of Airport Road.	None	•43	
Harrisons Creek	At the confluence with Cape Fear River	None	•59	Unincorporated Areas of Bladen County.
	Approximately 1.2 miles upstream of Camp Bowers Trial Dam.	None	•71	
Kitchens Branch	At the confluence with Carvers Creek	None	•42	Unincorporated Areas of Bladen County.
	Approximately 300 feet upstream of Cord Road	None	•69	
Mines Creek	At the confluence with Georgia Branch	None	•68	Unincorporated Areas of Bladen County.
	Approximately 0.8 miles upstream of Dam	None	•120	
Plummers Run	At the confluence with Cape Fear River	None	•30	Unincorporated Areas of Bladen County.
	Approximately 240 feet upstream of Brighten Road.	None	•64	
Plummers Run Tributary	At the confluence with Plummers Run	None	•43	Unincorporated Areas of Bladen County.
	Approximately 0.5 mile upstream of the confluence with Plummers Run.	None	•52	
Pub Mill Creek	At the confluence with Turnbull Creek	None	•48	Unincorporated Areas of Bladen County.
	Approximately 0.6 mile upstream of Unnamed Road.	None	•56	
South River	At the confluence with Black River	None	•26	Unincorporated Areas of Bladen County.
	At the Bladen/Cumberland County boundary	None	•71	
Steep Run	At the confluence with Cape Fear River	None	•28	Unincorporated Areas of Bladen County.
	Approximately 1.1 miles upstream of NC Highway 87.	None	•54	
Turnbull Creek	At the confluence with Cape Fear River	None	•48	Unincorporated Areas of Bladen County.
	Approximately 2,100 feet upstream of NC 242	None	•84	
Whites Creek	At the confluence with Hammond Creek	None	•43	Unincorporated Areas of Bladen County.
	Approximately 470 feet upstream of Airport Road	None	•43	

Town of Elizabethtown

Maps are available for inspection at Elizabethtown Town Hall, 805 West Broad Street, Elizabethtown, NC 28337.

Send comments to The Honorable Kenneth Kornegay, Mayor of the Town of Elizabethtown, P.O. Box 716, Elizabethtown, NC 28337.

Town of White Lake

Maps are available for inspection at White Lake Town Hall, 1879 White Lake Drive, White Lake, NC 28337.

Send comments to The Honorable Goldston Womble, Jr., Mayor of the Town of White Lake, P.M.B. 7250, White Lake, NC 28337.

Unincorporated Areas of Bladen County

Maps are available for inspection at Bladen County Courthouse, 106 East Broad Street, Room 107, Elizabethtown, NC 28337.

Send comments to Mr. Gregory Martin, Bladen County Manager, P.O. Box 1048, Elizabethtown, NC 28337.

NORTH CAROLINA
Cumberland County

Beaver Creek	At the confluence with Little Rockfish Creek	•118	•121	Unincorporated Areas of Cumberland County, City of Fayetteville, Town of Hope Mills.
	Approximately 0.9 mile upstream of All-American Expressway.	None	•199	
Beaver Creek Tributary A	At the confluence with Beaver Creek	•134	•135	Unincorporated Areas of Cumberland County, City of Fayetteville.
	Approximately 1,700 feet upstream of the confluence with Beaver Creek.	•134	•135	
Beaver Dam Creek	At the confluence with South River	None	•74	Unincorporated Areas of Cumberland County.
	Approximately 0.3 mile upstream of Spencer Road.	None	•106	
Big Branch	At the confluence with Beaver Creek	•193	•191	Unincorporated Areas of Cumberland County, City of Fayetteville.
	Approximately 1.4 miles upstream of the confluence with Beaver Creek.	None	•219	
Big Creek	At the confluence with South River	None	•102	Unincorporated Areas of Cumberland County.
	Approximately 5.1 miles upstream of Maxwell Road.	None	•145	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Black River	At the confluence with South River	None	•125	Unincorporated Areas of Cumberland County.
	At the Cumberland/Harnett County boundary	None	•140	
Bones Creek	At the confluence with Little Rockfish Creek	•144	•146	Unincorporated Areas of Cumberland County.
	Approximately 2.7 miles upstream of Morganton Road.	None	•225	
Browns Swamp	At the confluence with South River	None	•111	Unincorporated Areas of Cumberland County.
	Approximately 650 feet upstream of South River School Road.	None	•128	
Browns Swamp Tributary 1.	At the confluence with Browns Swamp	None	•111	Unincorporated Areas of Cumberland County.
	Approximately 650 feet upstream of Kennell Road	None	•124	
Buck Creek	At the confluence with Big Creek	None	•108	Unincorporated Areas of Cumberland County.
	Approximately 0.9 miles upstream of the confluence with Big Creek.	None	•113	
Buckhead Creek	At the confluence with Little Rockfish Creek	•105	•112	Unincorporated Areas of Cumberland County.
	Approximately 0.8 miles upstream of Raeford Road.	None	•198	
Cape Fear River Tributary 2.	Approximately 0.7 mile upstream of the confluence with Cape Fear River.	•96	•97	Unincorporated Areas of Cumberland County Town of Wade.
	Approximately 0.4 miles upstream of Interstate 95	None	•131	
Cold Camp Creek	At the confluence with Galberry Swamp	None	•144	Unincorporated Areas of Cumberland County.
	Approximately 500 feet downstream of Interstate 95.	None	•165	
Cold Camp Creek Tributary 1.	At the confluence with Cold Camp Creek	None	•145	Unincorporated Areas of Cumberland County.
	Approximately 1,100 feet upstream of Canady Pond Road.	None	•157	
Cold Camp Creek Tributary 2.	At the confluence with Cold Camp Creek	None	•153	Unincorporated Areas of Cumberland County.
	Approximately 0.8 mile upstream of John McMillan Road.	None	•166	
Cypress Creek	At the confluence with Little River	None	•165	Unincorporated Areas of Cumberland County.
	Approximately 1.7 miles upstream of West Manchester Road.	None	•204	
Galberry Swamp	At the Cumberland/Bladen County boundary	None	•134	Unincorporated Areas of Cumberland.
	At the confluence with Cold Camp Creek and Buckhorn Swamp.	None	•144	
Gum Swamp	At the confluence with South River	None	•94	Unincorporated Areas of Cumberland County.
	Approximately 0.9 mile upstream of Hollow Bridge Road.	None	•103	
Hector Creek	At the confluence with Little River	None	•178	Unincorporated Areas of Little River Cumberland County.
	At the Cumberland/Harnett County boundary	None	•194	
Jumping Run Creek	Approximately 1,250 feet upstream of NC 210 (Lillington Highway).	None	•136	Unincorporated Areas of Cumberland County.
	At the Cumberland/Harnett County boundary	None	•161	
Kirks Mill Creek	At the confluence with Willis Creek	None	•73	Unincorporated Areas of Cumberland County.
	Approximately 500 feet upstream of Point East Drive.	None	•84	
Little River Tributary 1	At the confluence with Little River	None	•112	Unincorporated Areas of Cumberland County.
	Approximately 1.3 miles upstream of the confluence with Lower Little River.	None	•138	Cumberland County.
Little River Tributary 2	At the confluence with Little River	•146	•144	Unincorporated Areas of Cumberland County, Town of Spring Lake.
	Approximately 0.7 mile of upstream of McCormick Road.	None	•284	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Little River Tributary 3	At the confluence with Little River Tributary 2	None	•154	Unincorporated Areas of Cumberland County.
	Approximately 300 feet upstream of Chapel Hill Road.	None	•209	
Little Rockfish Creek	Approximately 850 feet upstream of Cameron Road.	•81	•82	Unincorporated Areas of Cumberland County, Town of Hope Mills.
	At the confluence with Bones Creek	•144	•146	
Long Branch	At the confluence with Willis Creek	None	•95	Unincorporated Areas of Cumberland County.
	Approximately 1.2 miles upstream of the confluence with Willis Creek.	None	•116	
Lower Little River	Approximately 1.1 miles upstream of Mill Road	None	•103	Unincorporated Areas of Cumberland County, Town of Spring Lake.
	At the Cumberland/Hoke County boundary	None	•179	
Mingo Swamp	At the confluence with South River	None	•127	Unincorporated Areas of Cumberland County.
	At the Cumberland/Sampson/Harnett County boundary.	None	•134	
Muddy Creek	At the confluence with Little River	•152	•150	Unincorporated Areas of Cumberland County.
	At the Cumberland/Harnett County boundary	None	•175	
Peters Creek	At the Cumberland/Bladen County boundary	None	•71	Unincorporated Areas of Cumberland County.
	Approximately 1,400 feet upstream of C.S. Faircloth Road.	None	•94	
Reese Creek	Approximately 1,100 feet upstream of Locks Creek.	•83	•84	Unincorporated Areas of Cumberland County.
	Approximately 320 feet upstream of Murphy Road	None	•137	
Rockfish Creek	Approximately 10 feet downstream of Calico Street.	•82	•81	Unincorporated Areas of Cumberland County, Town of Hope Mills.
	At the Cumberland/Hoke County boundary	•125	•122	
Sandy Creek	At the confluence with South River	None	•97	Unincorporated Areas of Cumberland County, Town of Stedman.
	Approximately 375 feet upstream of Horne Farm Road.	None	•120	
South River	At the Cumberland/Bladen/Sampson County boundary.	None	•71	Unincorporated Areas of Cumberland County, Town of Falcon.
	Approximately 0.7 mile upstream of the confluence of Black River.	None	•127	
South River Tributary 1 ..	At the confluence with South River	None	•117	Unincorporated Areas of Cumberland County.
	Approximately 1.1. miles upstream of Smithfield Road.	None	•175	
South River Tributary 2 ..	At the confluence with South River Tributary 1	None	•122	Unincorporated Areas of Cumberland County.
	Approximately 0.4 mile upstream of Sambo Jackson Road.	None	•157	
South River Tributary 3 ..	At the confluence with South River	None	•123	Unincorporated Areas of Cumberland County, Town of Falcon.
	Approximately 0.7 mile of Falcon upstream of the confluence with South River.	None	•139	
South River Tributary 4 ..	Approximately 600 feet upstream of the confluence with South River.	None	•127	Unincorporated Areas of Cumberland County.
	Approximately 0.5 mile upstream of Rhodes Pond Road.	None	•138	
Stewarts Creek	At the confluence with Rockfish Creek	•125	•122	Unincorporated Areas of Cumberland County.
	At the Cumberland/Hoke County boundary	None	•199	
Stewarts Creek (North) ..	Approximately 0.8 mile Morganton Road	None	•204	Unincorporated Areas of upstream of Cumberland County, City of Fayetteville.
	Approximately 1.4 mile upstream of Morgantown Road.	None	•229	
Swans Creek	At the confluence with Willis Creek	None	•95	Unincorporated Areas of Cumberland County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 470 feet upstream of Yarborough Road.	None	•109	
Tank Creek	At the confluence with Little River	•150	•147	Unincorporated Areas of Cumberland County, Town of Spring Lake.
	Approximately 50 feet upstream of Railroad	•176	•175	
Willis Creek	Approximately 500 feet downstream of Highway 87.	•68	•69	Unincorporated Areas of Cumberland County.
	At the confluence of Swans Creek and Long Branch.	None	•95	

City of Fayetteville

Maps are available for inspection at The City of Fayetteville Zoning Department, 433 Hay Street, Fayetteville, NC.

Send comments to Mr. Roger Stancil, Fayetteville City Manager, 433 Hay Street, Fayetteville, NC 28301.

Town of Falcon

Maps are available for inspection at the Falcon Town Hall, 7156 South West Street, Falcon, NC.

Send comments to The Honorable Wayne Lucas, Mayor of the Town of Falcon, P.O. Box 112, Falcon, NC 28342.

Town of Hope Mills

Maps are available for inspection at the Hope Mills Town Hall, 5770 Rockfish Road, Hope Mills, NC.

Send comments to The Honorable Edwin Deaver, Mayor of the Town of Hope Mills, P.O. Box 127, Hope Mills, NC 28348.

Town of Spring Lake

Maps are available for inspection at the Spring Lake Town Hall, 300 Ruth Street, Spring Lake, NC.

Send comments to The Honorable Ethel Clark, Mayor of the Town of Spring Lake, P.O. Box 617, Spring Lake, NC 28390.

Town of Stedman

Maps are available for inspection at the Stedman Town Hall, 5110 Front Street, Stedman, NC.

Send comments to Ms. Connie Spell, Stedman Town Administrator, P.O. Box 220, Stedman, NC 28391.

Town of Wade

Maps are available for inspection at the Wade Town Hall, 7128 Main Street, Wade, NC.

Send comments to The Honorable Huell Aekins, Mayor of the Town of Wade, P.O. Box 127, Wade, NC 28395.

Unincorporated Areas of Cumberland County

Maps are available for inspection at the Cumberland County Mapping Department, 117 Dick Street, Fayetteville, NC.

Send comments to Mr. James E. Martin, Cumberland County Manager, P.O. Box 1829, Fayetteville, NC 28301.

NORTH CAROLINA
Guilford County

Back Creek	At the Alamance/Guilford County Boundary	None	•579	Unincorporated Areas of Guilford County.
	Approximately 150 feet upstream of SR 100	None	•644	
Back Creek Tributary 2	At the confluence with Back Creek	None	•589	Unincorporated Areas of Guilford County.
	At the Alamance/Guilford County Boundary	None	•634	
Beaver Creek	At the Alamance/Guilford County Boundary	None	•569	Unincorporated Areas of Guilford County.
	Approximately 0.8 mile upstream of Mount Hope Church Road.	None	•668	
Beaver Creek Tributary	At the confluence with Beaver Creek	None	•592	Unincorporated Areas of Guilford County.
	Approximately 0.7 mile upstream of Brick Church Road.	None	•631	
Benaja Creek	Approximately 1.2 miles upstream of Railroad Crossing.	None	•712	Unincorporated Areas of Guilford County.
	Approximately 1.4 miles upstream of Railroad Crossing.	None	•718	
Big Alamance Creek	At the confluence with Big Alamance Creek Tributary 1.	None	•686	Unincorporated Areas of Guilford County, Town of Pleasant Garden.
	Approximately 1.3 miles upstream of Minder Road	None	•757	
Big Alamance Creek Tributary 3.	At the confluence with Big Alamance Creek	None	•589	Unincorporated Areas of Guilford County.
	Approximately 325 feet upstream of Thacker Dairy Road.	None	•613	
Big Alamance Creek Tributary 4.	At the confluence with Big Alamance Creek	None	•592	Unincorporated Areas of Guilford County.
	Approximately 0.4 mile upstream of Alamance Church Road.	None	•672	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Big Alamance Creek Tributary 8.	At the confluence with Big Alamance Creek	None	•658	Unincorporated Areas of Guilford County, Town of Pleasant Garden.
	Approximately 100 feet upstream of Hagon Stone Park Road.	None	•712	
Big Alamance Creek Tributary 9.	At the confluence with Big Alamance Creek Tributary 8.	None	•663	Unincorporated Areas of Guilford County.
	Approximately 0.8 mile upstream of Fieldview Road.	None	•713	
Boulding Branch	Approximately 50 feet upstream of Montileu Avenue.	None	•845	City of High Point.
	At North Centennial Street	None	•888	
Boulding Branch Tributary 1.	At the confluence with Boulding Branch	None	•775	City of High Point.
	Approximately 1,350 feet upstream of Hickory Lane.	None	•844	
Boulding Branch Tributary 2.	At the confluence with Boulding Branch	None	•794	City of High Point.
	Approximately 350 feet upstream of Waynick Street.	None	•838	
Boulding Branch Tributary 3.	At the confluence with Boulding Branch	None	•797	City of High Point.
	Approximately 1,000 feet upstream of McGuinn Drive.	None	•849	
Brush Creek (Stream No. 54).	Approximately 1,600 feet upstream of Lewiston Road.	None	•772	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 1,550 feet upstream of Airport Center Drive.	None	•879	
Brush Creek Tributary	At the confluence with Brush Creek	None	•819	Unincorporated Areas of Guilford County, City of Greensboro.
	Approximately 1.5 miles upstream of Airport Parkway.	None	•924	
Bull Run	At the confluence with Deep River (#1)	•705	•704	Unincorporated Areas of Guilford County, City of Greensboro, Town of Jamestown.
	Approximately 1,000 feet upstream of Ruffin Road	None	•845	
Bull Run (Stream No. 28)	At the confluence with Deep River (#1)	•705	•704	Unincorporated Areas of Guilford County, City of Greensboro.
	Approximately 1,000 feet upstream of Ruffin Road	None	•845	
Bull Run Tributary (Stream No. 29).	At the confluence with Bull Run	•777	•778	City of Greensboro.
	Approximately 330 feet upstream of Old Fox Trail	None	•808	
Chocolate Creek	At the confluence with North Prong Stinking Quarter Creek.	None	•616	Unincorporated Areas of Guilford County.
	Approximately 3 miles upstream of Alamance Church Road.	None	•687	
Copper Branch	At the confluence with Deep River (#1)	None	•699	City of High Point, Unincorporated Areas of Guilford County.
	Approximately 600 feet upstream of I–85	None	•822	
Deep River Tributary 3 (#29a).	Approximately 50 feet upstream of Edinburgh Drive.	None	•762	City of High Point.
	Approximately 0.7 mile upstream of Edinburgh Drive.	None	•806	
Deep River Tributary 30	At the confluence with West Fork Deep River (#2)	None	•762	City of High Point.
	Approximately 0.5 mile upstream of the confluence with West Fork Deep River (#2).	None	•800	
Deep River Tributary 31	At the confluence with West Fork Deep River (#2)	None	•778	City of High Point.
	Approximately 650 feet upstream of Arden Place	None	•863	
East Fork Deep River (Stream No. 23).	Approximately 100 feet upstream of Regency Drive.	•798	•799	City of Greensboro, City of High Point, Unincorporated Areas of Guilford County.
	Approximately 1,275 fee upstream of Industrial Village.	None	•870	
East Fork Deep River Tributary 1.	At the confluence with East Deep River	None	•842	City of Greensboro.
	Approximately 0.4 mile upstream of U.S. Route 421.	None	•860	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
East Fork Deep River Tributary 2.	At the confluence with East Fork Deep River	None	•790	City of Greensboro, City of High Point, Unincorporated Areas of Guilford County.
	Approximately 1,300 feet upstream of I–40	None	•866	
Haw River Tributary 15 ..	Approximately 0.5 mile upstream of the confluence with Haw River.	None	•637	Unincorporated Areas of Guilford County.
	At the Alamance/Guilford County Boundary	None	•665	
Haw River Tributary 19 ..	Approximately 400 feet upstream of the confluence with Haw River.	None	•844	Unincorporated Areas of Guilford County.
	Approximately 400 feet upstream of the confluence with Haw River.	None	•901	
Hiatt Branch	Approximately 1,650 feet downstream of U.S. 311	None	•823	City of High Point.
	Approximately 0.5 mile upstream of U.S. 311	None	•870	
Horney Branch	Approximately 100 feet upstream of Old Mill Road	None	•839	City of High Point.
	Approximately 500 feet upstream of Viking Drive	None	•864	
Horsepen Creek (Stream No. 55.	At the confluence with Reedy Fork	•743	•742	City of Greesboro.
	Approximately 200 feet downstream of Distribution Drive.	None	•835	Unincorporated Areas of Guilford County.
Horsepen Creek Tributary 1 (Stream No. 57).	At the confluence with Horsepen Creek	•757	•756	City of Greensboro.
	Approximately 1,375 feet upstream of Derbyshire Drive.	None	•833	
Horsepen Creek, Tributary 2 (Stream No. 56).	At the confluence with Horsepen Creek	•763	•761	
	Approximately 1,800 feet upstream of Hobbs Road.	None	•853	
Horsepen Creek, Tributary A.	At the confluence with Horsepen Creek Tributary 2.	None	•777	City of Greensboro.
	Approximately 300 feet upstream of Friendly Acres Drive.	None	•811	
Horsepen Creek, Tributary B.	At the confluence with Horsepen Creek Tributary 2.	None	•778	City of Greensboro.
	Approximately 1.1 miles upstream of Hobbs Road	None	•860	
Horsepen Creek, Tributary C.	At the confluence with Horsepen Creek	None	•758	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 1,100 feet upstream of Four Farms Road.	None	•784	
Horsepen Creek, Tributary D.	At the confluence with Horsepen Creek	None	•772	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 0.8 mile upstream of Chance Road	None	•830	Unincorporated Areas of Guilford County.
Horsepen Creek, Tributary E.	At the confluence with Horsepen Creek	None	•775	City of Greensboro.
	Approximately 150 feet upstream of Green Meadow Drive.	None	•826	
Horsepen Creek, Tributary F.	At the confluence with Horsepen Creek	None	•786	City of Greensboro.
	Approximately 400 feet upstream of Joseph Bryan Boulevard.	None	•822	Unincorporated Areas of Guilford County.
Horsepen Creek, Tributary G.	At the confluence with Horsepen Creek	None	•796	City of Greensboro.
	Approximately 0.6 mile upstream of the confluence with Horsepen Creek.	None	•828	Unincorporated Areas of Guilford County.
Horsepen Creek, Tributary H.	At the confluence with Horsepen Creek	None	•796	City of Greensboro.
	Approximately 0.4 mile upstream of Bollinger Road.	None	•804	
Horsepen Creek, Tributary I.	At the confluence with Horsepen Creek Tributary H.	None	•807	City of Greensboro.
	Approximately 100 feet upstream of Friendway Road.	None	•861	
Horsepen Creek, Tributary J.	At the confluence with Horsepen Creek Tributary H.	None	•806	City of Greensboro.
	Approximately 700 feet upstream of Friendly Avenue.	None	•864	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Horsepen Creek, Tributary K.	At the confluence with Horsepen Creek	None	•823	City of Greensboro.
	Approximately 250 feet upstream of North Chimney Rock Road.	None	•888	
Jordan Branch	At the confluence with North Buffalo Creek	None	•704	City of Greensboro Unincorporated Areas of Guilford County.
	Approximately 50 feet downstream of Railroad	None	•769	
Knight Road Branch	At the confluence with West Ford Deep River (#2)	None	•819	City of High Point, Unincorporated Areas of Guilford County.
	At the Guilford/Forsyth County Boundary	None	•838	
Lake Hamilton	At the confluence with North Buffalo Creek	None	•785	City of Greensboro.
	Approximately 70 feet upstream of East Kemp Road.	None	•814	
Mears Fork Creek	At the upstream side of Strader Road	None	•790	City of Summerfield.
	Approximately 0.7 miles upstream of Strader Road.	None	•805	
Mile Branch Tributary 1	At the confluence with Mile Branch	None	•721	City of High Point.
	Approximately 0.7 mile Branch	None	•780	
Mile Run Creek	At the confluence with South Buffalo Creek	•728	•729	City of Greensboro Unincorporated Areas of Guilford County.
	Approximately 150 feet downstream of Orchard Street.	None	•767	
Muddy Creek	At the confluence with North Buffalo Creek	•710	•713	City of Greensboro Unincorporated Areas of Guilford County.
	Approximately 850 feet upstream of North Dudley Street.	None	•777	
Muddy Creek East Tributary.	At the Guilford/Randolph County Boundary	None	•814	City of High Point.
	Approximately 1,000 feet upstream of Baker Road	None	•855	
Muddy Creek East Tributary 2.	At the High Point ETJ/Archdale City Boundary	None	•789	City of High Point.
	At the High Point ETJ/Archdale City Boundary	None	•799	
Muddy Creek East, Tributary 4.	At the Guilford/Randolph County Boundary	None	•771	City of High Point.
	Approximately 1,500 feet upstream of Liberty Road.	None	•826	
Muddy Creek East Tributary 5.	At the High Point ETJ/Archdale City Boundary	None	•778	City of High Point.
	Approximately 550 feet upstream of Liberty Road	None	•814	
Muddy Creek East Tributary 6.	At the High Point ETJ/Archdale City Boundary	None	•777	City of High Point.
	Approximately 1,250 feet upstream of Liberty Road.	None	•816	
North Buffalo Creek (Stream No. 66).	Approximately 50 feet downstream of Rankin Mill Road.	•697	•699	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 90 feet upstream of South Holden Road.	None	•816	
North Buffalo Creek Tributary 1.	At the confluence with Jordan Branch	None	•753	City of Greensboro.
	Approximately 700 feet upstream of Allyson Avenue.	None	•779	
North Buffalo Creek Tributary 2.	At the confluence with Muddy Creek	None	•719	City of Greensboro.
	Approximately 2,050 feet upstream of Woodmore Drive.	None	•750	
North Buffalo Creek Tributary 3.	At the confluence with North Buffalo Creek	None	•744	City of Greensboro.
	Approximately 0.5 mile upstream of the confluence of North Buffalo Creek.	None	•754	
North Buffalo Creek Tributary 4.	At the confluence with North Buffalo Creek	None	•750	City of Greensboro.
	Approximately 200 feet upstream of South Aycock Street.	None	•769	
North Buffalo Creek Tributary 5.	At the confluence with North Buffalo Creek Tributary A.	None	•774	City of Greensboro.
	Approximately 75 feet upstream of Forest Hill Drive.	None	•843	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
North Buffalo Creek Tributary 6.	At the confluence with Lake Hamilton	None	•800	City of Greensboro.
	Approximately 100 feet upstream of Waycross Drive.	None	•823	
North Buffalo Creek Tributary A.	At the confluence with North Buffalo Creek	•757	•760	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 2,100 feet upstream of Joseph M. Bryan Boulevard.	•808	•806	
North Little Alamance Creek Tributary 6.	At the confluence with North Little Alamance Creek.	None	•627	Unincorporated Areas of Guilford County.
	Approximately 1,900 feet upstream of U.S. 70	None	•649	
North Prong Stinking Quarter Creek.	At the Alamance/Guilford County Boundary	None	•589	Unincorporated Areas of Guilford County.
	Approximately 700 feet upstream of Liberty Road	None	•735	
North Prong Stinking Quarter Creek Tributary.	At the confluence with North Prong Stinking Quarter Creek.	None	•637	Unincorporated Areas of Guilford County.
	Approximately 250 feet upstream of Cable Church Road.	None	•667	
Philadelphia Lake	At the confluence with North Buffalo Creek	None	•728	City of Greensboro.
	Approximately 1,100 feet upstream of West Cone Boulevard.	None	•809	
Polecat Creek Tributary 2.	At the confluence with Polecat Creek (#42)	None	•715	Unincorporated Areas of Guilford County, Town of Pleasant Garden.
	Approximately 2 miles upstream of the confluence with Polecat Creek (#42).	None	•745	
Polecat Creek Tributary 3.	At the confluence with Polecat Creek Tributary 2	None	•718	Unincorporated Areas of Guilford County, Town of Pleasant Garden.
	Approximately 1.7 miles upstream of the confluence with Polecat Creek Tributary 2.	None	•780	
Porks Creek	At the Alamance/Guilford County Boundary	None	•644	Unincorporated Areas of Guilford County.
	Approximately 1,000 feet upstream of the Alamance/Guilford County Boundary.	None	•656	
Reedy Fork Tributary 1	Approximately 1,200 feet upstream of the confluence with Reedy Fork Creek.	None	•626	Unincorporated Areas of Guilford County.
	Approximately 1,100 feet upstream of Turner Smith Road.	None	•728	
Reedy Fork Tributary 10	Approximately 0.9 mile upstream of the confluence with Reedy Fork Creek.	•742	•745	Unincorporated Areas of the Guilford County, City of Greensboro.
	Approximately 1.4 miles upstream of the confluence with Reedy Fork Creek.	None	•752	
Reedy Fork Tributary 2	Approximately 1,100 feet upstream of the confluence with Reedy Fork Creek.	None	•640	Unincorporated Areas of Guilford County.
	Approximately 350 feet upstream of Middlestream Road.	None	•743	
Reedy Fork Tributary 3	At the confluence with Reedy Fork Tributary 2	None	•686	Unincorporated Areas of Guilford County.
	Approximately 0.9 mile upstream of Turner Smith Road.	None	•715	
Reedy Fork Tributary 4	Approximately 1,000 feet upstream of the confluence with Reedy Fork.	None	•620	Unincorporated Areas of Guilford County.
	Approximately 0.6 mile upstream of Busick Quarry Road.	None	•636	
Reedy Fork Tributary 7	At the upstream side of Brookbank Road	None	•779	City of Summerfield.
	Approximately 1.1 miles upstream of Brookbank Road.	None	•795	
Reedy Fork Tributary 8	Approximately 800 feet upstream of the confluence with Reedy Fork Creek.	None	•633	Unincorporated Areas of Guilford County.
	Approximately 0.9 mile upstream of the confluence with Reedy Fork Creek.	None	•651	
Reedy Fork Tributary 9	At the upstream side of Reedy Fork Parkway	•685	•688	Unincorporated Areas of Guilford County, City of Greensboro.
	Approximately 0.5 mile upstream of U.S. Route 29.	None	•702	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Richland Creek	Approximately 0.5 mile upstream of Church Street	•720	•721	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 900 feet upstream of Guilford Courthouse National Park LP.	None	•805	
Richland Creek (#30)	At the confluence with Stream No. 31	None	•837	City of High Point.
	Approximately 1,350 feet upstream of West Green Drive.	None	•877	
Richland Creek Tributary 1.	At the confluence with Richland Creek	None	•750	City of Greensboro.
	Approximately 1,500 feet upstream of Pheasant Run Drive.	None	•810	
Richland Creek Tributary 10.	At the confluence with Richland Creek (#30)	None	•785	City of High Point.
	Approximately 400 feet upstream of East Springfield Road.	None	•828	
Richland Creek Tributary 11.	At the confluence with Richland Creek Tributary 10.	None	•805	City of High Point.
	Approximately 650 feet upstream of Model Farm Road.	None	•837	
Richland Creek Tributary 12.	At the confluence with Richland Creek (#30)	None	•792	City of High Point.
	Approximately 100 feet upstream of Tate Street ...	None	•863	
Richland Creek Tributary 14.	At the confluence with Richland Creek (#30)	None	•809	City of High Point.
	Approximately 400 feet upstream of Fraley Road	None	•863	
Richland Creek Tributary 15.	At the confluence with Richland Creek (#30)	None	•827	City of High Point.
	Approximately 100 feet upstream of South Elm Street.	None	•857	
Richland Creek Tributary 17.	At the confluence with Richland Creek (#30)	None	•849	City of High Point.
	Approximately 550 feet upstream of Lincoln Drive	None	•869	
Richland Creek Tributary 2.	At the confluence with Richland Creek (#30)	•714	•713	City of High Point.
	Approximately 0.6 mile upstream of the confluence with Richland Creek (#30).	None	•809	
Richland Creek Tributary 3.	Approximately 625 feet upstream of the confluence with Richland Creek.	None	•724	City of High Point.
	Approximately 75 feet upstream of Lawndale Avenue.	None	•828	
Richland Creek Tributary 4.	At the confluence with Richland Creek Tributary 3	None	•753	City of High Point.
	Approximately 1,500 feet upstream of Central Avenue.	None	•829	
Richland Creek Tributary 5.	At the confluence with Richland Creek Tributary 3	None	•747	City of High Point, Unincorporated Areas of Guilford County.
	Approximately 1,700 feet upstream of I-85	None	•803	
Richland Creek Tributary 6.	At the confluence with Richland Creek (#30)	None	•752	City of High Point.
	Approximately 1,700 feet upstream of I-85	None	•783	
Richland Creek Tributary 9.	At the confluence with Richland Creek (#30)	None	•778	City of High Point.
	Approximately 2,100 feet upstream of the confluence with Richland Creek (#30).	None	•807	
Rock Creek Tributary	Approximately 80 feet upstream of Sedalia Road	None	•640	Unincorporated Areas of Guilford County, Town of Sedalia.
	Approximately 1,900 feet upstream of Sedalia Road.	None	•648	
Rock Creek Tributary 3 ..	At the confluence with Rock Creek (Stream No. 80).	None	•632	Unincorporated Areas of Guilford County.
	Approximately 1.1 miles upstream of the confluence with Rock Creek (Stream No. 80).	None	•652	
Rose Creek	At the Guilford/Rockingham County Boundary	None	•679	Unincorporated Areas of Guilford County.
	Approximately 1,056 feet upstream of Chrismon Road.	None	•694	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Ryan Creek	At the confluence with South Buffalo Creek (Stream of No. 67).	•733	•735	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 350 feet upstream of U.S. Route 220.	None	•799	
Smith Branch	Approximately 1,800 feet upstream of the confluence with Reedy Fork Creek.	None	•676	Unincorporated Areas of Guilford County.
	Approximately 1.5 miles upstream of Turner Smith Road.	None	•750	
South Buffalo Creek (Stream No. 67).	Approximately 100 feet downstream of East Lee Street.	•712	•714	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 1,100 feet upstream of Guilford College Road.	None	•876	
South Buffalo Creek Tributary 1.	At the confluence with South Buffalo Creek	None	•814	City of Greensboro.
	Approximately 300 feet upstream of Pennoak Road.	None	•837	
South Buffalo Creek Tributary 10.	At the confluence with Ryan Creek	None	•735	City of Greensboro.
	Approximately 50 feet downstream of Webster Road.	None	•807	
South Buffalo Creek Tributary 11.	At the confluence with Ryan Creek	None	•746	City of Greensboro.
	Approximately 750 feet upstream of Pinecraft Road.	None	•807	
South Buffalo Creek Tributary 2.	At the confluence with South Buffalo Creek	None	•792	City of Greensboro.
	Approximately 1,050 feet upstream of Bernav Avenue.	None	•855	
South Buffalo Creek Tributary 3.	At the confluence with South Buffalo Creek	None	•745	City of Greensboro.
	Approximately 1,500 feet upstream of Oak Street	None	•834	
South Buffalo Creek Tributary 4.	At the confluence with South Buffalo Creek	None	•713	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 1,250 feet upstream of South English Street.	None	•769	
South Buffalo Creek Tributary 5.	At the confluence with South Buffalo Creek	None	•719	City of Greensboro.
	Approximately 1,100 feet upstream of South English Street.	None	•772	
South Buffalo Creek Tributary 6.	At the confluence with South Buffalo Creek	None	•720	City of Greensboro, Unincorporated Areas of Guilford County.
	Approximately 350 feet upstream of Barksdale Drive.	None	•737	
South Buffalo Creek Tributary 7.	At the confluence with South Buffalo Creek	None	•726	City of Greensboro.
	Approximately 900 feet upstream of Tuscaloosa Street.	None	•757	
South Buffalo Creek Tributary 8.	At the confluence with South Buffalo Creek	None	•727	City of Greensboro.
	Approximately 800 feet upstream of South Benbow Road.	None	•739	
South Buffalo Creek Tributary B.	At the confluence with South Buffalo Creek Tributary A.	•811	•816	City of Greensboro.
	Approximately 550 feet upstream of Richland Street.	None	•886	
South Prong Stinking Quarter Creek.	At the confluence with Stinking Quarter Creek	None	•575	Unincorporated Areas of Guilford County.
	At the Guilford/Randolph County Boundary	None	•625	
South Prong Stinking Quarter Creek Tributary 1.	At the confluence with South Prong Stinking Quarter Creek.	None	•575	Unincorporated Areas of Guilford County.
	Approximately 1.1 miles upstream of Smithwood Road.	None	•676	
Stinking Quarter Creek	At the Alamance/Guilford County Boundary	None	•556	Unincorporated Areas of Guilford County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	At the confluence with South Prong Stinking Quarter Creek Tributary 1 and South Prong Stinking Quarter Creek.	None	•575	
Stinking Quarter Creek Tributary 2.	At the confluence with Stinking Quarter Creek	None	•559	Unincorporated Areas of Guilford County.
	Approximately 0.7 mile upstream of the confluence with Stinking Quarter Creek.	None	•577	
Stream No. 13	Approximately 800 feet upstream of East Hartley Drive.	None	•817	City of High Point.
	Approximately 0.6 mile upstream of SR 68	None	•881	
Stream No. 13 Tributary 1.	At the confluence with Stream No. 13	None	•807	City of High Point.
	Approximately 2,250 feet upstream of the confluence with Stream No. 13.	None	•854	
Stream No. 13 Tributary 2.	At the confluence with Stream No. 13	None	•807	City of High Point.
	Approximately 1,700 feet upstream of the confluence with Stream No. 13.	None	•825	
Stream No. 13 Tributary 3.	At the confluence with Stream No. 13	None	•813	City of High Point.
	Approximately 400 feet upstream of Pine Valley Road.	None	•856	
Stream No. 13 Tributary 4.	At the confluence with Stream No. 13	None	•818	City of High Point.
	Approximately 1,650 feet upstream of SR 68	None	•893	
Stream No. 13 Tributary 5.	At the confluence with Stream No. 13	None	•818	City of High Point.
	Approximately 1,150 feet upstream of SR 68	None	•866	
Stream No. 18	At the confluence with West Fork Deep River	•776	•775	City of High Point, Unincorporated Areas of Guilford County.
	Approximately 1,350 feet upstream of Hickswood Road.	•820	•819	
Stream No. 27	Approximately 50 feet upstream of Rosecrest Drive.	None	•812	City of High Point.
	Approximately 1,850 feet upstream of Enterprise Drive.	None	•852	
Stream No. 27 Tributary 2.	At the confluence with Stream No. 27	None	•787	City of High Point.
	Approximately 1,700 feet upstream of Alpine Drive.	None	•833	
Stream No. 31	Approximately 80 feet upstream of Vail Avenue ...	None	•854	City of High Point.
	Approximately 300 feet upstream of Taylor Avenue.	None	•869	
Stream No. 33	Approximately 150 feet upstream of Wise Avenue	None	•813	City of High Point.
	Approximately 500 feet upstream of West Russell Avenue.	None	•850	
Stream No. 33 Tributary 2.	At the confluence with Stream No. 33	None	•813	City of High Point.
	Approximately 400 feet upstream of East Green Drive.	None	•841	
Stream No. 34	Approximately 450 feet downstream of Habersham Road.	None	•819	City of High Point.
	Approximately 1,850 feet downstream of Pendleton Street.	None	•851	
Stream No. 34 Tributary	At the confluence with Stream No. 34	None	•752	City of High Point.
	Approximately 1,700 feet upstream of Triangle Lake Road.	None	•828	
Stream No. 34A	Approximately 50 feet downstream of Jackson Lake Road.	None	•742	City of High Point.
	Approximately 200 feet upstream of Baker Road	None	•827	
Stream No. 34A Tributary 1.	At the confluence with Stream No. 34A	None	•753	City of High Point.
	Approximately 1,650 feet upstream of the confluence with Stream No. 34A.	None	•781	
Stream No. 34A Tributary 2.	At the confluence with Stream No. 34A	None	•753	City of High Point.
	Approximately 1,650 feet upstream of the confluence with Stream No. 34A.	None	•792	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Stream No. 34A Tributary 3.	At the confluence with Stream No. 34A	None	•769	City of High Point.
	Approximately 0.5 mile upstream of the confluence with Stream No. 34A.	None	•820	
Stream No. 34A Tributary 4.	At the confluence with Stream No. 34A Tributary 3.	None	•775	City of High Point.
	Approximately 1,700 feet upstream of the confluence with Stream No. 34A Tributary 3.	None	•824	
Stream No. 34A Tributary 6.	At the confluence with Stream No. 34A	None	•795	City of High Point.
	Approximately 450 feet upstream of North Hall Street.	None	•818	
Stream No. 34A Tributary 7.	At the confluence with Stream No. 34A	None	•819	City of High Point.
	Approximately 1,350 feet upstream of Baker Road	None	•864	
Tickle Creek	At the Alamance/Guilford County Boundary	None	•647	Unincorporated Areas of Guilford County.
	Approximately 1 mile upstream of the Alamance/Guilford County Boundary.	None	•659	
Travis Creek	At the Alamance/Guilford County Boundary	None	•618	Unincorporated Areas of Guilford County.
	Approximately 950 feet upstream of SR 61/Frieden Church Road.	None	•670	
Tributary A to Travis Creek.	At the Alamance/Guilford County Boundary	None	•624	Unincorporated Areas of Guilford County.
	Approximately 600 feet upstream of Howerton Road.	None	•674	
Tributary to Travis Creek	At the Alamance/Guilford County Boundary	None	•632	Unincorporated Areas of Guilford County.
	Approximately 0.6 mile upstream from the Alamance/Guilford County Boundary.	None	•660	
Tributary to West Fork Deep River.	Approximately 1,550 feet upstream of the confluence with West Fork Deep River (#2).	None	•816	Unincorporated Areas of Guilford County, City of High Point.
	Approximately 0.6 mile upstream of the confluence with West Fork Deep River (#2).	None	•831	
Twin Lakes Tributary	At the confluence with South Buffalo Creek	•750	•753	City of Greensboro.
	Approximately 100 feet downstream of Merryweather Road.	None	•827	
Twin Lakes Tributary 1	At the confluence with Twin Lakes Tributary	None	•797	City of Greensboro.
	Approximately 100 feet downstream of Merritt Drive.	None	•828	
Unnamed Tributary to Deep River.	At the Guilford/Randolph County Boundary	None	•701	Unincorporated Areas of Guilford County.
	Approximately 0.8 mile upstream of the Guilford/Randolph County Boundary.	None	•722	
Unnamed Tributary to Polecat Creek.	At the Guilford/Randolph County Boundary	None	•695	Unincorporated Areas of Guilford County.
	Approximately 1,400 feet upstream of SR 62	None	•712	
Unnamed Tributary to West Fork Deep River.	At the confluence with West Fork Deep River Tributary 1.	None	•831	Unincorporated Areas of Guilford County.
	Approximately 200 feet upstream of Adkins Road	None	•855	
West Fork Deep River (#2).	At the confluence with West Fork Deep RiverTributary 1.	•833	•831	Unincorporated Areas of Guilford County.
	At the Guilford/Forsyth County Boundary	None	•862	

City of Greensboro

Maps are available for inspection at Greensboro Stormwater Management Division, 2602 South Elm Eugine Street, Greensboro, NC.

Send comments to The Honorable Keith Holliday, Mayor, City of Greensboro, P.O. Box 3136, Greensboro, NC 27402–3136.

City of High Point

Maps are available for inspection at High Point City Hall, 211 South Hamilton Street, High Point, NC.

Send comments to The Honorable Rebecca Smothers, Mayor, City of High Point, P.O. Box 230, High Point, NC 27261.

City of Summerfield

Maps are available for inspection at Summerfield Town Planning Office, 4117 Oak Ridge Road (Highway 150), Summerfield, NC.

Send comments to The Honorable Dena Barnes, Mayor, Town of Summerfield, P.O. Box 970, Summerfield, NC 27358.

Town of Jamestown

Maps are available for inspection at Jamestown Town Hall, 301 East Main Street, Jamestown, NC.

Send comments to The Honorable William G. Ragsdale, Mayor, Town of Jamestown, P.O. Box 848, Jamestown, NC 27282.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	

Town of Pleasant Garden

Maps are available for inspection at Pleasant Garden Municipal Building, 4920 Alliance Church Road, Pleasant Garden, NC.

Send comments to The Honorable Eddy Patterson, Mayor, Town of Pleasant Garden, P.O. Box 307, Pleasant Garden, NC 27313.

Town of Sedalia

Maps are available for inspection at the Sedalia Town Hall, 6121 Burlington Road, Sedalia, North Carolina.

Send comments to The Honorable Jeanne Rudd, Mayor, Town of Sedalia, P.O. Box C, Sedalia, North Carolina 27342

Unincorporated Areas of Guilford County

Maps are available for inspection at Guilford County Planning and Development Office, 201 South Eugene Street, Greensboro, NC.

Send comments to Mr. Willie Best, Guilford County Manager, P.O. Box 3427, Greensboro, NC 27402.

NORTH CAROLINA
Lee County

Beaver Creek	At the Lee/Moore County boundary	None	•307	Unincorporated Areas of Lee County.
	At the Lee/Harnett County boundary	None	•310	
Big Branch	At the Lee/Moore County boundary	None	•297	Unincorporated Areas of Lee County.
	Approximately 0.7 mile upstream of the Lee/Moore County boundary.	None	•304	
Big Buffalo Creek	At the confluence with Deep River	None	•228	Unincorporated Areas of Lee County, City of Sanford.
	Approximately 0.3 mile upstream of U.S. Route 1	•290	•289	
Big Buffalo Creek Tributary 1.	At the confluence with Big Buffalo Creek	None	•253	City of Sanford.
	Approximately 0.5 mile upstream of Valley Road	None	•297	
Big Governors Creek	At the confluence with Deep River	None	•258	Unincorporated Areas of Lee County.
	At the confluence of Little Governors Creek	None	•258	
Bush Creek	At the confluence with Cape Fear River	None	•169	Unincorporated Areas of Lee County.
	Approximately 3.7 miles upstream of the confluence with Cape Fear River.	None	•234	
Bush Creek Tributary	At the confluence with Bush Creek	None	•170	Unincorporated Areas of Lee County.
	Approximately 1,000 feet upstream of Poplar Springs Church Road.	None	•239	
Cape Fear River	At the Lee/Harnett County boundary	None	•152	Unincorporated Areas of Lee County.
	At the confluence of Deep River	None	•177	
Cape Fear River Tributary 1.	At the confluence with Cape Fear River	None	•172	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of Poplar Springs Church Road.	None	•256	
Carrs Creek	At the confluence with Upper Little River	None	•259	Unincorporated Areas of Lee County.
	Approximately 0.7 mile upstream of the confluence with Upper Little River.	None	•264	
Copper Mine Creek	At the confluence with Hughes Creek and Gum Fork Creek.	None	•199	Unincorporated Areas of Lee County.
	Approximately 0.6 mile upstream of Farrell Road	None	•230	
Deep River	At the confluence with Cape Fear River	None	•177	Unincorporated Areas of Lee County.
	At the confluence of Big Governors Creek	None	•257	
Deep River Tributary 1	At the confluence with Deep River	None	•227	Unincorporated Areas of Lee County.
	Approximately 1.4 miles upstream of the confluence with Deep River Tributary 3.	None	•237	
Deep River Tributary 10	At the confluence with Deep River	None	•255	Unincorporated Areas of Lee County.
	Approximately 1.3 miles upstream of the confluence with Deep River.	None	•261	
Deep River Tributary 11	At the confluence with Deep River	None	•256	Unincorporated Areas of Lee County.
	Approximately 1.0 mile upstream of the confluence of Tributary to Deep River Tributary 11.	None	•282	
Deep River Tributary 2	At the confluence with Deep River Tributary 1	None	•227	Unincorporated Areas of Lee County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 0.8 mile upstream of the confluence with Deep River Tributary 1.	None	•235	
Deep River Tributary 3 ...	At the confluence with Deep River Tributary 1	None	•227	Unincorporated Areas of Lee County.
	Approximately 1.0 mile upstream of the confluence with Deep River Tributary 1.	None	•247	
Deep River Tributary 9 ...	At the confluence with Deep River	None	•252	Unincorporated Areas of Lee County.
	Approximately 0.9 mile upstream of the confluence with Deep River.	None	•256	
Dry Fork	At the confluence with Pocket Creek	None	•299	Unincorporated Areas of Lee County.
	Approximately 2.4 miles upstream of Dycus Road	None	•476	
Fall Creek	At the confluence with Cape Fear River	None	•156	Unincorporated Areas of Lee County.
	Approximately 0.4 mile upstream of Copeland Road.	None	•329	
Gasters Creek West	At the confluence with Upper Little River	None	•312	Unincorporated Areas of Lee County.
	Approximately 0.4 mile upstream of Minter School Road.	None	•401	
Gasters Creek West Tributary 1.	At the confluence with Gasters Creek West	None	•337	Unincorporated Areas of Lee County.
	Approximately 520 feet upstream of Lemon Springs Road.	None	•372	
Gum Fork Creek	At the confluence with Copper Mine Creek and Hughes Creek.	None	•199	Unincorporated Areas of Lee County.
	Approximately 1.3 miles upstream of US–1	None	•269	
Hughes Creek	At the confluence with Lick Creek	None	•173	Unincorporated Areas of Lee County.
	At the confluence of Copper Mine Creek and Gum Fork Creek.	None	•199	
Hughes Creek Tributary 1.	At the confluence with Hughes Creek	None	•173	Unincorporated Areas of Lee County.
	Approximately 0.5 mile upstream of Cletus Hall Road.	None	•194	
Juniper Creek	At the confluence with Upper Little River	None	•266	Unincorporated Areas of Lee County.
	Approximately 1.0 mile upstream of Nicholson Road.	None	•363	
Kendale Creek	Approximately 1,400 feet upstream of Hiawatha Trail.	None	•352	City of Sanford.
	Approximately 2,000 feet upstream of Hiawatha Trail.	None	•353	
Lick Creek	At the confluence with Cape Fear River	None	•173	Unincorporated Areas of Lee County, City of Sanford.
	Approximately 1.0 mile upstream of Pumping Station Road.	None	•373	
Lick Creek Tributary 2	At the confluence with Lick Creek	None	•239	Unincorporated Areas of Lee County.
	Approximately 1.6 miles upstream of the confluence with Lick Creek.	None	•325	
Lick Creek Tributary 3	At the confluence with Lick Creek	None	•296	Unincorporated Areas of Lee County.
	Approximately 0.9 mile upstream of the confluence with Lick Creek.	None	•338	
Little Buffalo Creek	At the confluence with Deep River	None	•222	Unincorporated Areas of Lee County, City of Sanford.
	Approximately 1,000 feet upstream of Highway 421/Highway 87.	None	•406	
Little Crane Creek Tributary 2.	Approximately 1,300 feet upstream of the confluence with Little Crane Creek.	None	•332	Unincorporated Areas of Lee County.
	Approximately 1.3 miles upstream of the confluence with Little Crane Creek.	None	•384	
Little Crane Creek Tributary 3.	Approximately 700 feet upstream of the confluence with Little Crane Creek.	None	•347	Unincorporated Areas of Lee County.
	Approximately 0.4 mile upstream of the confluence with Little Crane Creek.	None	•370	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Little Crane Creek Tributary 4A.	At the confluence with Little Crane Creek Tributary 4.	None	•363	Unincorporated Areas of Lee County.
	Approximately 1,500 feet upstream of Eakes Road.	None	•425	
Little Crane Creek Tributary 4B.	At the confluence with Little Crane Creek Tributary 4.	None	•370	Unincorporated Areas of Lee County.
	Approximately 750 feet upstream of White Meadows Drive.	None	•411	
Little Crane Tributary 4 ..	Approximately 600 feet upstream of the confluence with Little Crane Creek.	None	•349	Unincorporated Areas of Lee County.
	Approximately 1.4 miles upstream of the confluence with Little Crane Creek Tributary 4B.	None	•428	
Little Governors Creek ...	At the confluence with Big Governors Creek	None	•257	Unincorporated Areas of Lee County.
	Approximately 8.3 miles upstream of the confluence with Big Governors Creek.	None	•360	
Little Juniper Creek	At the confluence with Upper Little River and Mulatto Branch.	None	•332	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of Rocky Fork Church Road.	None	•403	
Little Juniper Creek Tributary 1.	At the confluence with Little Juniper Creek	None	•347	Unincorporated Areas of Lee County.
	Approximately 0.6 mile upstream of the confluence with Little Juniper Creek.	None	•369	
Little Juniper Creek Tributary 2.	At the confluence with Little Juniper Creek	None	•357	Unincorporated Areas of Lee County.
	Approximately 600 feet upstream of Lemon Springs Road.	None	•408	
Little Juniper Creek Tributary 3.	At the confluence with Little Juniper Creek	None	•360	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of Willett Road	None	•457	
Little Juniper Creek Tributary 4.	At the confluence with Little Juniper Creek	None	•366	Unincorporated Areas of Lee County.
	Approximately 0.3 mile upstream of the confluence with Little Juniper Creek.	None	•376	
Little Lick Creek	At the confluence with Lick Creek	None	•193	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of Kids Lane ...	None	•365	
Little Lick Creek Tributary 1.	At the confluence with Little Lick Creek	None	•206	Unincorporated Areas of Lee County.
	Just downstream of Womack Lake Circle	None	•351	
Little Lick Creek Tributary 1A.	At the confluence with Little Lick Creek Tributary 1.	None	•226	Unincorporated Areas of Lee County.
	Approximately 1.7 miles upstream of the confluence with Little Lick Creek Tributary 1.	None	•365	
Little Lick Creek Tributary 1B.	At the confluence with Little Lick Creek Tributary 1.	None	•247	Unincorporated Areas of Lee County.
	Approximately 1,000 feet upstream of NC 42 (Avents Ferry Road).	None	•390	
Little Pocket Creek	At the confluence with Pocket Creek	None	•238	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of McPherson Road.	None	•383	
Little Shaddox Creek	At the confluence with Cape Fear River	None	•175	Unincorporated Areas of Lee County.
	Approximately 450 feet upstream of Lower Moncure Road.	None	•196	
Long Branch	At the confluence with Juniper Creek	None	•311	Unincorporated Areas of Lee County.
	Approximately 0.9 mile upstream of John Godfrey Road.	None	•341	
Lonnie Wombles Creek ..	At the confluence with Cape Fear River	None	•175	Unincorporated Areas of Lee County.
	Approximately 0.6 mile upstream of US-1	None	•329	
Lonnie Wombles Creek Tributary 1.	At the confluence with Lonnie Wombles Creek	None	•182	Unincorporated Areas of Lee County.
	Approximately 0.9 mile upstream of US-1	None	•324	
Lonnie Wombles Creek Tributary 2.	At the confluence with Lonnie Wombles Creek Tributary 1.	None	•206	Unincorporated Areas of Lee County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 770 feet upstream of US-1	None	•266	
Mare Branch	At the confluence with Juniper Creek	None	•306	Unincorporated Areas of Lee County.
	Approximately 0.6 mile upstream of Landfill Road	None	•380	
Mulatto Branch	At the confluence with Upper Little River and Little Juniper Creek.	None	•332	Unincorporated Areas of Lee County.
	Approximately 830 feet upstream of Minter School Road.	None	•368	
Patchet Creek	At the confluence with Upper Little River	None	•245	Unincorporated Areas of Lee County.
	Approximately 630 feet upstream of John Rosser Road.	None	•325	
Patterson Creek	At the confluence with Deep River	None	•236	Unincorporated Areas of Lee County.
	Approximately 1,600 feet upstream of Wicker Street.	None	•391	
Persimmon Creek	At the confluence with Big Buffalo Creek	•290	•289	Unincorporated Areas of Lee County, City of Sanford.
	Approximately 1.2 miles upstream of Carthage Street.	None	•411	
Pocket Creek	At the confluence with Deep River	None	•238	Unincorporated Areas of Lee County.
	Approximately 250 feet upstream of Chris Cole Road.	None	•342	
Purgatory Branch	At the confluence with Big Buffalo Creek	None	•235	Unincorporated Areas of Lee County.
	Approximately 1.6 miles upstream of Forestwood Park Road.	None	•305	
Racoon Creek	At the confluence with Pocket Creek	None	•271	Unincorporated Areas of Lee County, City of Sanford.
	Approximately 1.7 miles upstream of South Franklin Drive.	None	•476	
Racoon Creek Tributary 1.	At the confluence with Racoon Creek	None	•295	Unincorporated Areas of Lee County.
	Approximately 0.9 mile upstream of the confluence with Racoon Creek.	None	•361	
Racoon Creek Tributary 2.	At the confluence with Racoon Creek	None	•317	Unincorporated Areas of Lee County.
	Approximately 1,700 feet upstream of the confluence with Racoon Creek.	None	•338	
Reedy Branch	At the confluence with Juniper Creek	None	•321	Unincorporated Areas of Lee County.
	Approximately 1,700 feet upstream of Blacks Chapel Road.	None	•378	
Roberts Creek	At the confluence with Hughes Creek	None	•175	Unincorporated Areas of Lee County.
	Approximately 0.4 miles upstream of Railroad	None	•271	
Run Branch	At the confluence with Reedy Branch	None	•324	Unincorporated Areas of Lee County.
	Approximately 1.4 miles upstream of the confluence with Reedy Branch.	None	•400	
Skunk Creek	Approximately 10 feet upstream of West Garden Street.	None	•320	City of Sanford.
	Approximately 0.5 mile upstream of West Garden Street.	None	•343	
Smith Creek	At the confluence with Deep River	None	•244	Unincorporated Areas of Lee County.
	Approximately 1.1 miles upstream of Carbonton Road.	None	•269	
Stony Creek	At the confluence with Lick Creek	None	•191	Unincorporated Areas of Lee County.
	Approximately 2.1 miles upstream of Poplar Springs Church Road.	None	•358	
Sugar Creek	At the confluence with Pocket Creek	None	•308	Unincorporated Areas of Lee County.
	Approximately 1.2 miles upstream of the confluence with Pocket Creek.	None	•337	
Tributary to Deep River Tributary 11.	At the confluence with Deep River Tributary 11	None	•256	Unincorporated Areas of Lee County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 2.1 miles upstream of the confluence with Deep River Tributary 11.	None	•275	
Upper Little River	At the Lee/Harnett County boundary	None	•240	Unincorporated Areas of Lee County.
	At the confluence of Mulatto Branch and Little Juniper Creek.	None	•332	
Upper Little River Tributary 1.	At the confluence with Upper Little River	None	•290	Unincorporated Areas of Lee County.
	Approximately 0.3 mile upstream of Holder Road	None	•355	
Upper Little River Tributary 1.	At the confluence with Upper Little River	None	•290	Unincorporated Areas of Lee County.
	Approximately 0.3 mile upstream of Holder Road	None	•355	
Wallace Branch	At the confluence with Lick Creek	None	•217	Unincorporated Areas of Lee County.
	Approximately 1.3 miles upstream of F.L. Dowdy Lane.	None	•268	
Wallace Branch Tributary 1.	At the confluence with Wallace Branch	None	•218	Unincorporated Areas of Lee County.
	Approximately 0.8 mile upstream of Riddle Road	None	•279	
Wallace Branch Tributary 2.	At the confluence with Wallace Branch	None	•220	Unincorporated Areas of Lee County.
	Approximately 0.6 mile upstream of Riddle Road	None	•246	
Wallace Branch Tributary 3.	At the confluence with Wallace Branch	None	•222	Unincorporated Areas of Lee County.
	Approximately 1.6 miles upstream of Riddle Road	None	•317	
Whitehorse Branch	At the confluence with Mulatto Branch	None	•358	Unincorporated Areas of Lee County.
	Approximately 0.2 mile upstream of Hickory House Road.	None	•382	

City of Sanford

Maps are available for inspection at the City of Sanford Planning Department, 900 Woodland Avenue, Sanford, North Carolina.

Send comments to The Honorable Winston Hester, Mayor of the City of Sanford, P.O. Box 3729, Sanford, North Carolina 27331–3729.

Unincorporated Areas of Lee County

Maps are available for inspection at the Lee County Planning Department, 900 Woodland Avenue, Sanford, North Carolina.

Send comments to Mr. David Smitherman, Lee County Manager, P.O. Box 1968, Sanford, North Carolina 27331.

NORTH CAROLINA
Sampson County

Bearskin Swamp	At the confluence with Little Coharie Creek	None	•87	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of Bearskin Road.	None	•153	
Beaverdam Creek	At the confluence with Clear Run	None	•57	Unincorporated Areas of Sampson County.
	Approximately 2.4 miles upstream of the confluence with Clear Run.	None	•97	
Beaverdam Run	At the confluence with Great Coharie Creek	None	•99	Unincorporated Areas of Sampson County.
	Approximately 0.6 mile upstream of High House Road.	None	•168	
Beaverdam Swamp	At the confluence with Mongo Swamp	None	•127	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of U.S. Highway 421.	None	•191	
Beaverdam Swamp 1	At the confluence with Six Runs Creek	None	•93	Unincorporated Areas of Sampson County.
	Approximately 350 feet upstream of Isaac Weeks Road.	None	•137	
Beaverdam Swamp 2	At the confluence with Great Coharie Creek	None	•106	Unincorporated Areas of Sampson County.
	Approximately 260 feet downstream of Keener Road.	None	•133	
Beaverdam Swamp 2 Tributary 1.	At the confluence with Beaverdam Swamp 2	None	•119	Unincorporated Areas of Sampson County.
	Approximately 0.4 mile upstream of Wigigns Road	None	•139	
Beaverdam Swamp 3	At the confluence with Great Coharie Creek	None	•134	Unincorporated Areas of Sampson County, Town of Newton Grove.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 1,000 feet upstream of the confluence of Beaverdam Swamp 3 Tributary 2.	None	•155	
Beaverdam Swamp 3 Tributary 2.	At the confluence with Beaverdam Swamp 3	None	•154	Town of Newton Grove.
	Approximately 800 feet upstream of Old Goldsboro Road.	None	•162	
Beaverdam Swamp Tributary 1.	At the confluence with Beaverdam Swamp	None	•121	Unincorporated Areas of Sampson County.
	Approximately 160 feet downstream of High House Road.	None	•135	
Big Branch	At the confluence with Black River	None	•42	Unincorporated Areas of Sampson County.
	Approximately 0.7 mile upstream of Harrells Highway (NC Highway 411).	None	•84	
Big Juniper Run	At the confluence with Mingo Swamp	None	•151	Unincorporated Areas of Sampson County.
	Approximately 1,200 feet upstream of Lee's Chapel Church Road.	None	•192	
Big Swamp	At the confluence with South River	None	•77	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of Minnie-Hall Road.	None	•128	
Bills Swamp	At the confluence with Great Coharie Creek	None	•56	Unincorporated Areas of Sampson County.
	Approximately 1.4 miles upstream of Norris Road	None	•89	
Black River	At the Bladen/Pender/Sampson County boundary	None	•23	Unincorporated Areas of Sampson County.
	Approximately 3.6 miles upstream of the confluence of Big Branch.	None	•45	
Black River Tributary 1 ..	At the confluence with Black River	None	•33	Unincorporated Areas of Sampson County.
	Approximately 1,300 feet upstream of G. Shaw Road.	None	•68	
Buckhorn Creek	At the confluence with Crane Creek	None	•69	Unincorporated Areas of Sampson County.
	Approximately 1.9 miles upstream of Boney Mill Road.	None	•103	
Bulltail Creek	At the Sampson/Duplin County boundary	None	•58	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of Bull Tail Road	None	•63	
Caesar Swamp	At the confluence with Little Coharie Creek	None	•132	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of Straw Pond School Road.	None	•180	
Canty Mill Branch	At the confluence with Black River	None	•38	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of Melvin Road	None	•57	
Cat Creek	At the confluence with Black River	None	•35	Unincorporated Areas of Sampson County.
	Approximately 1,750 feet upstream of Private Road.	None	•79	
Cat Tail Branch	At the confluence with Williams Old Mill Branch ...	None	•122	City of Clinton.
	Approximately 1,380 feet upstream of East Johnson Street.	None	•138	
Clear Run	At the confluence with Black River	None	•46	Unincorporated Areas of Sampson County.
	Approximately 1.5 miles upstream of the confluence of Beaverdam Creek.	None	•70	
Cobb Branch	At the confluence with Canty Mill Branch	None	•40	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of confluence with Canty Mill Branch.	None	•48	
Craddock Swamp	At the confluence with Ward Swamp	None	•141	Unincorporated Areas of Sampson County.
	Approximately 275 feet downstream of William R. King Road.	None	•167	
Crane Creek	At the confluence with Six Runs Creek	None	•57	Unincorporated Areas of Sampson County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 1.9 miles upstream of West Mount Gilead Church Road.	None	•106	
Cypress Lake	At the confluence with Black River	None	•27	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of Ivanhoe Road.	None	•65	
Devane Branch	At the confluence with Black River	None	•38	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of Tomahawk Highway (NC Highway 41).	None	•80	
Doctors Creek	At the Sampson/Duplin County boundary	None	•87	Unincorporated Areas of Sampson County.
	Approximately 250 feet upstream of the Sampson/Duplin County boundary.	None	•88	
Dollar Branch	Approximately 800 feet upstream of the confluence with Williams Old Mill Branch.	None	•105	Unincorporated Areas of Sampson County, City of Clinton.
	Approximately 1,060 feet upstream of W. Morisey Boulevard.	None	•140	
Encon Mill Creek	At the confluence with South River	None	•31	Unincorporated Areas of Sampson County.
	Approximately 1.4 miles upstream of Dam	None	•67	
Gilmore Swamp	At the confluence with Six Runs Creek	None	•100	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of King Road	None	•142	
Gilmore Swamp Tributary	At the confluence with Gilmore Swamp	None	•116	Unincorporated Areas of Sampson County.
	Approximately 1.6 miles upstream of King Road	None	•136	
Goshen Swamp	At the Sampson/Duplin County boundary	None	•117	Unincorporated Areas of Sampson County.
	Approximately 228 feet upstream of Preacher Henrys Road.	None	•167	
Great Coharie Creek	Approximately 0.8 mile upstream of the confluence with Black River and Six Runs Creek.	None	•52	Unincorporated Areas of Sampson County.
	Approximately 1 mile upstream of Oak Grove Church Road.	None	•182	
Great Coharie Creek Tributary 1.	At the confluence with Great Coharie Creek	None	•67	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of the confluence with Great Coharie Creek.	None	•103	
Great Coharie Creek Tributary 2.	At the confluence with Great Coharie Creek	None	•67	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of the confluence with Great Coharie Creek.	None	•101	
Great Coharie Creek Tributary 3.	At the confluence with Great Coharie Creek	None	•113	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of Keener Road.	None	•148	
Hornet Swamp	At the confluence with Little Cohane Creek	None	•133	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of North Salemburg Highway.	None	•170	
Johnson Mill Branch	At the confluence with Little Coharie Creek	None	•68	Unincorporated Areas of Sampson County.
	Approximately 1,240 feet upstream of Greens Bridge Road.	None	•109	
Jones Swamp	At the confluence with South River	None	•110	Unincorporated Areas of Sampson County.
	Approximately 810 feet upstream of Welcome School Road.	None	•138	
Keith Branch	At the confluence with Black River	None	•34	Unincorporated Areas of Sampson County.
	Approximately 1,430 feet upstream of Firetower Road.	None	•48	
Kill Swamp Tributary 1	At the confluence with Kill Swamp	None	•165	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of the confluence with Kill Swamp.	None	•169	
Kings Branch	At the confluence with Six Runs Creek	None	•121	Unincorporated Areas of Sampson County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 2.1 miles upstream of the confluence with Six Runs Creek.	None	•137	
Little Beaverdam Swamp	At the confluence with South River	None	•120	Unincorporated Areas Sampson County.
	Approximately 1 mile upstream of Phillips Road	None	•155	
Little Beaverdam Swamp Tributary 1.	At the confluence with Little Beaverdam Swamp	None	•123	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of the confluence with Little Beaverdam Swamp Tributary 2.	None	•138	
Little Beaverdam Swamp Tributary 2.	At the confluence with Little Beaverdam Swamp Tributary 1.	None	•123	Unincorporated Areas of Sampson County.
	Approximately 0.7 mile upstream of Charles Newland Road.	None	•145	
Little Coharie Creek	At the confluence with Great Coharie Creek	None	•58	Unincorporated Areas of Sampson County.
	Approximately 1.1 miles upstream of Newton Grove Highway (U.S. Highway 13).	None	•192	
Little Coharie Creek Tributary.	At the confluence with Little Coharie Creek	None	•87	Unincorporated Areas of Sampson County.
	Approximately 0.3 mile upstream of Andrews Chapel Road.	None	•117	
Little Juniper Run	At the confluence with Big Juniper Run	None	•172	Unincorporated Areas of Sampson County.
	Approximately 0.6 mile upstream of Draughon Road.	None	•214	
Lockamy Mill	At the confluence with Little Coharie Creek	None	•73	Unincorporated Areas of Sampson County.
	Approximately 0.9 mile upstream of Highway 411	None	•103	
Marsh Swamp	At the confluence with Great Coharie Creek	None	•112	Unincorporated Areas of Sampson County.
	Approximately 1,020 feet upstream of Odom Road.	None	•143	
McPhail Branch	At the confluence with Merkle Swamp	None	•131	Unincorporated Areas of Sampson County.
	Approximately 1.1 miles upstream of the confluence with Merkle Swamp.	None	•160	
Meetinghouse Branch	At the confluence with Great Coharie Creek	None	•103	Unincorporated Areas of Sampson County.
	Approximately 0.6 mile upstream of Basstown Road.	None	•128	
Merkle Swamp	At the confluence with Great Coharie Creek	None	•116	Unincorporated Areas of Sampson County.
	Approximately 0.7 mile upstream of Joel Jones Lane.	None	•155	
Mill Creek	At the Pender/Duplin County boundary	None	•51	Unincorporated Areas of Sampson County.
	Approximately 800 feet upstream of Matthews Road.	None	•66	
Mill Creek 2	At the confluence with Great Coharie Creek	None	•63	Unincorporated Areas of Sampson County.
	Approximately 1.4 miles upstream of Garland Highway (Highway 701).	None	•110	
Mill Creek Tributary	At the confluence with Mill Creek	None	•61	Unincorporated Areas of Sampson County.
	At the Sampson/Pender County boundary	None	•75	
Mill Run	At the confluence with Six Runs Creek	None	•86	Unincorporated Areas of Sampson County.
	Approximately 1.9 miles upstream of Rowan Road	None	•111	
Mill Swamp	At the confluence with Six Runs Creek	None	•102	Unincorporated Areas of Sampson County.
	Approximately 2.5 miles upstream of Lake Artesia Road.	None	•123	
Mill Swamp Tributary	At the confluence with Mill Swamp	None	•122	Unincorporated Areas of Sampson County.
	Approximately 0.4 mile upstream of the confluence with Mill Swamp.	None	•125	
Mingo Swamp	At the confluence with South River	None	•127	Unincorporated Areas of Sampson County.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	At the Sampson/Harnett/Johnston County boundary.	None	•173	
Old Mill Swamp	At the confluence with Great Coharie Creek	None	•113	Unincorporated Areas of Sampson County.
	Approximately 1 mile upstream of Church Road	None	•152	
Peters Creek	At the confluence with Buckhorn Branch	None	•69	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of the confluence with Buckhorn Branch.	None	•100	
Pharisee Creek	At the Sampson/Duplin County boundary	None	•58	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of Wilmington Highway (U.S. Highway 421).	None	•67	
Quewiffle Swamp	At the confluence with Six Runs Creek	None	•62	Unincorporated Areas of Sampson County.
	Approximately 2.2 miles upstream of Trinity Church Road.	None	•84	
Railer Branch	At the confluence of Goshen Swamp	None	•135	Unincorporated Areas of Sampson County.
	Approximately 0.5 mile upstream of Hollingsworth Road.	None	•166	
Rice Swamp	At the confluence with Little Coharie Creek	None	•99	Unincorporated Areas of Sampson County, Town of Salemburg.
	Approximately 0.4 mile upstream of Zoar Church Road.	None	•156	
Robinson Mill Branch	At the confluence with Six Runs Creek	None	•56	Unincorporated Areas of Sampson County.
	Approximately 1,100 feet upstream of Private Road.	None	•114	
Rocky Marsh Creek	At the confluece with Great Coharie Creek	None	•67	Unincorporated Areas of Sampson County.
	Approximately 0.6 mile upstream of Peterson Road.	None	•91	
Rocky Marsh Creek Tributary.	At the confluence with Rocky Marsh Creek	None	•78	Unincorporated Areas of Sampson County.
	Approximately 1.2 miles upstream of the confluence with Rocky Marsh Creek.	None	•138	
Rowan Branch	At the confluence with Six Runs Creek	None	•82	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of Rowan Road	None	•140	
Sevenmile Swamp	At the confluence with Great Coharie Creek	None	•129	Unincorporated Areas of Sampson County.
	Approximately 0.9 mile upstream of Easy Street	None	•193	
Shade Branch	At the confluence with Quewiffle Swamp	None	•80	Unincorporated Areas of Sampson County.
	Approximately 1,900 feet upstream of Rogers Mill Road.	None	•95	
Six Runs Creek	At the confluece with Black River	None	•52	Unincorporated Areas of Sampson County.
	Approximately 0.9 mile upstream of N. McCullen Road.	None	•137	
South River	At the confluence with Black River	None	•26	Unincorporated Areas of Sampson County, Town of Autryville.
	At the confluence with Mingo Swamp	None	•127	
South River Tributary 4	At the confluence with South River	None	•127	Unincorporated Areas of Sampson County.
	Approximately 650 feet upstream of the confluence with South River.	None	•127	
Spearmans Mill Creek	At the confluence with Six Runs Creek	None	•53	Unincorporated Areas of Sampson County.
	Approximately 0.6 mile upstream of Hayes Chapel Road.	None	•88	
Starlins Swamp	At the confluence with Beaverdam Swamp	None	•138	Unincorporated Areas of Sampson County.
	Approximately 0.4 mile upstream of Staley Hall Road.	None	•177	
Stewarts Creek (near Carroll).	At the confluence with Six Runs Creek	None	•67	Unincorporated Areas of Sampson County.
	At the Sampson/Duplin County boundary	None	•83	

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Stony Run	At the confluence with Mingo Swamp	None	•158	Unincorporated Areas of Sampson County.
	Approximately 600 feet upstream of the confluence with Mingo Swamp.	None	•160	
Tarkill Branch	At the confluence with Six Runs Creek	None	•52	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of Edmond Matthis Road.	None	•97	
Tenmile Swamp	At the confluence with Six Runs Creek	None	•97	Unincorporated Areas of Sampson County.
	Approximately 1 mile upstream of McGowan Road.	None	•135	
Tenmile Swamp Tributary.	At the confluence with Tenmile Swamp	None	•107	Unincorporated Areas of Sampson County.
	Approximately 320 feet upstream of Thompson Avenue.	None	•127	
Turkey Creek	At the confluence with Six Runs Creek	None	•90	Unincorporated Areas of Sampson County, Town of Turkey.
	At the Sampson/Duplin County boundary	None	•117	
Twomile Swamp	At the confluence with Caesar Swamp	None	•147	Unincorporated Areas of Sampson County.
	Approximately 1 mile upstream of Bynum Road	None	•162	
Ward Swamp	At the confluence with Great Coharie Creek	None	•124	Unincorporated Areas of Sampson County.
	Approximately 1.3 miles upstream of the confluence with Craddock Creek.	None	•159	
Ward Swamp Tributary 1	At the confluence with Ward Swamp	None	•129	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of Hobbton Highway (U.S. Highway 701).	None	•156	
Ward Swamp Tributary 2	At the confluence with Ward Swamp Tributary 1	None	•133	Unincorporated Areas of Sampson County.
	Approximately 1 mile upstream of Share Cake Road.	None	•158	
Ward Swamp Tributary 3	At the confluence with Ward Swamp	None	•133	Unincorporated Areas of Sampson County.
	Approximately 2.1 miles upstream of Hobbton Highway (U.S. Highway 701).	None	•159	
Ward Swamp Tributary 4	At the confluence with Ward Swamp Tributary 3	None	•138	Unincorporated Areas of Sampson County.
	Approximately 0.8 mile upstream of the confluence with Ward Swamp Tributary 3.	None	•152	
Williams Old Mill Branch Tributary.	At the confluence with Williams Old Mill Branch	None	•121	Unincorporated Areas of Sampson County, City of Clinton.
	Approximately 0.5 mile upstream of North Boulevard.	None	•149	
Williamson Swamp	At the confluence with Little Beaverdam Swamp	None	•129	Unincorporated Areas of Sampson County.
	Approximately 340 feet upstream of Stanley Hall Road.	None	•179	
Wolf Pit Branch	At the confluence with Buckhorn Creek	None	•85	Unincorporated Areas of Sampson County.
	Approximately 1,640 feet upstream of Ozzie Road	None	•120	
Youngs Swamp	At the Sampson/Duplin County boundary	None	•117	Unincorporated Areas of Sampson County.
	Approximately 1.9 miles upstream of Suttontown Road.	None	•137	

City of Clinton

Maps are available for inspection at Clinton City Hall, 227 Lisbon Street, Clinton, NC.
Send comments to The Honorable Lew Starling, Mayor of the City of Clinton, P.O. Box 199, Clinton, NC 28329–0199.

Town of Autryville

Maps are available for inspection at Autryville Town Hall, 215 South Gray Street, Autryville, NC.
Send comments to The Honorable Patricia Williams, Mayor of the Town of Autryville, P.O. Drawer 10, Autryville, NC 28318.

Town of Newton Grove

Maps are available for inspection at Newton Grove Town Hall, 304 West Weeksdale Street, Newton Grove, NC.
Send comments to The Honorable Gerald Darden, Mayor of the Town of Newton Grove, P.O. Box 4, Newton Grove, NC 28366.

Town of Salemburg

Maps are available for inspection at Salemburg Town Hall, 100 Methodist Drive, Salemburg, NC.

Source of flooding	Location	#Depth in feet above ground *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	

Send comments to The Honorable Bobby Strickland, Mayor of the Town of Salemburg, P.O. Box 190, Salemburg, NC 28385.

Town of Turkey

Maps are available for inspection at Turkey Town Hall, 51 Market Street, Turkey, NC.

Send comments to The Honorable Michael Cottle, Mayor of the Town of Turkey, P.O. Box 55, Turkey, NC 28393.

Unincorporated Areas of Sampson County

Maps are available for inspection at Sampson County Inspections Department, 335 County Complex Road, Clinton, NC.

Send comments to Mr. Scott Sauer, Sampson County Manager, 435 Rowan Road, Clinton, NC 28328.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: September 14, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–18727 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–P

Notices

Federal Register

Vol. 70, No. 181

Tuesday, September 20, 2005

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 14, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Select Agent Registration.

OMB Control Number: 0579–0213.

Summary of Collection: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 were signed into law June 12, 2002. This law is designed to prevent, prepare for and respond to bioterrorism and other public health emergencies. The law requires individuals possessing agents or toxins deemed a severe threat to animal or plant health, or to animal or plant products, to be registered with the Secretary of Agriculture unless they have been specifically exempted. The registration process entail the use of a number of separate forms designed to obtain critical information concerning individuals or facilities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins—including name, strain, and genetic information.

Need and Use of the Information: The Animal and Plant Health Inspection Service (APHIS) will collect information to determine the biosafety level of an entity as well as the entity's biosecurity situation. The collected information will also be used to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. If the information were not collected, APHIS efforts to more aggressively prevent a bioterrorism event in the United States would be compromised.

Description of Respondents: Business or other for profit; State, local and tribal government; Not-for-profit institutions

Number of Respondents: 545.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 938.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–18629 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 14, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: 7 CFR Part 3565, ''Guaranteed Rural Rental Housing Program'' and its Supporting Handbook.

OMB Control Number: 0575–0174.

Summary of Collection: On March 26, 1996, the Housing Opportunity Program

Extension Act of 1996 was signed. One of the provisions of the Act was the authorization of the section 538 Guaranteed Rural Rental Housing Program (GRRHP), adding the program to the Housing Act of 1949. The purpose of the GRRHP is to increase the supply of affordable rural rental housing through the use of loan guarantees that encourage partnerships between the Rural Housing Service (RHS), private lenders and public agencies. RUS will approve qualified lenders to participate and monitor lender performance to ensure program requirements are met. RHS will collect information from lenders on the eligibility cost, benefits, feasibility, and financial performance of the proposed project.

Need and Use of the Information: RHS will collect information from lenders to manage, plan, evaluate, and account for Government resources. The GRRHP regulation and handbook will provide lenders and agency staff with guidance on the origination and servicing of GRRHP loans and the approval of qualified lenders. RHS will use the information to evaluate a lender's request and make determination that the interests of the government are protected. Failure to collect information could have an adverse impact on the agency ability to monitor lenders and assess program effectiveness and effectively guarantee loans.

Description of Respondents: Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 150.

Frequency of Responses: Reporting: Quarterly; Monthly; Annually.

Total Burden Hours: 1,393.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–18630 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–XT–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 05–069–1]

Public Meeting; National Animal Identification System

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The Animal and Plant Health Inspection Service will hold a public meeting concerning the animal movement tracking database component for the National Animal Identification System. The purpose of the meeting is to initiate dialogue about this initiative with industry stakeholders, including representatives of national organizations that represent livestock and poultry production sectors, livestock producers, and other interested individuals. This notice provides information on the discussion topics as well as the date, time, and place of the meeting.

DATES: The meeting will be held on Wednesday, October 12, 2005, from 8:30 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Radisson Hotel & Suites Kansas City—City Center, 1301 Wyandotte Street, Kansas City, MO.

FOR FURTHER INFORMATION CONTACT: Mr. Neil Hammerschmidt, Coordinator, National Animal Identification System, VS, APHIS, 4700 River Road Unit 200, Riverdale, MD 20737; phone (301) 734–0739, fax (301) 734–7963, or e-mail: *Neil.E.Hammerschmidt @aphis.usda.gov*.

SUPPLEMENTARY INFORMATION: The National Animal Identification System (NAIS) has made steady progress in 2005. Over 109,000 premises have been registered in the NAIS, setting the foundation for the animal identification components. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) has reviewed over 600 comments on the draft strategic plan and draft program standards. There is significant support from the industry to move forward as proposed in the draft strategic plan, in particular, to implement a phased-in program in the proposed time frame. There was also support, especially from cattle producers, for having the animal tracking database maintained outside the Federal Government.

After considerable discussion regarding the design and administration of the animal tracking database, we have concluded that having multiple industry program databases ''feed'' a centralized, privately held repository with all animal movement data can be achieved and can meet the needs of our animal health programs.

To initiate the necessary dialogue with the industry, we will hold a public meeting on October 12, 2005. At the meeting, we will discuss the relationship between the industry and USDA that would have to be in place for such a system to function effectively. Among the options to be discussed is the formation of a new entity representing all sectors of the production industry to lead the effort to develop, and provide ongoing oversight of, a private animal tracking data repository. USDA and State representatives will define the system specifications and user requirements that the animal tracking database must meet to support ongoing animal health surveillance programs and traceback investigations.

Done in Washington, DC, this 15th day of September 2005.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–18760 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

National Urban & Community Forestry Advisory Council Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Urban and Community Forestry Advisory Council will meet in Sacramento, California, October 18–20, 2005. The purpose of the meeting is to discuss emerging issues in urban and community forestry.

DATES: The meeting will be held October 18–20, 2005.

ADDRESSES: The meeting will be held at the Holiday Inn Sacramento Northeast, 5321 Date Avenue, Sacramento, CA 95841. Individuals who wish to speak at the meeting or to propose agenda items must send their names and proposals to Suzanne M. del Villar, Executive Assistant, National Urban and Community Forestry Advisory Council, P.O. Box 1003, Sugarloaf, CA 92386–1003. Individuals may fax their names and proposed agenda items to (909) 585–9527.

FOR FURTHER INFORMATION CONTACT: Suzanne M. del Villar, Urban and Community Forestry Staff, (909) 585–9268, or via e-mail at *sdelvillar@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Council discussion is limited to Forest Service staff and Council members; however, persons who wish to bring urban and community forestry matters to the attention of the Council may file written statements with the Council staff before or after the meeting. Public input sessions will be provided.

Dated: September 13, 2005.

Robin L. Thompson,

Associate Deputy Chief, State and Private Forestry.

[FR Doc. 05–18658 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Glenn/Colusa County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn/Colusa County Resource Advisory Committee (RAC) will meet in Willows, California. Agenda items to be covered include: (1) Introductions, (2) Approval of Minutes, (3) Public Comment, (4) Project Proposal/Possible Action, (5) Web site Update, (6) Update on Colusa Title III Money, (7) General Discussion, (8) Next Agenda.

DATES: The meeting will be held on September 26, 2005, from 1:30 p.m. and end at approximately 4:30 p.m.

ADDRESSES: The meeting will be held at the Mendocino National Forest Supervisor's Office, 825 N. Humboldt Ave., Willows, CA 95988. Individuals wishing to speak or propose agenda items must send their names and proposals to Jim Giachino, DFO, 825 N. Humboldt Ave., Willows, CA 95988.

FOR FURTHER INFORMATION CONTACT: Bobbin Gaddini, Committee coordinator, USDA, Mendocino National Forest, Grindstone Ranger District, P.O. Box 164, Elk Creek, CA 95939. (530) 968–1815; e-mail *ggaddini@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service staff and Committee members. However, persons who wish to bring matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by September 23, 2005 will have the opportunity to address the committee at those sessions.

Dated: September 13, 2005.

James F. Giachino,

Designated Federal Official.

[FR Doc. 05–18648 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

RIN 0596–AC12

Rangeland Management Direction Regarding Grazing Permit Administration

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: On July 19, 2005, the Forest Service published a notice in the **Federal Register** with request for comment on the issuance of two (2) interim directives (IDs) to Forest Service Handbook (FSH) 2209.13, chapter 10—Term Grazing Permits and chapter 20—Grazing Agreements. These IDs established procedures and responsibilities for administering term grazing permits and grazing agreements (FR 70 41370). On that same day, several other amendments to FSH 2209.13, as well as amendments to several chapters of Forest Service Manual (FSM) 2200 on Range Management were issued. On August 19, 2005, the Forest Service published a notice in the **Federal Register** notifying the public that the IDs had been rescinded and a revised ID had been reissued on August 16, 2005. In addition, the Forest Service announced that proposed directives containing the direction removed from the two chapters had been prepared and were available for public comment (70 FR 48663). On September 2, 2005, a third **Federal Register** notice was published to correct the World Wide Web/Internet address and proposed direction that included incorrect restrictions of the base property and livestock ownership requirements (70 FR 52362). The Forest Service rescinded all of the direction referred to in these three **Federal Register** notices on September 9, 2005, and replaced it with the direction that was in place prior to July 19, 2005.

DATES: Rangeland Management direction in effect prior to July 19, 2005, in the Forest Service Manual 2200 contents, the zero code chapter, chapters 2210, 2230, 2240, 2250, and 2270; and direction in the Forest Service Handbook contents, zero code chapter, and chapters 30, 40, 50, 60, 70, 80, and 90 were reinstated on September 9, 2005.

FOR FURTHER INFORMATION CONTACT: Ralph Giffen, Rangeland Management Staff, USDA Forest Service, (202) 205–1455.

SUPPLEMENTARY INFORMATION: The Forest Service directives consist of the Forest Service Manual (FSM) and the Forest Service Handbook (FSH), which contain the agency's policies, practices, and procedures and serves as the primary basis for the internal management and control of programs and administrative direction to Forest Service employees. The directives for all agency programs are set out on the World Wide Web/Internet at *http://www.fs.fed.us/im/directives.*

The FSM contains legal authorities, objectives, policies, responsibilities, instructions, and guidance needed on a continuing basis by Forest Service line officers and primary staff to plan and execute programs and activities. The FSH is the principal source of specialized guidance and instruction for carrying out the policies, objectives, and responsibilities contained in the FSM.

The Forest Service is committed to providing adequate opportunities for the public to comment on the formulation of administrative directives that are of substantial public interest or controversy, as provided in the regulations at 36 CFR part 216.

The Forest Service will make an extra effort to ensure that proposed changes in FSM 2200 and FSH 2209.13 are well communicated to the public and that the public has ample opportunity to comment on and be appropriately involved in those changes.

Therefore, the 14 amended chapters and two ID chapters issued July 19, 2005, and the two revised ID chapters issued again on August 19, 2005, are rescinded. Rangeland management direction in effect prior to the July 19, 2005 releases is reinstated in full. Comment is also no longer requested on the proposed directives. The Forest Service's objective is to clarify its rangeland management directives and explain the proposed changes while ensuring that a clear process for public comment is provided. Proposed rangeland management policy along with procedures for comment will be reevaluated prior to requesting future public comment.

Dated: September 14, 2005.

Ann Bartuska,

Acting Chief.

[FR Doc. 05–18659 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shoshone National Forest, Wyoming, Revised Land and Resource Management Plan

AGENCY: Forest Service, USDA.

ACTION: Notice of initiation to revise the Shoshone National Forest Land and Resource Management Plan.

SUMMARY: The Forest Service will revise the Land and Resource Management Plan (hereafter referred to as the Forest Plan) for the Shoshone National Forest. This notice describes documents available for review and how to obtain them; summarizes the need to change the Forest Plan; provides information concerning public participation; and includes the names and addresses of agency officials who can provide additional information.

DATES: To be most beneficial to the planning process your comments on need for change should be submitted by October 21, 2005.

ADDRESSES: Send written comments to Forest Plan Revision, Shoshone National Forest, 808 Meadow Lane Avenue, Cody, WY 82414–4549. E-mail address: *shoshone_forestplan@fs.fed.us*.

FOR FURTHER INFORMATION CONTACT: Bryan Armel at (307) 578–1234, or Susan Douglas at (307) 578–1214, or e-mail *shoshone_forestplan@fs.fed.us*.

SUPPLEMENTARY INFORMATION:

Documents Available for Review

Two documents are available for review to assist the public in commenting on the need for change. The Forest Plan Comprehensive Evaluation Report, Version 1.0, describes the current social, economic, and ecological conditions and trends for management of the Shoshone National Forest. The Need for Change Evaluation report, Version 1.0, describes the results of public input on need for change. The document has four sections. The first section discusses the preliminary need for change. The document has four sections. The first section discusses the preliminary need for change topics that were suggested. The second section identifies topics that do not require a change in current management direction, but need to be updated in the revised plan. The third section identifies a number of topics that need to be considered during the process of developing the revised forest plan. The fourth section identifies those topics that were suggested but will not be addressed in the plan revision. The Need for Change Evaluation report includes items identified by the public. Forest Service personnel, and local governments in May, June, and July. The documents are available at *http://www.fs.fed.us/r2/shoshone/projects/planning/revision_index.shtml* or by request.

Need for Change Evaluation

From discussions internally and with the public, the forest planning team identified a set of preliminary need for change questions. More information on these items and other comments are documented in the Need for Change Evaluation report. After further need for change discussions with the public through October, the Forest Supervisor will decide what need for change items will be addressed in the forest plan revision.

Preliminary Need for Change Topics

1. How should hazardous fuels, fire use, fire, and wildland urban interface areas be managed?
2. How should the spread of invasive plants be managed?
3. What areas of the Forest are suitable for the extraction of leasable, locatable, and salable minerals?
4. What special uses are suitable for the Forest, and how should they be managed?
5. What types of recreation opportunities should the Forest provide? In what areas are the opportunities suitable?
6. What areas of the Forest should have roaded access to fulfill the needs of Forest users and managers?
7. What management direction is appropriate for roadless areas and other special areas? What rivers, streams, or segments of rivers or streams are eligible for Wild and Scenic Rivers designation? What roadless areas should be recommended for wilderness designation?
8. What areas of the Forest are suitable for timber harvest? What timber harvest methods should be available? What types of timber products should be available?
9. What vegetation conditions and types of habitats should the Forest provide? What management direction, if any, should be included in the revised plan for large scale insect infestations?
10. What management direction should the plan contain for contributing to sustainable populations of native fish and wildlife species on the Forest?
11. Should the acres designated suitable for domestic livestock grazing be reevaluated?
12. Should management direction specific to highway corridors be included in the revised forest plan? If yes, what is the direction?
13. Should the direction in the current Forest plan for increasing water yield be retained?

Comment Requested

The Forest Service is seeking information and comments from individuals, organizations, Native American Tribes, and Federal, State, and local governments and agencies on the need for change in Forest Plan direction. The Forest Service is asking for comment on the topics identified in the Need for Change Evaluation report and for other topics that individuals, organizations, tribes, and governments and agencies feel should be addressed during the revision process. If you submitted comments previously and feel they are addressed in the Need for Change Evaluation report, you do not need to resubmit your comments.

Planning Process Schedule

The revision process for the Shoshone National Forest officially begins in September 2005 with the publication of this notice of initiation in the**Federal Register**. A draft revised forest plan will be published in April 2007. The final revised forest plan will be issued for pre-decisional review in April 2008. Final plan approval is planned for September 2008.

Responsible Official

Rebecca Aus, Shoshone National Forest Supervisor at 808 Meadow Lane Ave, Cody, WY 82414–4549.

Public Participation

The revision process is designed to provide opportunities for public collaboration and open participation in the development of the revised forest plan. Additional information on the process, the documents being produced, and public opportunities to participate can be found on the Shoshone National Forest's planning Web site at *http://www.fs.fed.us/r2/shoshone/projects/planning/revision/revision_index.shtml*.

(Authority: 36 CFR part 219)

Dated: September 13, 2005.

Rebecca Aus,

Forest Supervisor.

[FR Doc. 05–18689 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Broad Creek Watershed, Delaware

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of intent to deauthorization of Federal funding.

SUMMARY: Pursuant to the Watershed Protection and Flood Prevention Act, Public Law 83–566, and the Natural Resources Conservation Service

Guidelines (7 CFR part 622), the Natural Resources Conservation Service gives notice of the deauthorization of Federal funding for the Broad Creek Watershed project Sussex and Kent Counties, Delaware.

FOR FURTHER INFORMATION CONTACT: Jon F. Hall, State Conservationist, Natural Resources Conservation Service, 1221 College Park Drive, Suite 100, Dover, Delaware 19904, 302–678–4160.

Notice of Intent To Deauthorize Federal Funding

SUPPLEMENTARY INFORMATION: A determination has been made by Jon F. Hall, State Conservationist, Delaware Natural Resources Conservation Service, that the proposed works of improvement for the Broad Creek Watershed project will not be installed. The sponsoring local organizations have concurred in this determination and agree that Federal funding should be deauthorized for the project. Information regarding this determination may be obtained at the above address and telephone number.

No administrative action on implementation of the proposed deauthorization will be taken until 60 days after the date of this publication in the **Federal Register**.

Dated: September 12, 2005.

Jon F. Hall,

State Conservationist.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of Management and Budget Circular A–95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable)

[FR Doc. 05–18702 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 050728205–5205–01]

Annual Trade Survey

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of consideration.

SUMMARY: The Bureau of the Census (Census Bureau) is proposing to expand the 2005 Annual Trade Survey (ATS) to include agents, brokers, and electronic markets (AGBR). The Census Bureau proposes this expansion at the request of the Bureau of Economic Analysis (BEA). The BEA considers this information vital to its accurate measurement of sales and value added for wholesale trade. These data are important inputs to BEA's preparation of National Income and Product accounts and its annual input-output tables.

DATES: Written comments must be submitted on or before October 20, 2005.

ADDRESSES: Direct all written comments to the Director, U.S. Census Bureau, Room 2049, Federal Building 3, Washington, DC 20233.

FOR FURTHER INFORMATION CONTACT: John R. Trimble, Chief, Annual Wholesale and Special Projects Branch, Service Sector Statistics Division, on (301) 763–7223, or by e-mail: *John.R.Trimble@census.gov*.

SUPPLEMENTARY INFORMATION: The Census Bureau is authorized to conduct surveys necessary to furnish current data on subjects covered by the major censuses authorized by Title 13, United States Code (U.S.C.), Sections 182, 224, and 225. Reporting by AGBR offices will be mandatory and will provide continuing and timely national statistical data. Data collected in this survey will be within the general scope, type, and character of those inquiries covered in the Economic Census.

The current ATS collects data for all merchant wholesalers. The expanded survey will include a selected sample of AGBRs that facilitate sales between businesses in the United States. These data will be a vital source for accurately measuring the sales, commissions, sales arranged for others, e-commerce, and operating expenses of these types of companies. The BEA has made repeated requests for this information. The expanded ATS will cover all sales from the wholesale sector compared to about 90 percent of sales in the present ATS sample.

Beginning with the survey year 2005, the goal will be to maximize industry coverage within our available resources. In order to establish reporting arrangements and reduce respondent burden, we will mail report forms to a sample of firms on a company basis and contact them in person, as well as by phone and mail. We will mail a survey introduction letter followed by report forms to the firms covered by this survey and require the report forms to be returned 30 days after receipt. The report forms will request similar data items, but different forms are needed to accommodate wholesale distributors, manufacturers' sales branches and offices (MSBOs), and AGBR companies, as well as both large and small firms. Later, if necessary, additional mail follow-ups and telephone follow-ups will be conducted.

The primary users of these data will be Federal, state and local government agencies, including the Census Bureau, BEA, and the Environmental Protection Agency. Other users will include business firms, academics, trade associations, and research and consulting organizations.

Executive Order 12866

This notice has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this notice would not have a significant economic impact on a substantial number of small entities. The Census Bureau is proposing to expand the 2005 ATS to includes AGBRs. If this notice of consideration is adopted, the expanded ATS would cover all sales from the wholesale sector compared to about 90 percent of sales in the present ATS sample.

If this notice is adopted, it is estimated that the survey will require an additional 514 respondents to respond to the survey. It is estimated that approximately 368 of the respondents would be small entities. The approximate total additional burden hours as a result of this rule is 238 hours (28 minutes per survey). This includes time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The total cost is estimated to be $5,614 based on an annual response burden of 238 hours and a rate of $23.59 per hour to complete the form. The total cost to respondents that are small entities is estimated to be $3,892.

Because small businesses are subject to minimal recording-keeping and reporting burdens as a result of this notice, the Chief Counsel for Regulation certifies that this notice of consideration will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current valid Office of Management and

Budget (OMB) control number. This notice contains a collection of information subject to the requirements of the PRA (44 U.S.C. 3501 *et seq.*). In accordance with the PRA, this collection of information will be submitted to OMB for approval. We estimate the number of additional respondents to be 514 and estimate an additional 238 annual burden hours with this expanded data collection. Also, we estimate that the time for the additional responses associated with this data collection will be approximately 28 minutes. We will furnish report forms to organizations included in the survey, and additional copies will be available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

Dated: September 13, 2005.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. 05–18605 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Producing Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration (EDA), Commerce.

ACTION: To give all interested parties an opportunity to comment.

Petitions have been accepted for filing on the dates indicated from the firms listed below.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD AUGUST 11, 2005–SEPTEMBER 15, 2005

Firm name	Address	Date petition accepted	Product
O'Brien Corporation and Cardinal Systems, Inc.	1900 Crystal Industrial Ct., St. Louis, MO 63114.	29–Jul–05	Industrial heat exchange products.
NRM Industries, Inc	1655 Industrial Drive, Owosso, MI 48867.	11–Aug–05	Injection molded plastic products for the house ware, home building, and automotive industries.
Clearwater Nursery, Inc	887 Mesa Road, Nipomo, CA 93444.	22–Aug–05	Fresh flowers.
Don Hume Leathergoods, Inc	400 Newman Road, N. Miami, OK 74358.	22–Aug–05	Leather and nylon enforcement products including holsters, belts and holders.
Philip Machine Company, Inc	184 Woonasquatucket Avenue, North Providence, RI 02911.	23–Aug–05	Metal findings, and custom metal stampings for belt buckles, clothes and accessories.
SSI Manufacturing Technologies Corporation.	675 Emmett Street, Bristol, CT 06010.	23–Aug–05	Medical instruments and parts for medical devices.
Printek, Inc	1517 Townline Road, Benton Harbor, MI 49022.	24–Aug–05	Printers for use with business machines.
Villa Rica Knitters, Inc	600 Rockmart Highway, Villa Rica, GA 30180.	25–Aug–05	Acrylic and wool knitted accessories including hats, watch caps, leg and arm warners, scarves, facemasks, etc.
Walco Electric Company	303 Allens Avenue, Providence, RI 02905.	27–Aug–05	Electric motors.
Restorative Medical, Inc	332 East Broadway, Brandenbrug, KY 40108.	29–Aug–05	Orthopedic, prosthetic, and surgical appliances and supplies.
George Koch Sons, LLC	10 S. Eleventh Avenue, Evansville, IN 47744.	14–Sep–05	Custom designed automated finishing systems for industries, *i.e.* spraying apparatus.
Hitachi Metals North Carolina, Ltd.	1 Hitachi Metals Drive, China Grove, NC 28023.	14–Sep–05	Magnets for the construction of motors to be used primarily in automotive applications.
Performance Stamping Co., Inc.	20 Lake Marina Road, Carpentersville, IL 60110.	14–Sep–05	Stamped metal for the household refrigerator appliance, automotive, computer, household fixture and electrical industries.
Schmald Tool and Die, Inc	4206 South Saginaw, Burton, MI 48529.	14–Sep–05	Plastic injection molds, dies, and machine tools for working metals and parts of plastic for vehicles.
W.L. Duffing, L.P	5223 West Orem Drive, Houston, TX 77045.	14–Sep–05	Parts for electronic measuring instruments.
Carlos Knitting Mill, LLC and Lifestyle Apparel, LLC.	3100 East 26th Street, Vernon, CA 90023.	15–Sep–05	Knitted fabric.
Galvotec Alloys, Inc	6712 South 36th Street, McAllen, TX 78503.	15–Sep–05	Aluminum alloys, including galvanic anodes.

The petitions were submitted pursuant to Section 251 of the Trade Act of 1974 (19 U.S.C. 2341). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm. Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by Trade Adjustment Assistance, Room 7812, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than the close of business of the tenth calendar day following the publication of this notice. The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.

Dated: September 14, 2005.

Anthony J. Meyer,

Senior Program Analyst, Office of Strategic Initiatives.

[FR Doc. 05–18685 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1411]

Grant of Authority for Subzone Status, Millipore Corporation (Polyvinylidene Fluoride Filtering Devices), Jaffrey, New Hampshire

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign–Trade Zones Act provides for ''. . . the establishment . . . of foreign–trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign–Trade Zones Board (the Board) to grant to qualified corporations the privilege of establishing foreign–trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special–purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Pease Development Authority, grantee of Foreign–Trade Zone 81 (Portsmouth, New Hampshire), has made application for authority to establish special–purpose subzone status at the polyvinylidene fluoride (PVDF) filtering device manufacturing plant of Millipore Corporation, located in Jaffrey, New Hampshire (Docket 55–2004, filed 11–30–2004);

Whereas, notice inviting public comment was given in the **Federal Register** (69 FR 70996, 12–8–2004); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest.

Now, therefore, the Board hereby grants authority for subzone status for activity related to polyvinylidene fluoride (PVDF) filtering device manufacturing at the facilities of Millipore Corporation, located in Jaffrey, New Hampshire (Subzone 81D), as described in the application and **Federal Register** notice, and subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 9th day of September 2005.

Joseph A. Spetrini,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 05–18717 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1406]

Grant Of Authority For Subzone Status, Epson Portland, Inc. (Inkjet Cartridges), Hillsboro, Oregon

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign–Trade Zones Act provides for '' . . . the establishment . . . of foreign–trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign–Trade Zones Board to grant to qualified corporations the privilege of establishing foreign–trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special–purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Port of Portland, grantee of FTZ 45, has made application to the Board for authority to establish special–purpose subzone status at the inkjet cartridge manufacturing plant of Epson Portland, Inc. (EPI), located in Hillsboro, Oregon (FTZ Docket 1–2005, filed 1–04–05, and amended 4–26–05, to accept the restriction described below).

Whereas, notice inviting public comment has been given in the **Federal Register** (70 FR 2850, 1/18/05); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations would be satisfied, and that approval of the application, as amended, would be in the public interest if approval were subject to specific conditions;

Now, therefore, the Board hereby grants authority for subzone status for activity related to inkjet cartridges at the manufacturing plant of Epson Portland, Inc., located in Hillsboro, Oregon (Subzone 45F), as described in the application, as amended, and **Federal Register** notice, and subject to the FTZ Act and the Board's regulations, including § 400.28, and further subject to the conditions listed below:

Privileged foreign status (19 CFR Part 146.41) shall be elected on foreign merchandise that falls under HTSUS Subheadings 3204, 3205, 3206, 3207, 3212, or 3901.20, or where the foreign merchandise in question is classified as a pigment, pigment preparation, coloring preparation, or colorant.[1] The above condition specifically excludes foreign inks, as described in the application, and classified under HTSUS Subheadings #3215.11.0060 and #3215.19.0060.

Signed at Washington, DC, this 9th day of September 2005.

Joseph A. Spetrini,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign–Trade Zones Board

Attest:

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 05–18716 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1412]

Expansion of Foreign–Trade Zone 247, Erie, Pennsylvania

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

Whereas, the Erie–Western Pennsylvania Port Authority, grantee of Foreign–Trade Zone 247, submitted an application to the Board for authority to expand FTZ 247 to include a site (Site 4 - 34 acres) at the Venango Regional Airport Industrial Park in the City of Franklin (Venango County), Pennsylvania, adjacent to the Erie Customs port of entry (FTZ Docket 13–2005; filed 3/11/05);

Whereas, notice inviting public comment was given in the **Federal Register** (70 FR 13450, 3/21/05) and the application has been processed

[1] This action specifically excludes the use of foreign-trade zone procedures for foreign synthetic indigo dye (HTSUS Subheadings #3204.15.1000, #3204.15.4000 and #3204.15.8000).

pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to expand FTZ 247 is approved, subject to the Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 9th day of September 2005.

Joseph A. Spetrini,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 05–18718 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1413]

Expansion of Foreign–Trade Zone 207, Richmond, Virginia

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

Whereas, the Capital Region Airport Commission, grantee of Foreign–Trade Zone 207, submitted an application to the Board for authority to expand FTZ 207 to include a site (Site 2 - 221 acres) within the 345–acre SouthPoint Business Park in Prince George (Prince George County), Virginia, within the Richmond Customs port of entry (FTZ Docket 14–2005; filed 3/14/05);

Whereas, notice inviting public comment was given in the **Federal Register** (70 FR 13451, 3/21/05) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to expand FTZ 207 is approved, subject to the Act and the Board's regulations, including Section 400.28, and subject to the Board's standard 2,000–acre activation limit for the overall zone project.

Signed at Washington, DC, this 9th day of September 2005.

Joseph A. Spetrini,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 05–18719 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–846]

Brake Rotors From the People's Republic of China: Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is currently conducting a changed circumstances review of the antidumping duty order on brake rotors from the People's Republic of China (''PRC''). We have preliminarily determined that Shandong Huanri Group Co., Ltd. (''Huanri Group'') is the successor–in-interest to Shandong Huanri Group General Company (''Huanri Group General'') for purposes of determining antidumping liability.

Interested parties are invited to comment on these preliminary results. The Department will issue the final results of this antidumping duty changed circumstances review not later than November 7, 2005, as the Department plans to issue the final results of this changed circumstance review at the same time as the final results of the concurrent administrative review.

EFFECTIVE DATE: September 20, 2005.

FOR FURTHER INFORMATION CONTACT: Catherine Bertrand or Carrie Blozy, 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) 482–3207 or (202) 482–5403, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 28, 2004, Huanri Group requested that the Department determine that it is the successor–in-interest to Huanri Group General for purposes of determining antidumping liability. On December 13, 2004, the Department initiated a changed circumstances review of Huanri Group's claim that it is the successor–of-interest to Huanri Group General. *See Brake Rotors from the People's Republic of China: Notice of Initiation of Changed Circumstances Review*, 69 FR 75508 (December 17, 2004).

On February 2, 2005, the Department issued a supplemental questionnaire to Huanri Group. On February 23, 2005, Huanri Group submitted a supplemental questionnaire response. On March 26, 2005, the Department verified the information submitted by the Huanri Group to support its successorship claim at Huanri's Group's office in Laizhou, China. See Verification Report, dated June 17, 2005 (''*Verification Report*'').

Scope of the Order

The products covered by the order are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, ranging in diameter from 8 to 16 inches (20.32 to 40.64 centimeters) and in weight from 8 to 45 pounds (3.63 to 20.41 kilograms). The size parameters (weight and dimension) of the brake rotors limit their use to the following types of motor vehicles: automobiles, all–terrain vehicles, vans, recreational vehicles under ''one ton and a half,'' and light trucks designated as ''one ton and a half.''

Finished brake rotors are those that are ready for sale and installation without any further operations. Semi–finished rotors are those rotors which have undergone some drilling and on which the surface is not entirely smooth. Unfinished rotors are those which have undergone some grinding or turning.

These brake rotors are for motor vehicles and do not contain in the casting a logo of an original equipment manufacturer (''OEM'') which produces vehicles sold in the United States (*e.g.*, General Motors, Ford, Chrysler, Honda, Toyota, and Volvo). Brake rotors covered in this review are not certified by OEM producers of vehicles sold in the United States. The scope also includes composite brake rotors that are made of gray cast iron which contain a steel plate but otherwise meet the above criteria. Excluded from the scope of the review are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, with a diameter less than 8 inches or greater than 16 inches (less than 20.32 centimeters or greater than 40.64

centimeters) and a weight less than 8 pounds or greater than 45 pounds (less than 3.63 kilograms or greater than 20.41 kilograms).

Brake rotors are classifiable under subheading 8708.39.5010 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Preliminary Results

The Department is currently conducting an administrative review regarding Huanri Group General. In the preliminary results of the administrative review, the Department preliminarily determined that Huanri Group General did not demonstrate that it was entitled to a separate rate under the Department's test. *See Brake Rotors From the People's Republic of China: Preliminary Results and Partial Rescission of the Seventh Administrative Review and Preliminary Results of the Eleventh New Shipper Review*, 70 FR 24382 (May 9, 2005). The final results of the administrative review are due on November 7, 2005. The Department will issue the final results of this changed circumstance review at the same time as the concurrent administrative review as both segments involve the company at issue. The separate rate issue will be decided in the context of the administrative review. However, the final results of the administrative review with respect to separate rates will be incorporated into the changed circumstance review final. The Department's decision in this changed circumstance preliminary results will focus solely on the successor–in-interest issue discussed below.

In its February 23, 2005, supplemental questionnaire response, Huanri Group provided documentation to support further its claim that effective June 9, 2004, it received approval from the local bureau to change its name to ''Shandong Huanri Group General Company.'' The company stated that the reason for the name change was based on the shareholders' decision to change the legal structure of the company from a collectively owned company to a limited liability company. Specifically, this documentation consisted of: (1) shareholders' meeting minutes detailing the company's reasoning for the name change; (2) Notice of Advanced Approval to Enterprise Name; (3) approval for the name change application; and (4) Huanri Group's business license issued on June 9, 2004 (*see* Exhibit 1 of the February 23, 2005, supplemental questionnaire response).

In its responses to the Department's supplemental questionnaires, Huanri Group also provided information in support of its statements that all personnel, operations, and facilities remain essentially unchanged as a result of changing the name of the company. The Department verified this information, and found that the managers, production facilities, equipment, suppliers, operations, and customer base remained unchanged after the name change.

In making such a successor–in-interest determination, the Department examines several factors including, but not limited to, changes in: (1) management; (2) production facilities; (3) supplier relationships; and (4) customer base. *See*, *e.g.*, *Brass Sheet and Strip from Canada: Final Results of Antidumping Duty Administrative Review*, 57 FR 20460 (May 13, 1992). While no single factor or combination of these factors will necessarily provide a dispositive indication of a successor–in-interest relationship, the Department will generally consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor. *See*, *e.g.*, *Industrial Phosphoric Acid from Israel: Final Results of Changed Circumstances Review*, 59 FR 6944 (February 14, 1994); *Canadian Brass, and Fresh and Chilled Atlantic Salmon from Norway: Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review*, 63 FR 50880 (September 23, 1998). Thus, if the evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the former company, the Department will accord the new company the same antidumping treatment as its predecessor.

Data placed on the record and verified by the Department indicates that Huanri Group has the same management, production facilities, customer base, and supplier relationships as Huanri Group General. At verification, the Department examined the issue of whether the two companies had the same management. The Department examined payroll records and appointment records before and after the name change. The Department found that there were no changes in the paid employees and that three of the five board members remained the same after the name change. *See Verification Report* at 9. The Department examined the production and sales activities at verification as well. The Department found that there were no changes in equipment or facilities after the name change. *See Verification Report* at 10. At verification, the Department also analyzed whether the suppliers were the same before and after the name change. The Department examined purchase entries and the material sub–ledger and found that there was no significant change in the names of the suppliers before and after the name change. *See Verification Report* at 11. The Department also analyzed whether the customer base was the same before and after the name change by examining the sales sub–ledger and invoices from selected months. The Department found that Huanri General continued to sell subject merchandise to two of its five U.S. customers. *Id.*

We find that there were no significant changes to the management, production facilities, supplier relationships and customer base after the name change. Further, we find that the operations of Huanri Group are essentially the same as Huanri Group General. Therefore, for the reasons stated above, we preliminarily determine that Huanri Group should receive the same antidumping duty treatment with respect to brake rotors as the former entity Huanri Group General.

If these preliminary results are adopted in our final results of this changed circumstances review, we will instruct the U.S. Customs and Border Protection (''CBP'') to assign Huanri Group the antidumping duty cash deposit rate applicable to Huanri Group General. The cash deposit determination from this changed circumstances review will apply to all entries of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this changed circumstances review. This deposit rate shall remain in effect until publication of the final results of the next administrative review in which Huanri Group participates.

Any interested party may request a hearing within 30 days of publication of this notice. Any hearing, if requested, will be held no later than 40 days after the date of publication of this notice, or the first workday thereafter. Interested parties who wish to request a hearing or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room B–099. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c).

Issues raised in the hearing will be limited to those raised in case briefs and rebuttal briefs. Case briefs from interested parties may be submitted not later than 30 days after publication of this notice. Rebuttal briefs, limited to the issues raised in the case briefs, may be filed not later than five days after the submission of case briefs. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument. Parties are encouraged to provide a summary of the arguments not exceeding five pages and a table of statutes, regulations, and cases cited.

The Department will publish the final results of this changed circumstances review, including the results of its analysis of issues raised in any written comments, not later than November 7, 2005.

We are issuing and publishing this determination and notice in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216.

Dated: September 14, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 05–18715 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–863]

Honey from the People's Republic of China: Extension of Time Limit for Preliminary Results of 2003/2004 New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 20, 2005.

FOR FURTHER INFORMATION CONTACT: Anya Naschak at (202) 482–6375; AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2001, the Department published in the **Federal Register** an antidumping duty order covering honey from the PRC. *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order; Honey from the People's Republic of China*, 66 FR 63670 (December 10, 2001). On December 22, 2004, the Department received a timely request from Kunshan Xin'an Trade Co., Ltd. (''Xinan'') in accordance with 19 CFR 351.214 (c), for a new shipper review of the antidumping duty order on honey from the PRC, which has a December annual anniversary month. On January 31, 2005, the Department initiated a review for Xinan. *See Honey from the People's Republic of China: Initiation of New Shipper Antidumping Duty Review*, 70 FR 6412 (February 7, 2005) (''NSR Xinan Initiation'')

On July 14, 2005, the Department extended the time limit for issuance of the preliminary results of this review by 45 days. *See Honey from the People's Republic of China: Extension of Time Limit for Preliminary Results of 2003/2004 New Shipper Review*, 70 FR 42033 (July 21, 2005). On August 10, 2005, the Department issued a memorandum that stated the Department's intent to rescind this new shipper review because of the non–*bona fide* nature of Xinan's sales transaction. *See* Memorandum From James C. Doyle, Director, Office 9, to Barbara E. Tillman, Acting Deputy Assistant Secretary for Import Administration: *Bona Fide* Analysis for Kunshan Xin'an Trade Co., Ltd.'s Sale in the New Shipper Review of Honey from the People's Republic of China, dated August 10, 2005. We received comments on our intent to rescind this new shipper review from Xinan on August 25, 2005. We received rebuttal comments from the American Honey Producers and the Sioux Honey Association (collectively, ''petitioners'') on August 31, 2005. The deadline for completion of the preliminary results is currently September 13, 2005.

Extension of Time Limits for Preliminary Results

Section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(i)(1) require the Department to issue the preliminary results of a new shipper review within 180 days after the date on which the new shipper review was initiated and final results of a review within 90 days after the date on which the preliminary results were issued. The Department may, however, extend the deadline for completion of the preliminary results of a new shipper review to 300 days if it determines that the case is extraordinarily complicated (19 CFR 351.214 (i)(2)).

Pursuant to section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214 (i)(2), we determine that this review is extraordinarily complicated and that it is not practicable to complete this new shipper review within the current time limit. Specifically, the Department requires additional time to analyze the comments received by parties on the Department's *bona fides* analysis. Accordingly, the Department is extending the time limit for the completion of the preliminary results by 20 days, to October 3, 2005, in accordance with section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214(i)(2).

This notice is issued and published in accordance with section 751(a)(3)(A) of the Act.

Dated: September 13, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 05–18714 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–806]

Silicon Metal from Brazil: Notice of Court Decision and Suspension of Liquidation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On August 26, 2005, in *Elkem Metals Company and Globe Metallurgical Inc. v. United States*, Slip Op. 05–109 (*Elkem Metals III*), the Court of International Trade (CIT) affirmed the Final Results of Redetermination Pursuant to Remand (*Remand Results II*) released by the Department of Commerce (the Department), on March 16, 2005. Consistent with the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) in *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), the Department will continue to order the suspension of liquidation of the subject merchandise, where appropriate, until there is a ''conclusive'' decision in this case. If the case is not appealed, or if it is affirmed on appeal, the Department will instruct U.S. Customs and Border Protection (CBP) to liquidate all relevant entries from Rima Industrial, S.A. (Rima), as appropriate.

EFFECTIVE DATE: September 20, 2005.

FOR FURTHER INFORMATION CONTACT: Maisha Cryor, AD/CVD Enforcement, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230, telephone 202–482–5831, fax 202–482–5105.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 2002, the Department published in the **Federal Register** a notice of final results of the antidumping duty administrative review on silicon metal from Brazil. *See Silicon Metal From Brazil: Final Results of Antidumping Duty Administrative Review*, 67 FR 6488 (February 12, 2002) (*Final Results*). Following publication of the Final Results, Elkem Metals Company and Globe Metallurgical Inc. (collectively petitioners), filed a lawsuit with the CIT challenging the Department's findings in the Final Results, regarding the calculation of Rima's constructed value (CV). In *Elkem Metals Company and Globe Metallurgical Inc. v. United States*, No. 02–00232, (CIT February 25, 2004) (*Elkem Metals I*), the CIT remanded this matter to the Department for it to recalculate Rima's CV to include certain value–added taxes (VAT). In its Final Results of Redetermination Pursuant to Court Remand (*Remand Results I*), filed on June 8, 2004, in response to *Elkem Metals I*, the Department determined that such VAT were not incurred by Rima and therefore did not constitute a material cost for purposes of calculating CV. Consequently, in *Remand Results I*, the Department found that no adjustment was necessary to Rima's CV. In *Elkem Metals Company and Globe Metallurgical Inc. v. United States*, 350 F. Supp 2d 1270 (CIT 2004) (*Elkem Metals II*), the CIT once again instructed the Department to include VAT paid by Rima in the re–calculation of CV and to make any necessary adjustments to the dumping margin.

The Draft Results of Redetermination Pursuant to Court Remand (*Draft Remand Results II*) were released to parties on January 24, 2005. The Department received comments from interested parties on the *Draft Remand Results II* on January 24, 2005, and rebuttal comments on February 4, 2005. On March 16, 2005, the Department responded to the CIT's Order of Remand by filing the *Remand Results II*. In *Remand Results II*, pursuant to the CIT's order, the Department included VAT paid by Rima in the re–calculation of CV.

As a result of the remand determination, the antidumping duty rate for Rima was increased from 0.35 percent to 0.48 percent. The CIT did not receive comments from either petitioners or Rima.

On August 26, 2005, the CIT affirmed the Department's findings in *Remand Results II*. Specifically, the CIT upheld the Department's inclusion of VAT in Rima's CV. See *Elkem Metals III*..

The only revision made to the *Final Results* was the inclusion of VAT in the calculation of Rima's CV, as noted above. This revision resulted in a change in Rima's margin. However, Rima continues to have a *de minimis* margin, as it had in the *Final Results*.

Suspension of Liquidation

The CAFC, in *Timken*, held that the Department must publish notice of a decision of the CIT or the CAFC which is not ''in harmony'' with the Department's final determination or results. Publication of this notice fulfills that obligation. The CAFC also held that the Department must suspend liquidation of the subject merchandise until there is a ''conclusive'' decision in the case. Therefore, pursuant to *Timken*, the Department must continue to suspend liquidation pending the expiration of the period to appeal the CIT's August 26, 2005, decision, or, if that decision is appealed, pending a final decision by the CAFC. The Department will instruct CBP to revise cash deposit rates, as appropriate, and to liquidate relevant entries covering the subject merchandise effective September 20, 2005, in the event that the CIT's ruling is not appealed, or if appealed and upheld by the CAFC.

Dated: September 14, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 05–18713 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 20, 2005.

SUMMARY: The Department of Commerce (the Department) hereby publishes a list of scope rulings completed between April 1, 2005, and June 30, 2005. In conjunction with this list, the Department is also publishing a list of requests for scope rulings and anticircumvention determinations pending as of June 30, 2005. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Alice Gibbons, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0498.

SUPPLEMENTARY INFORMATION:

Background

The Department's regulations provide that the Secretary will publish in the **Federal Register** a list of scope rulings on a quarterly basis. *See* 19 CFR 351.225(o). Our most recent ''Notice of Scope Rulings'' was published on July 19, 2005. *See* 70 FR 41374. The instant notice covers all scope rulings and anticircumvention determinations completed by Import Administration between April 1, 2005, and June 30, 2005, inclusive. It also lists any scope or anticircumvention inquiries pending as of June 30, 2005, as well as scope rulings inadvertently omitted from prior published lists. As described below, subsequent lists will follow after the close of each calendar quarter.

Scope Rulings Completed Between April 1, 2005, and June 30, 2005:

Brazil

A–351–832; C–351–833: Carbon and Certain Alloy Steel Wire Rod from Brazil
Requestors: Companhia Siderugica Belgo Mineira Participacao Industria e Comercio S.A. and B.M.P. Siderugica S.A.; for grade 1080 tire cord quality wire rod and tire bead quality wire rod (1080 TCBQWR), the phrase ''having no inclusions greater than 20 microns'' means no inclusions greater than 20 microns in any direction; May 9, 2005.

India

A–533–810: Stainless Steel Bar from India; A–533–808: Stainless Steel Wire Rod from India
Requestor: Mukand International, Ltd.; stainless steel bar, manufactured in the United Arab Emirates out of stainless steel wire rod that is manufactured in India, is not included in the scope of the antidumping duty order; May 23, 2005.

Japan

A–588–824: Certain Corrosion–Resistant Carbon Steel Flat Products from Japan
Requestor: Metal One Corporation; diffusion–annealed nickel plate is within the scope of the anti–dumping duty order; August 26, 2005.

People's Republic of China

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: Target Corporation; a snowball candle (stock no. 08 0986) and set of snowball candles (stock no. 08 0959) are within the scope of the antidumping duty order; April 1, 2005.
A–570–804: Petroleum Wax Candles from the People's Republic of China

Requestor: Rokeach Foods; a ''Yahrzeit'' candle is within the scope of the antidumping duty order; April 15, 2005.

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: Crazy Mountain Imports, Inc., wax–filled ceramic containers with a single ''snowman'' or ''snow–woman'' figurine attached to the top of each container's lid with the words ''Merry Christmas,'' are included within the scope of the antidumping duty order; April 20, 2005.

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: Rokeach Foods; 44 Chanukah candles are within the scope of the antidumping duty order; April 29, 2005.

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: Access Business Group; one candle and five candle sets with various components are within the scope of the antidumping duty order; May 4, 2005.

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: New Spectrum Gift Gallery; seventy candles in various shapes are within the scope of the antidumping duty order. Thirty candles also in various shapes are not included in the scope of the antidumping duty order; May 12, 2005.

A–570–804: Petroleum Wax Candles from the People's Republic of China
Requestor: Home Interiors and Gifts; set of six ''rose blossom'' candles (item number 11538) and set of three ''American heart'' candles (item number 12117) are within the scope of the antidumping duty order. Three ''sunflower'' candles (item number 12116) and two sets of 12 ''baked apple pie'' and ''vanilla'' tea light candles (item numbers 11611 and 11612) are not included in the scope of the antidumping duty order; May 13, 2005.

A–570–504: Petroleum Wax Candles from the People's Republic of China
Requestor: Pier 1 Imports, Inc.; 12 models of candles are not included in the scope of the antidumping duty order (requestor removed one of the 13 candles from its original request); May 13, 2005.

A–570–803: Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, from the People's Republic of China
Requestor: Olympia Group Inc.; cast tampers are not included in the scope of the antidumping duty order; May 23, 2005.

A–570–827: Cased Pencils from the People's Republic of China
Requestor: Fiskars Brands, Inc.; certain compasses are not included in the scope of the antidumping duty order; June 3, 2005.

A–570–891: Hand Trucks and Certain Parts Thereof from the People's Republic of China
Requestor: Central Purchasing, LLC; accessory carts are within the scope of the antidumping duty order; June 3, 2005.

A–570–891: Hand Trucks and Certain Parts Thereof from the People's Republic of China
Requestor: Faultless Starch/Bon Ami Co.; RuXXac and RuXXac Long hand trucks are within the scope of the antidumping duty order; June 3, 2005.

Russian Federation

A–821–819: Magnesium Metal From the Russian Federation
Requestor: Leeds Specialty Alloys; Mg–15Zr magnesium master alloy, made in the Russian Federation by Solikamsk Magnesium Works, is within the scope of the antidumping duty order; May 31, 2005.

Multiple Countries

A–570–886: Polyethylene Retail Carrier Bags from the People's Republic of China; A–557–813: Polyethylene Retail Carrier Bags from Malaysia; A–549–821: Polyethylene Retail Carrier Bags from Thailand

Requestor: Dimensions Trading, Inc.; polyethylene sample bags are within the scope of the antidumping duty order; May 9, 2005.

Anticircumvention Determinations Completed Between April 1, 2005, and June 30, 2005:

None.

Scope Inquiries Terminated Between April 1, 2005, and June 30, 2005:

None.

Scope Inquiries Pending as of June 30, 2005:

People's Republic of China

A–570–502: Iron Construction Castings from the People's Republic of China
Requestor: A.Y. McDonald Mfg. Co.; whether certain cast iron articles (meter box frames, covers, extension rings; meter box bases, upper bodies, lids), if imported separately, are within the scope of the antidumping duty order; requested November 16, 2004.

A–570–890: Wooden Bedroom Furniture from the People's Republic of China
Requestor: Dorel Asia; whether certain infant furniture (i.e., infant (baby) changing tables, toy boxes or chests, infant (baby) armories, and toddler beds) is within the scope of the antidumping duty order; requested February 15, 2005.

A–570–868: Folding Metal Tables and Chairs from the People's Republic of China

Requestor: Spencer Gifts LLC; whether ''butterfly chairs'' are within the scope of the antidumping duty order; requested March 21, 2005.

A–570–890: Wooden Bedroom Furniture from the People's Republic of China
Requestor: Sunrise Medical Inc.; whether long–term care patient room furniture is within the scope of the antidumping duty order; requested March 25, 2005.

A–570–868: Folding Metal Tables and Chairs from the People's Republic of China

Requestor: Korhani of America; whether its ''wood–seated folding chair'' is within the scope of the antidumping duty order; requested April 28, 2005.

A–570–803: Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, from the People's Republic of China
Requestor: Avalanche Industries LLC; whether ''Smart Splitter'' is within the scope of the antidumping duty order; requested March 10, 2005; initiated May 12, 2005.

A–570–894: Certain Tissue Paper Products from the People's Republic of China
Requestor: Seaman Paper Company of Massachusetts, Inc. (MA); American Crepe Corporation (PA); Eagle Tissue LLC (CT); Flower City Tissue Mills Co. (NY); Garlock Printing &Converting, Inc. (MA); Paper Service Ltd. (NH); Putney Paper Co., Ltd. (VT); and the Paper, Allied–Industrial, Chemical and Energy Workers International Union AFL–CIO, CLC; whether certain tissue paper products are within the scope of the antidumping duty order when imported as part of a kit or set of goods that includes other non–subject items; requested June 7, 2005.

A–570–504: Petroleum Wax Candles from the People's Republic of China
Requestor: Kohl's Department Stores, Inc.; whether candles contained in a ceramic basket, which are in the shape of Easter eggs and painted with multiple Easter colors, are within the scope of the antidumping duty order; requested June 7, 2005.

Republic of Korea

C–580–851: Dynamic Random Access Memory Semiconductors from the Republic of Korea
Requestor: Cisco Systems, Inc.; whether removable memory modules placed on motherboards that are imported for repair or refurbishment are within the scope of the countervailing duty order;

requested December 29, 2004; initiated February 4, 2005.

Russian Federation

A–821–802: Antidumping Suspension Agreement on Uranium
Requestor: USEC, Inc. and its subsidiary, United States Enrichment Corporation; whether enriched uranium located in Kazakhstan at the time of the dissolution of the Soviet Union is within the scope of the order; requested August 6, 1999.

Vietnam

A–552–801: Certain Frozen Fish Fillets From the Socialist Republic of Vietnam
Requestor: Piazza Seafood World LLC; whether certain basa and tra fillets from Cambodia which are a product of Vietnam are not included within the antidumping duty order; requested May 12, 2004; initiated October 22, 2004.

Anticircumvention Inquiries Pending as of June 30, 2005:

People's Republic of China

A–570–504: Petroleum Wax Candles from the People's Republic of China
Requestor: National Candle Association; whether imports of palm and vegetable–based wax candles from the PRC can be considered later–developed merchandise which is now circumventing the antidumping duty order; requested October 8, 2004; initiated February 25, 2005.
A–570–504: Petroleum Wax Candles from the People's Republic of China
Requestor: National Candle Association; whether imports of palm and vegetable–based wax candles from the PRC can be considered a minor alteration to the subject merchandise for purposes of circumventing the antidumping duty order; requested October 12, 2004; initiated February 25, 2005.

Vietnam

A–552–801: Certain Frozen Fish Fillets From the Socialist Republic of Vietnam
Requestor: Catfish Farmers of America and certain individual U.S. catfish processors; whether imports of frozen fish fillets from Cambodia made from live fish sourced from Vietnam, and falling within the scope of the order, can be considered ''merchandise completed or assembled in other foreign countries'' and are circumventing the antidumping duty order; requested August 20, 2004; initiated October 22, 2004.

Scope Rulings Inadvertently Omitted from Prior Published Lists:

A–570–803: Heavy Forged Hand Tools, Finished or Unfinished, With or Without Handles, from the People's Republic of China
Requestor: Olympia Group Inc.; whether pry bars, with a bar length under 18 inches, are within the scope of the antidumping duty order; initiated December 20, 2004; terminated due to lack of information on March 7, 2005.

Interested parties are invited to comment on the completeness of this list of pending scope and anti–circumvention inquiries. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Import Administration, International Trade Administration, 14th Street and Constitution Avenue, NW, Room 1870, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o) of the Department's regulations.

Dated: September 14, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 05–18712 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091405D]

Mid-Atlantic Fishery Management Council (MAFMC); Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council), its Research Set-Aside Committee, its Joint Spiny Dogfish Committee, its Ecosystems Committee, its Law Enforcement Committee, its Atlantic Mackerel, Squid, Butterfish Committee, and its Executive Committee will hold public meetings.

DATES: The meetings will be held from Tuesday, October 4, 2005, through Thursday, October 6, 2005. See **SUPPLEMENTARY INFORMATION** for more detailed information regarding the meeting agenda.

ADDRESSES: This meeting will be held at the Southampton Inn, 91 Hill Street, Southampton, NY, telephone 631–283–6500.

Council address: Mid-Atlantic Fishery Management Council, 300 S. New Street, Dover, DE 19904, telephone 302–674–2331.

FOR FURTHER INFORMATION CONTACT: Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council; telephone: 302–674–2331, ext. 19.

SUPPLEMENTARY INFORMATION: Agenda items for the Council's committees and the Council itself are: Meeting of the Research Set-Aside Committee will review, discuss and establish 2007 priorities and project selection criteria. The Committee will also review the NMFS grants review/approval process. The Joint Dogfish Committee will discuss, develop and adopt 2006/2007 quotas and associated management measures. The Ecosystems Committee will review comments and feedback on the Council's ecosystems scoping document; and, develop and provide comments on H.R. 2939. The Law Enforcement Committee will meet to review Fisheries Achievement Award nominations. The swearing in of new and reappointed Council members and the election of Council Officers will take place following lunch. The Council will review the Joint Spiny Dogfish Committee's recommendations, develop and adopt quota and associated management measures for the 2006/2007 fishing year. NMFS will make a presentation on its proposed rule to consolidate its Atlantic Highly Migratory Species Fishery Management Plan. An Ecosystems Scoping meeting will be held at 7 p.m. The Atlantic Mackerel, Squid, Butterfish Committee will meet to review Amendment 9, receive updates on Amendment 10, and address developing a butterfish rebuilding schedule under Framework 5 to the FMP. The Council will address Framework 6 and priorities for Amendment 14 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan. The Council will also conduct its regular business session to approve minutes and receive reports. The Executive Committee will meet to develop and adopt its annual work plan for 2006. The Council will then convene to receive a NMFS presentation on law enforcement issues, a New England Council presentation on Habitat Areas of Particular Concern (HAPCS), and address any continuing or new business.

Meeting Agenda

On Tuesday, October 4, the Research Set-Aside Committee will meet from 8 - 10 a.m. Concurrent sessions of the Joint Dogfish Committee and the Ecosystems Committee will meet from 10 a.m.-12 noon. The Law Enforcement Committee will meet from 1–1:30 p.m. The Council will convene at 1:30 p.m. at which time new and reappointed Council members will take their oaths of

office. The election of Council Officers will occur from 1:30–1:45 p.m. From 1:45 -4 p.m., the Council will meet to adopt dogfish specifications for the 2006/2007 fishing year. From 4 p.m. until 5:30 p.m., the Council will receive a presentation from NMFS officials regarding its proposed rule to consolidate its Atlantic Highly Migratory Species FMP. An Ecosystems Scoping meeting will be held from 7 -8 p.m.

On Wednesday, October 5, the Atlantic Mackerel, Squid, Butterfish Committee will meet from 8–11 a.m. The Council will convene at 11 a.m. to address Summer Flounder, Scup, and Black Sea Bass issues and conduct its regular business activities.

On Thursday, October 6, the Executive Committee will meet from 8–9 a.m. and the Council will convene at 9 a.m. until approximately 1 p.m. to receive third party reports and presentations, and address any continuing or new business.

Although non-emergency issues not contained in this agenda may come before the Council for discussion, these issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final actions to address such emergencies.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at least 5 days prior to the meeting date.

Dated: September 14, 2005.

Alan D. Risenhoover,

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

[FR Doc. E5–5121 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091405A]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Groundfish Oversight Committee will meet to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Wednesday, October 5, 2005, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn, 31 Hampshire Street, Mansfield, MA 02048; telephone: (508) 339-2200.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978)465-0492.

SUPPLEMENTARY INFORMATION: The items of discussion in the committee's agenda are as follows:

Wednesday, October 5, 2005

The committee will meet to continue development of Framework Adjustment 42 to the Northeast Multispecies Fishery Management Plan. The Committee will review the results of recent groundfish assessments and will consider changes to management measures that may be necessary to achieve Amendment 13 mortality objectives. These changes may include, but are not limited to, changes in days-at-sea, closed areas, possession limits, or gear requirements. Changes may be considered to the regulations for both commercial and recreational vessels. The committee will consider a report from the Groundfish Plan Development Team when developing these alternatives. The Committee's decisions will be forwarded to the Council at a future meeting.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: September 14, 2005.

Alan D. Risenhoover,

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

[FR Doc. E5–5124 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091405B]

North Pacific Fishery Management Council; Notice of Public Meetings

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

ACTION: Notice of meetings of the North Pacific Fishery Management Council and its advisory committees.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will hold public meetings October 5 through 11, 2005, at the Anchorage Hilton Hotel, 500 West 3rd Avenue, Anchorage, AK.

DATES: The Council's Advisory Panel (AP) will begin at 8 a.m., Monday, October 3 and continue through Friday October 7, 2005. The Scientific and Statistical Committee (SSC) will begin at 8 a.m. on Monday October 3 and continue through Wednesday, October 5, 2005.

The Council will begin its plenary session at 8 a.m. on Wednesday, October 5, continuing through October 11, 2005. All meetings are open to the public except executive sessions. The Enforcement Committee will meet Tuesday, October 4, from 1 to 5 pm.

ADDRESSES: Anchorage Hilton Hotel, 500 West 3rd Avenue, Anchorage, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Council staff, Phone: 907–271–2809.

SUPPLEMENTARY INFORMATION:

Council Plenary Session

The agenda for the Council's plenary session will include the following issues. The Council may take appropriate action on any of the issues identified.

1. Reports

Executive Director's Report (including report on freezer longline buyback and report on SSC operations per peer review requirements)

NMFS Management Report (includes update on Amendment 79)

U.S. Coast Guard Report

Alaska Department of Fish & Game (ADF&G) Report

U.S. Fish & Wildlife Service Report

Protected Species Report (Report on Right Whale critical habitat designation; receive report on Board of Fisheries/North Pacific Fishery Management Council pollock fishery subcommittee; update on Endangered Species Act (ESA) Salmon consultation; Fishery Management Plan (FMP) level Biological Opinion (BiOp) discussion/schedule)

2. Halibut Charter

Guideline Harvest Levels (GHLs) Status Report and action as necessary. Review Halibut Charter Individual Fishing Quotas (IFQ) letter from Dr. Hogarth.

3. Community Development Quotas (CDQ) Issues

Initial review of Environmental Assessment/Regulatory Impact Review (EA/RIR) on management CDQ reserves; report from Blue Ribbon Panel, update on Amendment 71 and status on CDQ allocation process and action as necessary.

4. Improved Retention/Improved Utilization (IR/IU)

Initial review of Amendment 80 Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) (Head and Gut Cooperatives); Select preliminary preferred alternative.

5. Bering Sea Aleutian Islands (BSAI) Salmon Bycatch

Final action on EA/RIR for Amendment 84; Discuss package B; review alternatives and timelines for analysis; SSC workshop on salmon stock ID; review cooperative salmon research.

6. BSAI Pacific Cod Allocations

Review alternatives, components, and options, action as necessary.

7.Gulf of Alaska (GOA) Groundfish Rationalization

Review preliminary community data; review other data and information and revise alternatives/options as appropriate; review crab and salmon bycatch data, alternatives, and options.

8. Bairdi Crab Split

Final action on amendment.

9. Halibut/Sablefish IFQ Program

Initial review of omnibus amendment package (T).

10. Groundfish Management

Initial review EA and proposed specifications for 2006/07, Review Stock Assessment Fishery Evaluation (SAFE) ecosystem chapter, Rockfish Management, review discussion paper (T); Review discussion paper on BSAI pollock A-season start date; Review strawman problem statement and alternatives for Bering Sea Habitat Conservation/Essential Fish Habitat. (T)

11. Ecosystem Approaches

Status report on Aleutian Island Fishery Ecosystem Plan and Ecosystem Approach Management.

12. Crab Management

Review SAFE report for Crab Management.

13. Staff Tasking

14. Other Business

The SSC agenda will include the following issues:

1. SSC Operations
2. IR/IU
3. BSAI Salmon Bycatch
4. CDQ Issues
5. Halibut/Sablefish IFQs
6. Groundfish Management
7. Ecosystem Approaches
8. Crab Management

The Advisory Panel will address the same agenda issues as the Council.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at 907–271–2809 at least 7 working days prior to the meeting date.

September 14, 2005.

Alan D. Risenhoover,

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

[FR Doc. E5–5122 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091405C]

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Council) Highly Migratory Species Management Team (HMSMT) and Ad Hoc Highly Migratory Species Management Committee (HMSMC) will hold work sessions, which are open to the public.

DATES: The HMSMT work session will be Monday, October 3, 2005, from 8 a.m. until 5 p.m. On Tuesday, October 4, 2005, beginning at 8 a.m. until business is completed, the HMSMT will hold a joint work session with the HMSMC. The HMSMT may continue its own work on Tuesday after the joint session ends, time permitting.

ADDRESSES: The work sessions will be held at the National Marine Fisheries Service, Southwest Fisheries Science Center, Large Conference Room, 8604 La Jolla Shores Drive, Room D–203, La Jolla, CA 92037, (858) 546–7000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Fishery Management Council (503) 820–2280.

SUPPLEMENTARY INFORMATION: The main purpose of the HMSMT work session is to further develop a preliminary range of alternatives for the modification of the annual August 15 through November 15 prohibition on drift gillnet fishing in federal and state waters in Monterey Bay, California and vicinity north to the 45 N latitude intersect with the Oregon Coast (66 FR 44549). The HMSMT discussed preliminary concepts for alternatives at their August 3–5, 2005, meeting. At this meeting they will further develop these alternatives and review available analyses. These alternatives will then be presented to the Council at their October 31–November 4, 2005, meeting, when the Council will consider adopting a range of alternatives for public review.

The purpose of the joint session of the HMSMT and HMSMC is to consider initial proposals which would allow prosecution of a pelagic longline fishery for swordfish while not increasing the overall incidental take of Endangered Species Act-listed sea turtles. These work sessions are for the purpose of developing information for the Council's consideration at a future Council meeting; no management actions will be decided by the HMSMT or HMSMC at these work sessions.

Although nonemergency issues not contained in the meeting agendas may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that

require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820–2280 at least five days prior to the meeting date.

Dated: September 14, 2005.

Alan D. Risenhoover,

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

[FR Doc. E5–5123 Filed 9–19–05; 8:45 am]

BILLING CODE 3510–22–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the proposed renewal of its Volunteer Service Hour Tracking Tool (Record of Service). The Record of Service was established in 2002 as a tool to help Americans answer the President's call to service and keep track of their volunteer service hours.

Copies of the information collection requests can be obtained by contacting the office listed in the address section of this notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by November 21, 2005.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Office of Public Affairs; Attention Kari Dunn, Executive Director, President's Council on Service and Civic Participation; 1201 New York Avenue, NW., Washington, DC, 20525.

(2) By hand delivery or by courier to the Corporation's mailroom at Room 8410 at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

(3) By fax to: (202) 606–3460, Attention Kari Dunn, Executive Director, President's Council on Service and Civic Participation.

(4) Electronically through the Corporation's e-mail address system: *kdunn@cns.gov*.

FOR FURTHER INFORMATION CONTACT: Kari Dunn, (202) 606–6708, or by e-mail at *kdunn@cns.gov*.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.*, permitting electronic submissions of responses).

Background

In January of 2002, in his State of the Union Address, President Bush called on all Americans to dedicate 4,000 hours or two years of their lives to volunteer service. He created the USA Freedom Corps, a coordinating office at the White House, to oversee these efforts and to bring increased attention to the ways in which the Administration could work together to enhance opportunities for all Americans to serve their neighbors and their nation. The response has been positive. Last year, 64.5 million Americans volunteered, an increase of more than 5 million since 2002.

In support of the President's call to service, the Corporation created an electronic Record of Service to provide the general public a way to track their service activities and individually record their volunteer service hours. Use of this tracking tool is 100 percent electronic in that users establish a user ID and password that automatically creates an account which is only accessible to that individual user. The Record of Service can only be updated by the user who established the account. The Record of Service has received heavy public use and is a primary way for individuals to track their eligibility for the President's Volunteer Service Award.

Individuals may link to this tracking tool through the USA Freedom Corps Web site at *http://www.usafreedomcorps.gov* or the President's Volunteer Service Award Web site at, *http://www.presidentialserviceawards.gov*.

Current Action

The Corporation seeks to renew the current Record of Service. The Record of Service will be used in the same manner as the existing Record of Service.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Volunteer Service Hour Tracking Tool.

OMB Number: 3045–0077.

Agency Number: None.

Affected Public: General Public.

Total Respondents: 100,000.

Frequency: On occasion.

Average Time Per Response: 3 minutes.

Estimated Total Burden Hours: 5,000 hours.

Total Burden Cost (Capital/Startup): None.

Total Burden Cost (Operating/Maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: September 13, 2005.

Sandy Scott,

Acting Director, Office of Public Affairs.

[FR Doc. 05–18611 Filed 9–19–05; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Notice of Intent To Prepare an Environmental Impact Statement/ Environmental Impact Report for the Ballona Creek Ecosystem Restoration Feasibility Study, Los Angeles County, CA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The Los Angeles District intends to prepare an Environmental Impact Statement/Environmental Impact Report (EIS/EIR) to support a cost-shared ecosystem restoration feasibility study with the Santa Monica Bay Restoration Commission. The proposed project study areas has been degraded by encroachment of non-native plants, placement of fill from Marina Del Rey, interruption of the hydrologic regime, trash accumulation, and varied attempts at bank protection along the creek using rock and concrete. Direct benefits of the proposed project include improved habitat and water quality, reductions in waste and trash, and aesthetics. The watershed is an important resource for both recreational uses and for fish, and wildlife and further degradation could jeopardize remaining. The purpose of the feasibility study is to evaluate alternatives for channel modification, habitat restoration (coastal and freshwater wetlands and riparian), recreation, and related purposes along the lower reach of the Ballona Creek.

DATES: A public scoping meeting will be held on September 29, 2005 at 6 p.m.

ADDRESSES: U.S. Army Corps of Engineers, Los Angeles District, CESPL–PD, P.O. Box 532711, Los Angeles, CA 90053 and Santa Monica Bay Restoration Commission, 320 West 4th Street, Los Angeles, CA 90013.

FOR FURTHER INFORMATION CONTACT: Shannon Dellaquila, Project Environmental Manager, at (213) 452–3850 or Malisa Martin, Project Study Manager at (213) 452–3828.

SUPPLEMENTARY INFORMATION:

1. Authorization

This study was prepared as an interim response to the following authorities provided by Congress under Section 216 of the Flood Control Act of 1970, which states:

> The Secretary of the Army, acting through the Chief of Engineers, is authorized to review the operation of projects the construction of which has been completed and which were constructed by the Corps of Engineers in the interest of navigation, flood control, water supply, and related purposes, when found advisable due the significantly changed physical or economic conditions, and to report thereon to Congress with recommendations on the advisability of modifying the structures or their operation, and for improving the quality of the environment in the overall public interest;

supplemented by House Resolution on Public Works and Transportation dated September 28, 1994 which states:

> The Secretary of the Army is requested to review the report of the Chief of Engineers on Playa del Rey Inlet and Basin, Venice, California, published as House Document 389, Eighty-third Congress, Second Session, and other pertinent reports, to determine whether modifications of the recommendations contained therein are advisable at present time, in the interest of navigation, hurricane and storm damage reduction, environmental restoration, and other purposes at Marina del Rey Harbor, Los Angeles, California, with consideration given to disposal of contaminated sediments from the entrance channel required under the existing operation and maintenance program at Marina del Rey.

2. Background

The Ballona Creek Ecosystem Restoration study area lies within Los Angeles County, CA and includes portions of Marina del Rey, Culver City, Playa del Rey, and the City of Los Angeles. The study area, a component of the greater Ballona Creek Watershed, includes the lower reach of Ballona Creek extending southwest from Cochran Avenue, in Los Angeles, to Pacific Ocean in Marina del Rey. specific features of the Ballona Creek watershed, including existing and historic wetland areas, the Ballona Lagoon, Del Rey Lagoon, Venice Canal, Grand Canal, the Oxford Drain and the Ballona Channel and tributaries, will be addressed in this study.

The greater Ballona Creek system drains a watershed of approximately 329 square kilometers (81,300 acres), and is the largest tributary that drains into the Santa Monica Bay. Ballona Creek collects runoff from several partially urbanized canyons on the south slopes of the Santa Monica Mountains as well as from intensely urbanized areas of West Los Angeles, Culver City, Beverly Hills, Hollywood, and parts of Central Los Angeles. The urbanized areas account for 80 percent of the watershed area, and the partially developed foothills and mountains make up the remaining 20 percent. The watershed boundary includes the Santa Monica Mountains on the north, the unincorporated area known as Baldwin Hills, and the City of Inglewood on the south.

The Ballona Creek Ecosystem Restoration study footprint's southern boundary is defined by the Westcheste Bluffs, which run southwest from the San Diego (405) Freeway beyond Loyola Marymount University. The western boundary extends from the Pacific Ocean. The eastern boundary begins where Ballona Creek daylights at Cochran Avenue and Venice Boulevard in a section of Los Angeles known as the Mid City. Tributaries of Ballona Creek include Centinela Creek, Sepulveda Canyon Channel, Benedict Canyon Channel, and numerous storm drains.

The Ballona Creek watershed ecosystem has been altered by intense land development, encroachment of non-native plants, trash accumulation, and varied attempts at bank protection along the creek using rock and concrete. Although an important function of the Ballona Creek is as a flood control channel, the lower watershed is still an important resource for both recreational uses and for fish and wildlife habitat. Further impairment could jeopardize remaining habitat. This study will evaluate opportunities for habitat restoration (including wetland and riparian habitat), improvements to water quality, trash mitigation, and recreation and related purposes along the lower reach of the Ballona creek.

3. Problems and Needs

At least ninety (90) percent of historic coastal wetlands in California have been lost due to filing, dredging, flood control and intensive development. Within the Lower Ballona Creek Watershed, remaining fragmented wetland areas have been degraded due to diminished hydraulic function, poor water quality and introduction of exotic plants and animals. While functioning wetland systems and riparian habitat remain, they are stressed.

- Channelization of the Ballona Creek and filling of historic wetland and riparian areas have contributed to degradation and loss of habitat due to impeded tidal exchange and circulation.
- Contaminated stormwater runoff and trash loading has degraded Ballona Creek water quality.
- Habitat alteration and loss has decreased biodiversity and overall ecological health, threatening the survival of native endangered species such as the California least tern (Sterna antillarum brown), snowy plover (Charadrius alexandrinus), and the Belding's Savannah Sparrow (Sandwichensis beldingi).
- The current design of the Flood Control channel has resulted in a lack

of recreational opportunities and is considered aesthetically challenged.

• At present there is no integrated approach and partnership amongst stakeholders to resolve lower Ballona Creek in-stream and wetland degradation issues, which has led to uncoordinated and sometimes redundant and unsuccessful improvement measures.

4. Proposed Action and Alternative

The Los Angeles District will investigate and evaluate all reasonable alternatives to address the problems and need stated above. In addition to a without project (No Action) Alternative, both structural and non-structural environmental measures will be investigated. An assessment of the feasibility of removing impervious surfaces from the Ballona Channel will also be evaluated. Proposed restoration measures include: re-grading and removal of fill, remove invasive and non-native plant species, reintroduction of a water source and installation of native plants to restore previously filled coastal wetlands. Other measures to be evaluated include features to improve or restore tidal regime in Oxford Basin, the Grand and Venice canals, and Ballona and Del Rey Lagoons; the potential for in stream wetland development in Centinela, Sepulveda and Ballona Creek; sediment loading in the upper watershed; and related recreation and educational opportunities.

5. Scoping Process

The scoping process is on-going, and has involved preliminary coordination with Federal, State, and local agencies and the general public. A public scoping meeting is scheduled for Thursday September 29th from 6–8 p.m. at the Rotunda Room of the Veteran's Memorial Building, 4117 Overland Avenue, Culver City, CA. This information is being published in the local news media, and a notice is being mailed to all parties on the study mailing list to ensure that public will have an opportunity to express opinions and raise any issues relating to the scope of the Feasibility Study and the Environmental Impact Study/ Environmental Impact Report. The public as well as Federal, state, and local agencies are encouraged to participate by submitting data, information, and comments identifying relevant environmental and socioeconomic issues to be addressed in the study. Useful information includes other environmental studies, published and unpublished data, alternatives that could be addressed in the analysis, and, potential mitigation measures associated with the proposed action. All comments will be considered in the project development. Concerns may be submitted in writing to the Santa Monica Bay Restoration Commission, or to the Los Angeles District (*see* **ADDRESSES**). Comments, suggestions, and request to be placed on the mailing list for announcements should be sent to MaLisa Martin (*see* **ADDRESSES**) or by e-mail to *MaLisa.M.Martin@ sp101.usace.army.mil.*

Availability of the Draft EIS/EIR

The Draft EIS/EIR is scheduled to be published and circulated in December 2007, and a public hearing to receive comments on the Draft EIS/EIR will be held after it is published.

Dated: September 13, 2005.

Alex C. Dornstauder,

Colonel, U.S. Army, District Engineer.

[FR Doc. 05–18651 Filed 9–19–05; 8:45 am]

BILLING CODE 3710–KF–M

DEPARTMENT OF DEFENSE

Department of the Army

Advisory Committee Meeting Notice

AGENCY: Department of the Army, DOD.

ACTION: Notice of meeting.

SUMMARY: In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following meeting:

Name of Committee: Distance Learning/Training Technology Applications Subcommittee of the Army Education Advisory Committee.

Date: October 5–6, 2005.

Place: Crowne Plaza Williamsburg at Fort Magruder, Williamsburg, VA.

Time: 0800–1630 on 5 Oct 05; 0800–1630 on 6 Oct 05.

Proposed Agenda: The meeting agenda includes updates on The Army Distributed Learning Program (TADLP) and infrastructure, review of selected courseware, and discussions focused on learning and technology.

Purpose of the Meeting: To provide for the continuous exchange of information and ideas for distance learning between the HQ, U.S. Army Training and Doctrine Command (TRADOC), Department of the Army, and the academic and business communities.

FOR FURTHER INFORMATION CONTACT: All communications regarding this subcommittee should be addressed to Mr. Mike Faughnan, at Headquarters TRADOC, Deputy Chief of Staff for Operations and Training, ATTN: ATTG–CF (Mr. Faughnan), Fort Monroe, VA 23651–5000; e-mail *faughnanm@monroe.army.mil.*

SUPPLEMENTARY INFORMATION: Meeting of the advisory committee is open to the public. Because of restricted meeting space, attendance will be limited to those persons who have notified the Advisory Committee Management Office in writing, at least 5 days prior to the meeting, of their intention to attend. Contact Mr. Faughnan (*faughnanm@monroe.army.mil*) for meeting agenda and specific locations.

Any member of the public may file a written statement with the committee before, during, or after the meeting. To the extent that time permits, the committee chairman may allow public presentations or oral statements at the meeting.

Robert E. Seger,

Senior Executive Service, Assistant Deputy Chief of Staff for Operations and Training.

[FR Doc. 05–18649 Filed 9–19–05; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Department of Defense Historical Advisory Committee; Meeting

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L 92–463), announcement is made of the following committee meeting:

Name of Committee: Department of Defense Historical Advisory Committee.

Date: October 27, 2005.

Time: 9 a.m. to 4:30 p.m.

Place: U.S. Army Center of Military History, Collins Hall, Building 35, 103 Third Avenue, Fort McNair, DC 20319–5058.

Proposed Agenda: Review and discussion of the status of historical activities in the United States Army.

FOR FURTHER INFORMATION CONTACT: Dr. Jeffrey J. Clarke, U.S. Army Center of Military History, ATTN: DAMH–ZC, 103 Third Avenue, Fort McNair, DC 20319–5058; telephone number (202) 685–2709.

SUPPLEMENTARY INFORMATION: The committee will review the Army's historical activities for FY 2005 and those projected for FY 2006 based upon reports and manuscripts received throughout the period. And the committee will formulate recommendations through the Chief of

Military History to the Chief of Staff, Army, and the Secretary of the Army for advancing the use of history in the U.S. Army.

The meeting of the advisory committee is open to the public. Because of the restricted meeting space, however, attendance may be limited to those persons who have notified the Advisory Committee Management Office in writing at least five days prior to the meeting of their intention to attend the October 27, 2005 meeting.

Any members of the public may file a written statement with the committee before, during, or after the meeting. To the extent that time permits, the committee chairman may allow public presentations or oral statements at the meeting.

Dated: August 29, 2005.

Jeffrey J. Clarke,

Chief Historian.

[FR Doc. 05–18650 Filed 9–19–05; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 20, 2005.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: September 13, 2005.

Angela C. Arrington,

Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.

Title: Case Service Report.

Frequency: Annually.

Affected Public: State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 80.

Burden Hours: 3,600.

Abstract: As required by Sections 13, 101(a)(10), 106 and 626 of the Rehabilitation Act, the data are submitted annually by State VR agencies. The data contain personal and program-related characteristics, including economic outcomes of persons with disabilities whose case records are closed.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2786. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address *Sheila.Carey@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 05–18603 Filed 9–19–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before November 21, 2005.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.,* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility,

and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: September 15, 2005.

Angela C. Arrington,

Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: Revision.

Title: Consolidated State Performance Report.

Frequency: Annually.

Affected Public: State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden: Responses: 14,652. *Burden Hours:* 61,449.

Abstract: This information collection package contains the Consolidated State Performance Report (CSPR). It collects data that is required under section 1111 of the No Child Left Behind Act (NCLB) which mandates the requirements for the Secretary's report to Congress and information necessary for the Secretary to report on the Department's Government Performance and Results Act (GPRA) indicators.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2872. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to (202) 245–6621. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her e-mail address *Kathy.Axt@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 05–18679 Filed 9–19–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–662–000]

ANR Pipeline Company; Notice of Service Agreement Filing

September 13, 2005.

Take notice that on September 9, 2005 ANR Pipeline Company (ANR), tendered for filing and approval, amendments to three previously approved non-conforming service agreements (Amendments) extending the term of the agreements between ANR and Constellation Newenergy—Gas Division WI pursuant to ANR's Rate Schedule FTS–1. ANR requests the Commission accept the Amendments effective October 31, 2005.

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 and 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. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

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.

Intervention and Protest Date: 5 p.m. Eastern Time on September 21, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5133 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–663–000]

ANR Pipeline Company; Notice of Service Agreement Filing

September 13, 2005.

Take notice that on September 9, 2005 ANR Pipeline Company (ANR) tendered for filing and approval, one non-conforming service agreement (Agreement) between ANR and Constellation Newenergy—Gas Division WI pursuant to ANR's Rate Schedule FTS–1. ANR requests the Commission accept the Agreement effective November 1, 2005.

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 and 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. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

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 online 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.

Intervention and Protest Date: 5 p.m. Eastern Time on September 21, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5134 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Non-Project Use of Project Lands and Soliciting Comments, Motions To Intervene, and Protests

September 13, 2005.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Project Use of Project Lands.

b. *Project No:* 1490–040.

c. *Date Filed:* August 24, 2005.

d. *Applicant:* Brazos River Authority.

e. *Name of Project:* Morris Sheppard Project.

f. *Location:* The project is located on the Possum Kingdom Reservoir on the Brazos River in Palo Pinto County, Texas. This project does not occupy any federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r) and 799 and 801.

h. *Applicant Contact:* Mr. Phillip J. Ford, General Manager/CEO, Brazos River Authority, 4600 Cobbs Drive, P. O. Box 7555, Waco, TX, 76714–7555, (254) 761–3100.

i. *FERC Contacts:* Any questions on this notice should be addressed to Mr. Jon Cofrancesco at (202) 502–8951, or e-mail address: *jon.cofrancesco@ferc.gov.*

j. *Deadline for Filing Comments and or Motions:* September 30, 2005.

All Documents (Original and Eight Copies) Should be Filed With: Ms. Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. Please include the project number (P–1490–040) on any comments or motions filed. Comments, protests, and interventions 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 e-filings.

k. *Description of the Application:* On August 24, 2005, the Brazos River Authority filed a request seeking Commission approval to authorize an existing, 21-slip marina owned and operated by the Ranch Owners' Association. No new construction is proposed.

l. *Location of the Application:* The filing is available for review at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, 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, please contact FERC Online support at *FERCOnLineSupport@ferc.gov* or toll free (866) 208–3676 or TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments:* Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions 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 at *http://www.ferc.gov* under the ''e-Filing'' link.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5126 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–618–000]

Colorado Interstate Gas Company; Notice of Proposed Changes in FERC Gas Tariff

September 13, 2005.

Take notice that on August 31, 2005, Colorado Interstate Gas Company (CIG) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheet to become effective October 1, 2005:

Thirty-Eighth Revised Sheet No. 11A

CIG states that copies of its filing have been sent to all firm customers, interruptible customers, and affected state commissions.

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 and 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. Such notices, motions, or protests must be filed in accordance with the provisions of § 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

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 online 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 email 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5132 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

(866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5129 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

(866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5131 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–391–001]

Guardian Pipeline, LLC; Notice of Compliance Filing

September 13, 2005.

Take notice that on September 2, 2005, Guardian Pipeline, LLC (Guardian) tendered for filing to become part of Guardian Pipeline, LLC's FERC Gas Tariff, Original Volume No. 1, the following tariff sheets to become effective September 1, 2005:

Substitute Fourth Revised Sheet No. 103
Substitute Fifth Revised Sheet No. 109
First Revised Sheet No. 145
First Revised Sheet No. 146
Substitute Second Revised Sheet No. 217
Substitute Original Sheet No. 217A

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online 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

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–511–001]

OkTex Pipeline Company; Notice of Proposed Change in FERC Gas Tariff

September 13, 2005.

Take notice that on August 11, 2005, OkTex Pipeline Company (OkTex), filed a substitute tariff sheet in compliance with the Commission's directives in Docket No. RP05–511. OKTex has requested an effective date of September 1, 2003.

OkTex states that copies of the filing have been mailed to all affected customers and state regulatory commissions.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–664–000]

OkTex Pipeline Company; Notice of Annual Charge Adjustment

September 13, 2005.

Take notice that on September 9, 2005, OkTex Pipeline Company (OkTex) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, with an effective date of October 1, 2005:

5th Revised Sheet No. 5A
3rd Revised Sheet No. 5B
2nd Revised Sheet No. 5C

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 and 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. Such notices, motions, or protests must be filed in accordance with the provisions of §n 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

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 online 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5135 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–455–001]

Sabine Pipe Line LLC; Notice of Compliance Filing

September 13, 2005.

Take notice that on August 25, 2005, Sabine Pipe Line LLC (Sabine) submitted a compliance filing pursuant to the Commission's Letter Order issued August 12, 2005 in Docket No. RP05–455–000.

Sabine states that copies of the filing were served on parties on the official service list in the above-captioned proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of § 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests 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 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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5130 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–665–000]

Trunkline Gas Company, LLC; Notice of Annual Report of Flow Through of Cash Out and Penalty Revenues

September 13, 2005.

Take notice that on September 12, 2005, Trunkline Gas Company, LLC (Trunkline) submitted its Annual Report of Flow Through of Cash Out and Penalty Revenues.

Trunkline states that copies of the filing are being served on affected customers and applicable state regulatory agencies.

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 and 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. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

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 online 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.

Intervention and Protest Date: 5 Eastern Time on September 21, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5136 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–150–000]

Richard Blumenthal, Attorney General for the State of Connecticut, the Connecticut Office of Consumer Counsel, the Connecticut Municipal Electric Energy Cooperative and the Connecticut Industrial Energy Consumers v. ISO–New England, Inc.; Notice of Complaint Requesting Fast Track Processing

September 13, 2005.

Take notice that on September 12, 2005, Richard Blumenthal, Attorney General for the State of Connecticut (CTAG), the Connecticut Office of Consumer Counsel (CT OCC), the Connecticut Municipal Electric Energy Cooperative (CMEEC) and the Connecticut Industrial Energy Consumers (CICE) (collectively, Connecticut Representatives) filed a formal complaint against ISO–New England, Inc. (ISO–NE) pursuant to section 206 of the Federal Power Act and Rule 206 of the Commission's Rules of Practice and Procedure, seeking to amend the ISO–NE's Market Rule 1 with regard to the compensation of electric generation facilities in Connecticut.

The Connecticut Representatives certify that copies of the complaint were served on the contacts for SIO–NE 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 and 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. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

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 October 3, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5137 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF05–10–000]

Northern Star Natural Gas LLC; Notice of Intent To Prepare an Environmental Impact Statement for the Bradwood Landing LNG Project, Request for Comments on Environmental Issues, and Notice of a Joint Public Meeting, and Site Visit

September 13, 2005.

The Federal Energy Regulatory Commission (FERC or Commission) and the U.S. Department of Homeland Security, U.S. Coast Guard (Coast Guard) are in the process of evaluating the Bradwood Landing Liquefied Natural Gas (LNG) Project planned by Northern Star Natural Gas LLC (Northern Star). The project would consist of an onshore LNG import and storage terminal, located about 38 miles up the Columbia River from its mouth, in Clatsop County, Oregon, and an approximately 34-mile-long natural gas sendout pipeline, extending from the terminal through Columbia County, Oregon, to an interconnection with the Williams Northwest Pipeline (Williams Northwest) system in Cowlitz County, Washington.

As a part of this evaluation, FERC staff will prepare an environmental impact statement (EIS) that will address the environmental impacts of the project and the Coast Guard will assess the safety and security of the project. As described below, the FERC and the Coast Guard will hold a joint public meeting to allow the public to provide input to these assessments.

The Commission will use the EIS in its decision-making process to determine whether or not to authorize the project. This Notice of Intent (NOI) explains the scoping process we [1] will use to gather information on the project from the public and interested agencies and summarizes the process that the Coast Guard will use. Your input will help identify the issues that need to be evaluated in the EIS and in the Coast Guard's safety and security assessment.

The FERC will be the lead Federal agency in the preparation of an EIS that will satisfy the requirements of the National Environmental Policy Act (NEPA). The Coast Guard and the U.S. Army Corps of Engineers will serve as cooperating agencies during preparation of the EIS. In addition, we have invited the U.S. Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service; the U.S. Environmental Protection Agency; the U.S. Department of the Interior, Fish and Wildlife Service; the Oregon Department of Energy; and the Washington Department of Ecology to serve as cooperating agencies in preparation of the EIS.

Comments on the project may be submitted in written form or verbally. Further details on how to submit written comments are provided in the Public Participation section of this NOI. In lieu of sending written comments, we invite you to attend the public scoping meeting scheduled as follows:

Thursday, September 29, 2005, 7 p.m. (PST), Knappa High School, 41535 Old Highway 30, Astoria, OR 97102, 503–458–6166.

The public scoping meeting listed above will be combined with the Coast Guard's public meetings regarding the safety and security of the project. At the meeting, the Coast Guard will discuss: (1) the waterway safety assessment that it will conduct to determine whether or not the waterway can safely accommodate the LNG carrier traffic and operation of the planned LNG marine terminal; and (2) the security assessment it will conduct in accordance with the requirements of the Maritime Transportation Security Act. The Coast Guard will issue a separate meeting notice for the safety and security aspects of the project.

This NOI is being sent to Federal, state, and local government agencies; elected officials; affected landowners; environmental and public interest groups; Indian tribes and regional Native American organizations; commentors and other interested parties; and local libraries and newspapers. We encourage government representatives to notify their constituents of this planned project and encourage them to comment on their areas of concern.

Site Visit

Also, on Thursday, September 29, 2005, starting at 9 a.m., we will be conducting a site visit to view selected points along the proposed pipeline route, and the location of the LNG import terminal. Anyone interested in participating in the site visit should meet at the parking lot for the Cowlitz County Public Utilities District Building, 961 12th Avenue, Longview, Washington 98632; (telephone: 360–423–2210). Participants must provide their own transportation. For additional information, please contact the Commission's Office of External Affairs at 1–866–208–FERC (3372).

Summary of the Planned Project

Northern Star proposes to construct and operate an LNG import terminal and storage facility, and associated natural gas sendout pipeline with a capacity of 1.0 billion cubic feet per day. More specifically, Northern Star's facilities would consist of:

- A marine LNG terminal, including a dredged turning basin and a single dock, capable of handling about 125 LNG tankers per year, ranging in size from 100,000 to 200,000 cubic meters (m^3) per ship;
- Four 16-inch-diameter unloading arms on the dock, with an unloading capacity rate of 12,000 m^3 of LNG per hour, and 6-inch-diameter and 30-inch-diameter unloading lines to transfer LNG from the dock to the storage tanks;
- Two insulated LNG storage tanks, each with a capacity of 160,000 m^3;
- Boil-off gas management system, and sendout pumps;
- Ambient air vaporizers to convert LNG into natural gas;

[1] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the FERC's Office of Energy Projects.

• Electric substation and distribution lines and emergency diesel-fueled generator at the terminal;

• Ancillary terminal facilities, including control room, maintenance shop, warehouse, office, security, and safety systems;

• Measurement controls and natural gas metering facilities;

• A ca. 34-mile-long, 30 and 36-inch-diameter natural gas sendout pipeline extending from the LNG terminal to the interconnection with Williams Northwest;

• Delivery points at the Georgia-Pacific paper mill at Wauna, Oregon, and the Portland General Electric (PGE) Beaver power plant at Port Westward, Oregon;

• Interconnections with the Northwest Natural intrastate pipeline adjacent to the PGE Beaver delivery point, and with Williams Northwest; and

• A pig launcher at the LNG terminal, pigging facilities along the pipeline at transitions between 30-inch-diameter and 36-inch-diameter pipe sizes; and a pig receiver at the eastern end of the pipeline at its interconnection with Williams Northwest.

A location map depicting Northern Star's proposed facilities is attached to this NOI as Appendix 1.[2]

The EIS Process

The NEPA requires the Commission to take into account the environmental impacts that could result from an action when it considers whether or not an LNG import terminal or an interstate natural gas pipeline should be approved. The FERC will use the EIS to consider the environmental impacts that could result if it issues project authorizations to Northern Star under Sections 3 and 7 of the Natural Gas Act. The NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. With this NOI, the Commission staff is requesting public comments on the scope of the issues to be addressed in the EIS. All comments received will be considered during preparation of the EIS.

In the EIS we will discuss impacts that could occur as a result of the construction, operation, maintenance, and abandonment of the proposed project under these general headings:

• Geology and soils.

• Water resources.

• Aquatic resources.

• Vegetation and wildlife.

• Threatened and endangered species.

• Land use, recreation, and visual resources.

• Cultural resources.

• Socioeconomics.

• Marine transportation.

• Air quality and noise.

• Reliability and safety.

• Cumulative impacts.

In the EIS, we will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on affected resources.

Our independent analysis of the issues will be included in a draft EIS. The draft EIS will be mailed to Federal, state, and local government agencies; elected officials; affected landowners; environmental and public interest groups; Indian tribes and regional Native American organizations; commentors; other interested parties; local libraries and newspapers; and the FERC's official service list for this proceeding. A 45-day comment period will be allotted for review of the draft EIS. We will consider all comments on the draft EIS and revise the document, as necessary, before issuing a final EIS. We will consider all comments on the final EIS before we make our recommendations to the Commission. To ensure that your comments are considered, please follow the instructions in the Public Participation section of this NOI.

Although no formal application has been filed, the FERC staff has already initiated its NEPA review under its pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before an application is filed with the FERC. In addition, the Coast Guard, which would be responsible for reviewing the safety and security aspects of the planned project and regulating safety and security if the project is approved, has initiated its review of the project as well.

With this NOI, we are asking Federal, state, and local agencies with jurisdiction and/or special expertise with respect to environmental issues, in addition to those agencies that have already agreed to serve as cooperating agencies (as noted above), to formally cooperate with us in the preparation of the EIS. These agencies may choose to participate once they have evaluated the proposal relative to their responsibilities. Additional agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this NOI.

Currently Identified Environmental Issues

We have already identified issues that we think deserve attention based on comment letters received during our pre-filing process, interagency meetings, a preliminary review of the project area, and the planned facility information provided by Northern Star. This preliminary list of issues, which is presented below, may be revised based on your comments and our continuing analyses.

• Impact of LNG ship traffic on other river users, including recreational boaters and fishing.

• Safety issues relating to LNG ship traffic, including transit over the Columbia River bar.

• Potential impacts on the residents of Puget Island, including safety issues at the import and storage facility, noise, air quality, and visual resources.

• Potential impacts of dredging the LNG marine terminal turning basin on Clifton Channel and related fishery.

• Potential geological hazards at the Bradwood Landing terminal, including seismic issues and landslides.

• Impact of the Bradwood Landing terminal on the railroad through this site.

• Project impacts on threatened and endangered species and nearby National Wildlife Refuges.

• Project impacts on cultural resources.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the planned project. By becoming a commentor, your concerns will be addressed in the EIS and considered by the Commission. Your comments should focus on the potential environmental effects, reasonable alternatives (including alternative facility sites and pipeline routes), and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please follow these instructions:

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies are available on the Commission's Web site (excluding maps) at the ''e-Library'' link or from the Commission's Public Reference Room or call (202) 502–8371. For instructions on connecting to e-Library refer to the end of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

• Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.

• Label one copy of your comments for the attention of OEP/DG2E/Gas Branch 3, PJ–11.3.

• Reference Docket No. PF05–10–000 on the original and both copies.

• Mail your comments so that they will be received in Washington, DC on or before October 17, 2005.

The Commission strongly encourages electronic filing of any comments in response to this NOI. For information on electronically filing comments, please see the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide as well as information in 18 CFR 385.2001(a)(1)(iii). Before you can file comments you will need to create a free account, which can be accomplished on-line.

The public scoping meeting (date, time, and location listed above) is designed to provide another opportunity to offer comments on the proposed project. Interested groups and individuals are encouraged to attend the meeting and to present comments on the environmental issues that they believe should be addressed in the EIS. A transcript of the meeting will be generated so that your comments will be accurately recorded.

Once Northern Star formally files its application with the Commission, you may want to become an ''intervenor,'' which is an official party to the proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in a Commission proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that you may not request intervenor status at this time. You must wait until a formal application is filed with the Commission.

Environmental Mailing List

If you wish to remain on the environmental mailing list, please return the attached Mailing List Retention Form (Appendix 2 of this NOI). Also, indicate on the form your preference for receiving a paper or electronic version of the EIS. If you do not return this form, we will remove your name from our mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC (3372) or on the FERC Internet Web site (*http://www.ferc.gov*) using the ''eLibrary link.'' Click on the eLibrary link, select ''General Search'' and enter the project docket number excluding the last three digits (*i.e.*, PF05–10) in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance with eLibrary, the eLibrary helpline can be reached at 1–866–208–3676, TTY (202) 502–8659, or by e-mail at *FERCOnlineSupport@ferc.gov*. The eLibrary link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

In addition, the FERC now offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm*.

Public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Finally, Northern Star has established an Internet Web site for this project at *http://www.Northernstar-NG.com*. The Web site includes a project overview, status, potential impacts and mitigation, and answers to frequently asked questions. You can also request additional information by calling Northern Star directly at 503–914–1905 or 503–325–3335.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5127 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the Record Communications; Public Notice

September 13, 2005.

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received in the Office of the Secretary. The communications listed are grouped by docket numbers in ascending order. These filings are 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 (FERRIS) 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 for TTY, contact (202) 502–8659.

Docket No.	Date received	Presenter or requester
Prohibited:		
1. ER03–563–030, EL04–112–000	9–6–05	Neal W. Allen.
2. ER05–1207–000	9–1–05	Donna Brent.
Exempt:		
1. Project No. 2210–116	9–6–05	Hon. George Allen.
2. Project No. 2210–116	9–6–05	Hon. Virgil H. Goode, Jr.
3. Project No. 2486–000	8–31–05	Hon. Russell D. Feingold.
4. ER03–563–000, EL04–112–000	9–7–05	Hon. M. Jodi Rell.

Magalie R. Salas,

Secretary.

[FR Doc. E5–5128 Filed 9–19–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OECA–2005–0014; FRL–7969–4]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Comment Request; State Review Framework; EPA ICR Number 2185.01; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: The Environmental Protection Agency published a document in the **Federal Register** of August 31, 2005, concerning request for comments on guidance requirements for state reporting (State Review Framework). The document contained incorrect dates and incorrect summary language.

FOR FURTHER INFORMATION CONTACT: Arthur Horowitz, (202) 564–2612.

Corrections

In the **Federal Register** of August 31, 2005, in FR Doc. 05–17361, on page 51779, at the top of the second column, correct the **SUPPLEMENTARY INFORMATION** caption to read:

Any comments related to this ICR should be submitted to EPA within 30 days of this notice.

In the **Federal Register** of August 31, 2005, in FR Doc. 05–17361, on page 51778, in the last column, correct the **SUMMARY** caption to read:

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request for a new collection. This ICR describes the nature of the information collection and its estimated burden and cost.

Dated: September 6, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–18709 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[RCRA–2005–0006; FRL–7970–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Hazardous Remediation Waste Management Requirements (HWIR-Media) (Renewal), EPA ICR Number 1755.04, OMB Control Number 2050–0161

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on September 30, 2005. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before October 20, 2005.

ADDRESSES: Submit your comments, referencing docket ID number RCRA–2005–0006, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *RCRA-docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, RCRA Docket, mail code 5305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mike Fitzpatrick, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–8411; fax number: 703–308–8638; e-mail address: *fitzpatrick.mike@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 14, 2005 (70 FR 19757), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. RCRA–2005–0006, which is available for public viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 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 Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the

version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Hazardous Remediation Waste Management Requirements (HWIR-Media) (Renewal).

Abstract: The Resource Conservation and Recovery Act of 1976 (RCRA), as amended, requires EPA to establish a national regulatory program to ensure that hazardous wastes are managed in a manner protective of human health and the environment. Under this program (known as the RCRA Subtitle C program), EPA regulates newly generated hazardous wastes, as well as hazardous remediation wastes (*i.e.*, hazardous wastes managed during cleanup). To facilitate prompt and protective treatment, storage, and disposal of hazardous remediation wastes, EPA established three requirements for remediation waste management sites that are different from those for facilities managing newly generated hazardous waste:

- Performance standards for remediation waste management sites (40 CFR 264.1(j));
- A provision excluding remediation waste management sites from requirements for facility-wide corrective action; and
- A new form of RCRA permit for treating, storing, and disposing of hazardous remediation wastes (40 CFR part 270, subpart H). The new permit, a Remedial Action Plan (RAP), streamlines the permitting process for remediation waste management sites to allow cleanups to take place more quickly.

In addition, EPA created a new kind of unit called a ''staging pile'' (40 CFR 264.554) that allows more flexibility in storing remediation waste during cleanup. 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 and are identified on the form and/or instrument, if applicable.

Burden Statement: For owners/operators of hazardous remediation waste management sites subject to the 40 CFR 264.1(j) and part 270, subpart H requirements, the reporting burden is estimated to be 27 hours per respondent per year. The recordkeeping burden is estimated to be 42 hours per respondent per year. For owners/operators of hazardous remediation waste management sites subject to the 40 CFR 264.554 requirements for staging piles, the reporting burden is estimated to be 7 hours per year per respondent. The recordkeeping burden is estimated to be 13 hours per respondent per year.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Facility owners and operators.

Estimated Number of Respondents: 176.

Frequency of Response: one-time.

Estimated Total Annual Hour Burden: 4,944.

Estimated Total Annual Cost: $361,000, includes $0 annualized capital/startup costs, $26,000 annual O&M costs and $335,000 annual labor costs.

Changes in the Estimates: There is a decrease of only 15 hours in the total estimated annual hourly burden currently identified in the OMB Inventory of Approved ICR Burdens. The total annual O&M cost burden in this ICR decreased by $9,000 from the previous renewal (ICR #1775.03), which is due to refinements in the burden estimates. This decrease of $9,000 is therefore considered an ''adjustment''.

Dated: September 12, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–18710 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ORD–2005–0010; FRL–7971–1]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Comment Request; Population-Based Pilot Study of Children's Environmental Health in Support of The National Children's Study, EPA ICR Number 2187.01

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request for a new collection. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Comments must be submitted on or before October 20, 2005.

ADDRESSES: Submit your comments, referencing docket ID No. ORD–2005–0010, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *ord.docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Office of Research and Development Docket, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Pauline Mendola, Office of Research and Development, National Health and Environmental Effects Research Library, Human Studies Division, Environmental Protection Agency, Mail Code MD 58 A, Research Triangle Park, NC 27711; telephone number: (919) 966–6953; fax number: (919) 966–7584; e-mail address: *mendola.pauline@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to procedures prescribed in 5 CFR 1320.12. On April 12, 2005 (70 FR 19076), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA has addressed the comments received.

EPA has established a public docket for this ICR under Docket ID No. ORD–2005–0010, which is available for public viewing at the Office of Research and Development Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 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

Reading Room is (202) 566–1744, and the telephone number for the Office of Research and Development Docket is (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Population-based Pilot Study of Children's Environmental Health in Support of The National Children's Study.

Abstract: The proposed study will be conducted by the Epidemiology and Biomarkers Branch, Human Studies Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. EPA. The U.S. EPA will conduct this research in partnership with the National Children's Study (NCS) Program Office at the National Institute of Child Health and Human Development (NICHD) as well as the other lead agencies of the NCS: the Centers for Disease Control and Prevention (CDC) and the National Institute of Environmental Health Sciences (NIEHS). This proposed data collection will pilot test logistics, protocols and procedures for the NCS, a long term study of the influence of environmental factors on child health and development. The goal is to improve the efficiency of the implementation of NCS by testing procedures for population-based sampling and subject recruitment, proposed study logistics and estimates of subject burden, and evaluating data collection strategies including interviews and acquisition of biologic and environmental samples. Further details on the NCS, including the Study Plan, can be found at *http://www.nationalchildrensstudy.gov.*

Approximately 10,000 households will be screened and 2,740 women will be enrolled who meet eligibility criteria, primarily defined by age and likelihood of pregnancy. The schedule of visits follows the proposed NCS Study Plan. Briefly, women who are planning pregnancy will be visited bimonthly, women with lower likelihood of pregnancy will be visited once; pregnant women will have a home visit in the first trimester and a clinic visit in the second and third trimester. A hospital visit at birth is planned as well as home visits to follow-up with the mother and infant at 1, 6, 12, and 18 months of age. Data from interviews as well as biologic and environmental samples will address the relationship between common environmental factors and the physical and developmental growth of children. Qualitative assessments of the participants' perceptions about the study will be gathered at each visit to enhance the lessons that can be learned to aid the successful implementation of the NCS.

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 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information varies depending on the eligibility and pregnancy status of women at the time of enrollment. Detailed estimates regarding the number of potential respondents and burden associated with each visit are provided in the EDOCKET. Approximately 10 minutes per household is required to determine potentially eligible occupants. Potentially eligible women are asked to complete a 10-minute screening interview. The estimated total burden for a fully participating woman ranges from 8 hours (for a woman enrolled at delivery) to 21 hours (for a ''high likelihood'' woman who receives all contacts in the preconception period) over a three year period. The burden for husbands/partners is somewhat more consistent because they only receive one visit in each of the preconception, pregnancy, and childhood visit periods; each visit is approximately 1 hour. The burden for children ranges from 10 minutes at the birth visit to approximately 2 hours for full participation up to 18 months of age. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Women aged 18–40 years, pregnant women, their husbands or partners, and their children who live in selected areas of North Carolina.

Estimated Number of Respondents: 10,000.

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 4,585.

Estimated Total Annual Cost: $82,728. There are no annualized capital costs or O&M costs.

Changes in the Estimates: Not applicable; this is a new information collection.

Dated: September 6, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–18711 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OECA–2005–0016; FRL–7970–8]

Agency Information Collection Activities; Submission for OMB Review and Approval; Comment Request; NSPS for Petroleum Refineries (Renewal), ICR Number 1054.09, OMB Number 2060–0022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act, this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on November 30, 2005. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before October 20, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OECA–2005–0016, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code 2201T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Dan Chadwick, Compliance Assessment and Media Programs Division, Office of Compliance, 2223A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–7054; fax number: (202) 564–0050; e-mail address: *chadwick.dan@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 6, 2005 (70 FR 24020), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OECA–2005–0016, which is available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center is: (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: NSPS for Petroleum Refineries (Renewal).

Abstract: This information collection request addresses Clean Air Act information collection requirements in standards published at 40 CFR part 60, subpart J, which have mandatory recordkeeping and reporting requirements. These regulations were proposed on June 11, 1973, promulgated on March 8, 1974, and they apply to the following affected facilities in petroleum refineries: Fluid catalytic cracking unit catalyst regenerators, fuel gas combustion devices, and Claus sulfur recovery plants of more than 20 long tons per day commencing construction, modification or reconstruction after the date of proposal. In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. The frequency of the excess emissions report was changed from quarterly to semiannually on February 12, 1999 (64 FR 7465) They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NSPS.

Any owner/operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least two years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

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 are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 50 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners and operators of petroleum refineries.

Estimated Number of Respondents: 132.

Frequency of Response: Semiannually, on occasion.

Estimated Total Annual Hour Burden: 14,134 hours.

Estimated Total Annual Costs: $1,682,453, which includes $0 annualized capital/startup costs, $541,464 annual O&M costs, and $1,140,989 in Respondent Labor costs.

Changes in the Estimates: Adjustment of burden hours added 2,183 hours, but was more than offset by Program Change decrease of 5,408 hours, so that the overall decrease in burden was 3,225 hours per year. This decrease is due to the removal of quarterly emission reporting requirements. Only semiannual emission reporting is required by the standards. The increase in O&M cost is due to use of a more accurate source for this information.

Dated: September 12, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 05–18720 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OEI–2005–0008, FRL–7971–2]

Agency Information Collection Activities: Proposed Collection; Comment Request; Delisting the Fish Tainting Beneficial Use Impairment in the Saginaw River/Bay Area of Concern, EPA ICR Number 2199.01

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request for a new collection. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before November 21, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OEI–2005–0008, to EPA online using EDOCKET (our preferred method), by e-mail to *oei.docket@epa.gov*, or by mail to: Environmental Protection Agency, Office of Environmental Information Docket, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: James Schardt, Environmental Protection Agency, Great Lakes National Program Office, 77 W. Jackson Blvd (G–17J), Chicago, IL 60604; telephone number: (312) 353–5085; fax number: (312) 353–2018; e-mail address: *schardt.james@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OEI–2005–0008, which is available for public viewing at the OEI Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 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 Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752. Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov./edocket.*

Affected entities: Entities potentially affected by this action are members of the public, specifically local residents of the Saginaw Bay region of Michigan.

Title: Delisting the Fish Tainting Beneficial Use Impairment in the Saginaw River/Bay Area of Concern

Abstract: The 1988 Saginaw River/Bay RAP cited 12 impairments of the 14 categories specifically listed by the IJC for the Saginaw River/Bay AOC, including tainting of fish (*i.e.*, taste and odor concerns). Chemical odors and tastes associated with harvested fish were frequently reported from the 1940s through the 1970s in the Saginaw and Tittabawassee Rivers, and in the Saginaw Bay. In the 1994 Remedial Action Plan Update, the Michigan Department of Natural Resources reported that no off-flavor was detected in taste tests conducted on fish taken from these waters. Since taste and odor complaints related to edible fish taken from both Saginaw River and Bay have disappeared in recent years, this project will distribute a voluntary survey to 7,680 local residents and anglers to determine if taste and odor problems in fish fillets have abated to the extent that delisting of the beneficial use impairment may be recommended for the Area of Concern (AOC). Results of the individual survey respondents will be confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 4 CFR are listed in 40 CFR part 9.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden Statement: The voluntary survey instrument is expected to take .5 hours to review and complete per individual response. The targeted frequency of response is 20 percent, or 1,536 completed surveys. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the

existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: September 9, 2005.

Gary V. Gulezian,

Director, Great Lakes National Program Office.

[FR Doc. 05–18721 Filed 9–19–05; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Farm Credit System Insurance Corporation Board; Regular Meeting

SUMMARY: Notice is hereby given of the regular meeting of the Farm Credit System Insurance Corporation Board (Board).

DATE AND TIME: The meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on September 22, 2005, from 9 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Jeanette C. Brinkley, Secretary to the Farm Credit System Insurance Corporation Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

Closed Session

- Report on System Performance

Open Session

A. Approval of Minutes

- June 23, 2005 (Regular Meeting)

B. Reports

- Financials
- Report on Insured Obligations
- Quarterly Report on Annual Performance Plan

C. New Business

- Review of Insurance Premium Rates

—Rate for June to December 2005
—Planning Range for 2006

- Proposed 2006 and 2007 Budgets
- Annual Performance Plan for 2006–2007

Dated: September 13, 2005.

Jeanette C. Brinkley,

Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. 05–18609 Filed 9–19–05; 8:45 am]

BILLING CODE 6710–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 4, 2005.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. John Joseph Mullins, Jacob Mullins, and Angelia M. Mullins, Cullman, Alabama; to acquire voting shares of FCB Bancshares, Inc., Cullman, Alabama, and thereby indirectly acquire voting shares of Premier Bank of the South, Good Hope, Alabama.

Board of Governors of the Federal Reserve System, September 15, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–18696 Filed 9–19–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 14, 2005.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106-2204:

1. Butler Bancorp, MHC, and Butler Bancorp, Inc., both of Lowell, Massachusetts; to become bank holding companies by acquiring 100 percent of the voting shares of Butler Bank, Lowell, Massachusetts.

Board of Governors of the Federal Reserve System, September 15, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–18694 Filed 9–19–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages

either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 4, 2005.

A. Federal Reserve Bank of Cleveland (Cindy West, Manager) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. The PNC Financial Services Group, Inc., Pittsburgh, Pennsylvania; to acquire HW Holdings, Richmond, Virginia, and thereby indirectly acquire Harris Williams & Co., and Harris Williams Advisors, Inc., and engage in broker dealer activities and advising clients on merger and acquisition matters, pursuant to sections 225.28(b)(6)(iii) and (b)(7)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, September 15, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–18695 Filed 9–19–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Childhood Lead Poisoning Prevention.

Times and Dates: 8:30 a.m.–5:45 p.m., October 25, 2005. 8:30 a.m.–12:45 p.m., October 26, 2005.

Place: The Hubert Humphrey Federal Building, 200 Independence Avenue, SW., Washington, DC 20201. Telephone: (202) 619–0100.

Status: Open to the public, limited only by the space available. Non-federal attendees must call Crystal Gresham prior to October 24, 2005, in order to be received as a visitor at the Humphrey building on the day of the meeting. The meeting room accommodates approximately 60 people.

Purpose: The Committee provides advice and guidance to the Secretary; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The Committee also reviews and reports regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

Matters To Be Discussed: Agenda items includes: Primary Prevention Workgroup update; Forum on strategies for implementation of housing-based Primary Prevention of Lead Poisoning-federal agency perspective; Forum-local agencies and non-governmental organization perspective; Washington, DC Childhood Lead Poisoning Prevention Program; Update on the Centers for Medicare and Medicaid Services and CDC Policy on Targeted Screening of Medicaid Children; update on adverse health effects of blood lead levels <10 mg/dl—follow-up; and update on clinical papers.

Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

Contact Person for More Information: Crystal M. Gresham, Management and Program Analyst, Lead Poisoning Prevention Branch, Division of Emergency and Environmental Health Services, NCEH, CDC, 4770 Buford Hwy, NE., M/S F–40, Atlanta, Georgia 30341. Telephone: (770) 488–7490, fax: (770) 488–3635.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 12, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–18690 Filed 9–19–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment.

Time and Date: 8 a.m.–5 p.m., October 19, 2005.

Place: Hotel Washington, 15th and Pennsylvania Avenue, NW., Washington, DC 20004. Telephone: (202) 638–5900.

Time and Date: 8 a.m.–12 p.m., October 20, 2005.

Place: Ronald Reagan Building and International Trade Center, Horizon Room, 1300 Pennsylvania Avenue, NW., Washington, DC 20004. Telephone: (202) 213–1300.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Secretary; the Director, CDC; and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS and other STDs.

Matters To Be Discussed: Agenda items include issues pertaining to (1) syphilis elimination, (2) HIV Prevention Priorities for African American Men Who Have Sex With Men, (3) Medicare Part D Outreach/TA, and (4) Ryan White CARE Act Reauthorization.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Paulette Ford-Knights, Public Health Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, Georgia 30333. Telephone (404) 639–8008, fax: (404) 639–3125, e-mail *pbf7@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 12, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–18687 Filed 9–19–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR titled, ''Anti-Cancer Chemotherapy for Colorectal Cancer (CRC) System, System No. 09–70–0554.'' National Coverage Determinations (NCD) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act (the Act) section 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member'' (section 1862(a)(1)(A).

Under authority of section 1861(t)(2) of the statute, Medicare provides coverage for Food and Drug Administration (FDA) approved indications for anticancer chemotherapeutic agents and for other indications that are in the specific approved compendia listed below. Increased understanding of the biology of cancer and emerging technologies is making possible new approaches in treating cancer. To ensure that beneficiaries have access to the most appropriate cancer treatments, it is imperative that adequate clinical trial data for off-label uses be made available to patients and providers for clinical decision-making and to policy-making. CMS has determined that Medicare will cover the use of oxaliplatin (Eloxatin®), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™), in clinical trials identified by CMS and sponsored by the National Cancer Institute (NCI).

The purpose of this system is to provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimen to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) to an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

EFFECTIVE DATE: CMS filed a new SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 13, 2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m. to 3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Rosemarie Hakim, Epidemiologist, Office of Clinical Standards and Quality, CMS, Mail Stop C1–09–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1849. Her telephone number is (410) 786–3934, she can also be reached via e-mail at *rhakim@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: CMS has determined that oxaliplatin, irinotecan, cetuximab, and bevacizumab are Medicare covered for the FDA-approved and compendia-supported use in 1st and/or 2nd line treatment of advanced colorectal cancer. The off-label use of irinotecan for the treatment of non-small cell lung cancer is supported in one of the approved drug compendia; therefore this off-label use is covered by Medicare. No other off-label use for irinotecan, oxaliplatin, cetuximab, or bevacizumab appears as supported in the approved drug compendia. Off-label coverage of these agents is therefore determined by the Medicare contractors based on their review of the medical literature. During our NCD review of the medical literature, we found studies of off-label indications for these agents that varied widely in quality.

At the request of CMS, NCI identified high priority clinical trials studying off-label uses of the four agents that are the subject of this national coverage determination review. It was agreed that the selected trials should address questions likely to lead to important changes in therapy and that by covering the use of these agents in selected trials; we will:

- Offer consistent national coverage for these specific trials,
- Ensure continued advancement in knowledge for the appropriate use of these agents,
- Accelerate the development of evidence for new or emerging cancer treatment regimens for these agents,
- Ensure beneficiaries rapid access to promising new uses of approved technologies under controlled clinical trial conditions,
- Serve as a potential model for additional coverage expansions in clinical trials for other anti-cancer chemotherapeutic agents,
- Encourage industry to invest in studies that will expand knowledge base for patient and doctor discussions.

Although we did not find sufficient evidence to support coverage of off-label use of cancer chemotherapy for all persons who have cancer, a sufficient inference of benefit can be drawn to support limited coverage in the context of an NCI-sponsored clinical trial that provides rigorous safeguards for patients. We base this inference on the evidence discussed above regarding the benefits of chemotherapy for labeled uses. We further believe that NCI-sponsored clinical trials offer safeguards for patients to ensure appropriate patient evaluation and selection and

reasonable use of cancer chemotherapy. We conclude that coverage for the off-label use of cancer chemotherapy could provide clinical benefits to Medicare beneficiaries with cancer, and that those benefits are likely to be present in the context of a clinical trial that assures informed individualized analysis and evaluation of the response to chemotherapy and patient health status, as well as an adequate plan for data and safety monitoring.

The proposed policy does not obviate the need for contractors to continue to review the medical literature and determine the conditions under which off-label indications of FDA-approved drugs and biologicals used in anti-cancer chemotherapeutic regimens for medically accepted indications are reasonable and necessary (Sec. 1861(t)(2)(B)(ii)(II)). Contractors will not infer from this NCD that any other uses of these drugs should not be approved.

This policy also does not withdraw Medicare coverage for items and services that may be covered according to the existing national coverage policy for Routine Costs in a Clinical Trial (National Coverage Determination Manual, section 310.1). Routine costs will continue to be covered as well as other items and services provided as a result of coverage of these specific trials in this NCD. Specific reimbursements will be determined as the protocols are completed and the trials begin.

In addition to covering these specific NCI trials, we are interested in establishing other processes to identify appropriate trials for which we may provide coverage. We are also interested in identifying additional means of gathering evidence outside of a clinical trial setting for use in decision-making such as registries and analyses of routinely collected electronic data. Therefore, we will shortly begin a process to develop appropriate guidance (Medicare Prescription Drug Improvement, Modernization Act of 2003 section 731) that will include an Open Door Forum and an expert panel convened by the Institute of Medicine and will result in the publication of a draft guidance document. We encourage broad public participation in this process.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for linking coverage decisions to the collection of additional data is derived from Sec. 1862(a)(1)(A) of the Act, which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provisions of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

B. Collection and Maintenance of Data in the System

The data collection should include baseline patient characteristics. The collected information will also contain, but is not limited to, name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as, background information relating to Medicare or Medicaid issues.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release CRC information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of CRC. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the SOR will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimens to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors or consultants who have been engaged by the agency to assist in the performance of a service related to this system and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS function relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimens to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary.

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

Other Federal or state agencies in their administration of a Federal health program may require CRC information in order to provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimens to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The CRC data will provide for research or in support of evaluation projects, a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use this data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policy that governs the care.

4. To a member of Congress or to a congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an issue relating to a matter before CMS. The member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

5. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS' policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

6. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

CMS occasionally contracts out certain of its functions and makes grants when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

7. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

Other agencies may require CRC information for the purpose of combating fraud and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations Parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E. Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130,

Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures (see item IV above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Lori Davis,

Acting Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09–70–0554

SYSTEM NAME:

''Anti-Cancer Chemotherapy for Colorectal Cancer (CRC) System;'' HHS/CMS/OCSQ.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various co-locations of CMS contractors.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

CMS will cover the use of oxaliplatin (Eloxatin®), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™), on all Medicare beneficiaries who are in clinical trials identified by CMS and sponsored by the National Cancer Institute.

CATEGORIES OF RECORDS IN THE SYSTEM:

The data collection should include baseline patient characteristics. The collected information will also contain, but is not limited to, name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as, background information relating to Medicare or Medicaid issues.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for linking coverage decisions to the collection of additional data is derived from section 1862(a)(1)(A) of the Social Security Act, which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provision of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimens to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) to an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health or payment related projects; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A.The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Provide reimbursement for CRCs and assist in the collection of data on patients receiving CRC as a new or emerging cancer treatment regimens to a data collection process to assure patient safety and protection and to determine that the CRC is reasonable and necessary,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

4. To a member of Congress or to a congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

5. To the Department of Justice (DOJ), court or adjudicatory body when:

a. the agency or any component thereof, or

b. any employee of the agency in his or her official capacity, or

c. any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. the United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are

both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

7. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures: This system contains Protected Health Information (PHI) as defined by Department of Health and Human Services (HHS) regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations (CFR) parts 160 and 164, 65 FR 82462 (12–28–00), subparts A and E. Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored electronically.

RETRIEVABILITY:

The data are retrieved by an individual identifier *i.e.*, name of beneficiary or provider.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 10 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Clinical Standards and Quality, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For the purpose of access, use the same procedures outlines in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonable identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Records maintained in this system are derived from Carrier and Fiscal Intermediary Systems of Records, Common Working File System of Records, clinics, institutions, hospitals and group practices performing the procedures, and outside registries and professional interest groups.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–18488 Filed 9–19–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to create a new SOR titled, ''Carotid Artery Stenting (CAS) System, System No. 09–70–0556.'' National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act (the Act) section 1869(f) (1) (B). In order to be covered by Medicare, an item or service must fall within one

or more benefit categories contained within part A or part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' section 1862(a) (1) (A). CMS has determined that the evidence is adequate to conclude that CAS with embolic protection is reasonable and necessary to symptomatic patients who are at high risk for carotid endarterectomy (CEA), have significant comorbidities, or have anatomic risk factors. The reasonable and necessary determination requires that patients meet the criteria and are consistent with the trials discussed. Collection of these data elements allows that determination to be made.

The purpose of this system is to collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) to an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

EFFECTIVE DATE: CMS filed a new SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 13, 2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this SOR or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Rosemarie Hakim, Epidemiologist, Office of Clinical Standards and Quality, CMS, Mail Stop C1–09–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1849. She can be reached by telephone at (410) 786–3934, or via email at *rhakim@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Each year about 700,000 people in the United States experience a new or recurrent stroke. About 500,000 of these are first attacks and 200,000 are recurrent attacks. The term stroke refers to a ''group of cerebrovascular disorders in which part of the brain is transiently or permanently affected by ischemia or hemorrhage, or in which one or more blood vessels of the brain are primarily affected by a pathologic process, or both.'' There are three main categories of strokes: Cerebral infarction (greater than 80%), intracerebral hemorrhage, and subarachnoid hemorrhage. Of the cerebral infarctions, ''20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels.''

Risk factors for stroke include advanced age, male gender, hypertension, history of stroke or transient ischemic attack, atrial fibrillation, valvular heart disease, diabetes mellitus, carotid artery stenosis, hypercoagulable conditions, and cigarette smoking. Hypertension is ''the single most important risk factor for both ischemic and hemorrhage stroke.'' Awareness of stroke warning signs is important since ''the inability of patients and bystanders to recognize stroke symptoms and to quickly access the emergency medical system are the largest barriers to effective acute stroke therapy.''

Prevention of stroke remains important and includes among others, treatment of hypertension and diabetes mellitus; smoking cessation; limiting alcohol intake; control of diet and obesity; antiplatelet drugs or anticoagulants for atrial fibrillation and appropriate acute myocardial infarctions; antiplatelet drugs for symptomatic carotid or vertebrobasilar atherosclerosis; and CEA for specifically defined populations of patients with symptomatic carotid artery stenosis. CEA is a surgical procedure used to prevent stroke in which the surgeon removes fatty deposits or ulcerated and stenotic plaques from the carotid arteries, the two main arteries in the neck supplying blood to the brain. Although carotid artery stenosis is an important risk factor, it was estimated that ''approximately 20% and 45% of strokes in the territory of symptomatic and asymptomatic carotid arteries with 70% to 99% stenosis, respectively, are unrelated to carotid stenosis.'' In these patients, optimal medical therapy would be most important since CEA does not reduce lacunar and cardio embolic strokes. CAS is performed with a catheter, usually inserted through the femoral artery, and threaded up to the carotid artery beyond the area of narrowing. A distal embolic protection device or filter is usually placed first to catch emboli or debris that may dislodge during the procedure. A self-expandable or balloon-expandable, metal mesh stent is then placed to widen the stenosis and the protection device is removed.

On June 18, 2004, CMS began an NCD process for CAS with distal embolic protection for patients at high risk for CEA. Previously, Medicare covered percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stent placement in accordance with the Food and Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption clinical trials and in FDA required post approval studies. Effective July 1, 2001, PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service only when provided in the context of such a clinical trial, and therefore is considered a covered service for the purposes of these trials. Effective October 12, 2004, Medicare covered PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for linking coverage decisions to the collection of additional data is derived from Sec. 1862(a)(1)(A) of the Act, which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provision of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

B. Collection and Maintenance of Data in the System

Information will be collected on individuals where CMS has determined that the evidence is adequate to conclude that certain identified diagnoses are reasonable and necessary in several patient groups where certain criteria for these patients have been met and the criteria are consistent with the trials reviewed. The collected information will contain name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as background information relating to Medicare or Medicaid issues.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release CAS information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of CAS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors or consultants who have been engaged by the agency to assist in the performance of a service related to this system and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS function relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Assist in the review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

Other Federal or state agencies in their administration of a Federal health program may require CAS information in order to assist in the review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The CAS data will provide for research or in support of evaluation projects, a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policy that governs the care.

4. To a member of Congress or to a congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an issue relating to a matter before CMS. The member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

5. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS' policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

6. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

CMS occasionally contracts out certain of its functions and makes grants when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

7. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

Other agencies may require CAS information for the purpose of combating fraud and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E. Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures (see item IV above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Lori Davis,

Acting Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09–70–0556

SYSTEM NAME:

''Carotid Artery Stenting (CAS) System,'' HHS/CMS/OCSQ.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare and Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various co-locations of CMS contractors.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals where CMS has determined that the evidence is adequate to conclude that certain identified diagnoses are reasonable and necessary in several patient groups where certain criteria for these patients have been met and the criteria are consistent with the trials reviewed.

CATEGORIES OF RECORDS IN THE SYSTEM:

The data collection should include baseline patient characteristics. The collected information will contain name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as, background information relating to Medicare or Medicaid issues.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for linking coverage decisions to the collection of additional data is derived from section 1862(a)(1)(A) of the Social Security Act, which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provision of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for carotid endarterectomy. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) to an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' We are proposing to establish the following routine use disclosures of information maintained in the system. Information will be disclosed to:

1. To agency contractors or consultants who have been engaged by the agency to assist in the performance of a service related to this system and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Assist in the review determinations of ''reasonable and necessary'' with respect to carotid artery stenting in patients who are at high risk for carotid endarterectomy.

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

4. To a member of congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

5. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

7. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures: This system contains Protected Health Information (PHI) as defines by Department of Health and Human Services (HHS) regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations (CFR) parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the complaint population is so small that individuals who are familiar with the complainants could, because of the small size, use this information to deduce the identity of the complainant).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored electronically.

RETRIEVABILITY:

The data are retrieved by an individual identifier *i.e.*, name of beneficiary.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 10 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Clinical Standards and Quality, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For the purpose of access, use the same procedures outlines in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Records maintained in this system are derived from Carrier and Fiscal Intermediary Systems of Records, Common Working File System of Records, clinics, institutions, hospitals and group practices performing the procedures, and outside registries and professional interest groups.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–18489 Filed 9–19–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission of OMB Review; Comment Request

Title: Compassion Capital Fund Evaluation.

OMB No.: New Collection.

Description: This proposed information collection activity is for two rounds of surveys to be completed by faith-based and community organizations participating in two studies within the Compassion Capital Fund (CCF) evaluation project. The first survey will be conducted as a baseline survey and the second will be a follow-up survey conducted several months later.

The CCF evaluation is an important opportunity to examine the effectiveness of the Compassion Capital Fund in meeting its objective of improving the capacity of faith-based and community organizations. The evaluation includes three distinct studies: a random assignment impact study, an outcome study, and a retrospective study. This notice pertains to the impact and outcome studies. The impact study will involve up to 1,000 faith-based and community organizations that seek services from CCF-funded intermediary organizations. Information will be collected from these faith-based and community-based organizations to assess change and improvement in various areas of capacity. The study design includes the random assignment of faith-based and community organizations to either a treatment group that receives capacity-building services from a CCF intermediary grantee or to a control group that does not. The impact of the services provided by intermediaries, primarily through sub-awards and/or technical assistance (TA), will be determined by comparing the changes in organizational and service capacity of the recipient organizations with those of the control group.

The outcome study will examine changes and improvements in a representative sample of about 750 faith-based and community organizations served by all CCF intermediaries operating in FY2005 and FY2006, except those already part of the impact study. The survey instruments will be used to track changes in the faith-based and community organizations' organizational capacity between baseline and follow-up.

Respondents: The respondents for both studies will be faith-based and community organizations that seek sub-awards or TA from CCF intermediary grantees. The baseline survey will be primarily self-administered and is expected to be completed as part of the intermediary's sub-award application or TA request process. The follow-up survey also will be primarily self-administered and contain questions similar to those in the baseline survey as well as additional questions related to services received from the intermediary or other organizations. It is expected that the follow-up survey will be administered approximately 12 months after the baseline survey. As needed to increase response rates, the survey will be administered by telephone to organizations that do not initially return a completed survey.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Baseline Survey	1,750	1	.33 hours (approx. 20 minutes)	577.5
Follow-up Survey	1,750	1	.42 hours (approx. 25 minutes)	735
Estimated Total Annual Burden Hours	3,500			1,312.5

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, *E-mail address: Katherine_T._Astrich@omb.eop.gov*.

Dated: September 13, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–18735 Filed 9–19–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trials Statutory and Regulatory Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop will be held on Wednesday, December 7, 2005, from 8:15 a.m. to 5 p.m. and Thursday, December 8, 2005, from 8:15 a.m. to 4 p.m.

Location: The public workshop will be held at The Westin Cincinnati, 21 East 5th St., Cincinnati, OH 45202–3160, 513–621–7700, FAX: 513–852–5670.

Contact: Marie Falcone, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of $485 (member), $560 (nonmember), or $460 (government employee nonmember) (includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA_Conference.htm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–345–7749, or FAX: 215–345–7369, or e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at The Westin Cincinnati at the reduced conference rate, contact The Westin Cincinnati see *Location*) through November 7, 2005, or until the SoCRA room block is full.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- FDA and confidence in the conduct of clinical research;
- Medical device, drug, and biological product aspects of clinical research;
- Investigator initiated research;
- Pre-investigational new drug application (IND) meetings and FDA meeting process;
- Informed consent requirements;
- Ethics in subject enrollment;
- FDA regulation of Institutional Review Boards;
- Electronic records requirements;
- Adverse event reporting;
- How FDA conducts bioresearch inspections; and
- What happens after the FDA inspection.

Dated: September 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18654 Filed 9–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0337]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque.'' This guidance document describes a means by which oral rinse to reduce the adhesion of dental plaque may comply with the requirements of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify oral rinse to reduce the adhesion of dental plaque into class II (special controls). This guidance document is immediately in effect as the special control for the oral rinse to reduce the adhesion of dental plaque, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs). General comments on agency guidance documents are welcomed at any time.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert Betz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 125.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the oral rinse to reduce the adhesion of dental plaque device into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the generic device oral rinse to reduce the adhesion of dental plaque. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on oral rinse to reduce the adhesion of dental plaque. 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

To receive ''Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1559) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic

comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–18655 Filed 9–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0266]

Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' Elsewhere in this issue of the **Federal Register**, we are issuing proposed regulations on CGMPs for positron emission tomography (PET) drug products. We are making the draft guidance available so that producers of PET drugs can better understand FDA's thinking on CGMP compliance if the proposed regulations become final after notice-and-comment rulemaking.

DATES: Submit written or electronic comments on the draft guidance by December 19, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8941.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Public Law 105–115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of the drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), FDA published preliminary draft regulations on CGMP for PET drug products. FDA received comments on the preliminary draft regulations at another public meeting on the same subject on September 28, 1999. FDA made changes in the working draft in response to the public comments. In the **Federal Register** of April 1, 2002 (67 FR 15344), FDA published a preliminary draft proposed rule, in conjunction with the first draft guidance (67 FR 15404, April 1, 2002). FDA received written and oral comments on the preliminary draft proposed rule and the first draft guidance at a public meeting on May 21, 2002, and written comments after the May 2002 meeting, FDA has taken all comments into consideration in revising the preliminary draft proposed rule and the draft guidance. The draft guidance provides more details for discussion purposes on acceptable approaches to complying with the proposed regulations should they be published in final form.

Elsewhere in this issue of the **Federal Register**, we are publishing a proposed rule on CGMP for PET drug products. We are making this draft guidance available so that PET drug producers can better understand FDA's thinking on compliance with the proposed CGMP regulations if they become final after notice-and-comment rulemaking. We invite comments on whether the draft guidance would be a useful accompaniment to the proposed rule.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination 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/cder/guidance/index.htm*, *http://www.fda.gov/ohrms/dockets/default.htm*, or *http://www.fda.gov/cder/fdama* under ''Section 121—PET (Positron Emission Tomography).''

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18509 Filed 9–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Indian Health Board

AGENCY: Indian Health Service, HHS.

ACTION: Notice to supplement the single-source cooperative agreement with the National Indian Health Board.

SUMMARY: The Indian Health Service (IHS) announces a supplement to the single-source cooperative agreement award to the National Indian Health Board (NIHB) for costs in providing advice and technical assistance to the IHS on behalf of federally recognized Tribes in the area of health care policy analysis and program development. The

NIHB is a non-profit organization as described in section 501(c)(3) of the Internal Revenue Code. The mission of the IHS is to work in partnership with American Indian and Alaska Native people to raise their health to the highest level. Under the original cooperative agreement published in the **Federal Register**, 69 FR 11447, on March 10, 2004, the NIHB assists the IHS in carrying out its mission through access to a broad based consumer network involving the Areas Health Boards or Health Board representatives from each of the 12 IHS Areas. The NIHB communicates with these boards and with Tribes and Tribal organizations in order to raise health of AI/AN people to the highest level. NIHB also disseminates health care information which serves to improve and expand access for American Indians and Alaska Natives (AI/AN) Tribal Governments to all available health programs in the Department of Health and Human Services (HHS). The NIHB assists in the coordination of the Tribal consultation activities associated with formulating the IHS annual budget request.

The program supplement to the single-source cooperative agreement is for $321,800 of non-recurring funding for use during the current budget period in effect from 01/01/2005 to 12/31/2005. The annual funding level of this single-source cooperative agreement is approximately $230,000, subject to the availability of appropriations.

Justification for Program Supplement

The program supplement is issued under the authority of the Public Health Service Act, section 301(a) and is included under the *Catalog of Federal Domestic Assistance* number 93.933. This supplement funding is related to the original goals of the cooperative agreement and does not represent an expansion of activities outside of the present scope of work. The **Federal Register** Notice for the sole-source cooperative agreement award can be found in 69 FR 11447, published on March 10, 2004. The specific objectives and justifications for this program supplement are as follows:

1. Outreach and Education Within the AI/AN Community Concerning the Programs of the Centers for Medicare and Medicaid Services (CMS)

We anticipate funding will be transferred through an inter-agency agreement between CMS and the IHS to supplement the NIHB cooperative agreement. the NIHB will inform and educated AI/AN beneficiaries on programs and opportunities that can be accessed in CMS. The NIHB will dedicate one full day of its upcoming annual health conference (*i.e.,* the 22nd Annual NIHB Consumer Conference in October 2005) to familiarize the anticipated 800 attendees with CMS and its programs. In addition the NIHB will provide expertise and assistance to he Tribal Technical Advisory Group (TTAG) with consultation efforts to ensure that Tribes have input in the development of both the CMS Tribal strategic plan and the CMS consultation policy for AI/AN's. This supplement will benefit AI/AN's by informing a AI/AN's of CMS programs established address health care needs of which they may not otherwise be aware. The benefit to the IHS is increased funding resources to the AI/AN beneficiaries. This effort is consistent with the NIHB's goals of expanding the access to other programs of the HHS for AI/AN.

2. Enumeration of the Public Health Infrastructure in AI/AN Communities

We anticipate funding will be transferred to the IHS from the CDC to conduct a study of the status of Tribal public health capacity in areas such as epidemiology disease surveillance, public health nursing, community environmental health, health education and promotion, and other preventative health capacities. A paucity of information exists about the prevention capacity available throughout the Tribal Public Health System (TPHS) which broadly includes Tribal health departments, health committees, service units, and services provided by Indian Health Boards. The study, which will be undertaken by the NIHB, will provide current and accurate date on the Tribal Public Health System and will serve as a foundation for public health workforce research, workforce development efforts and demonstration programs and discussions on the training needs of public health workers. This effort is consistent with the NIHB's goal of providing advice and assistance in the areas of health care policy analysis and program development.

3. Support of the Activities of the Tribal Leader's Diabetes Committee

Efforts to prevent and combat diabetes and its complications have been major activities for the IHS over the last several years that have resulted in numerous positive accomplishments. A major reason for this success had been the active involvement of AI/AN Tribal Leadership in determining, with the IHS, how resources should be targeted, and ''best practices'' that can be replicated throughout the Indian Country. Funding through the supplement will enable the NIHB to provide support to the Tribal Leaders Diabetes Committees (TLDC), which provide advice and recommendations to the NIHB on the public health effort to prevent and control diabetes. This effort is consistent with the NIHB goals of providing advice and assistance in the areas of policy analysis and program development and in ensuring that health care advocacy is based on input from Tribal Government.

Justification for Single Source: This project has been awarded on a non-competitive, single-source basis. The NIHB is the only national AI/AN organization with health expertise that represents the interest of all federally recognized Tribes.

Use of Cooperative Agreement: The program supplement to the original cooperative agreement has been awarded because of anticipated substantial programmatic involvement by IHS staff in the project. The substantial programmatic involvement includes the following:

1. The IHS staff will have approval over the hiring of key personnel as defined by regulation or provisions in the cooperative agreement.

2. The IHS will provide technical assistance to the NIHB as requested and attend and participate in all NIHB board meetings.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Black, Director, Office of Tribal Programs, Office of the Director, Indian Health Service, 801 Thompson Avenue, Reyes Building, Suite 220, Rockville, Maryland 20852, (301) 443–1104. For grants information, contact Ms. Sylvia Ryan, Grants Management Specialist, Division of Grants Policy, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, (301) 443–5204.

Dated: September 13, 2005.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. 05–18653 Filed 9–19–05; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: Standard Flood Hazard Determination Form.

OMB Number: 1660–0040.

Abstract: On September 23, 1994, the President signed the Riegle Community Development and Regulatory Improvement Act of 1994. Title V of this Act is the National Flood Insurance Reform Act (NFIRA). Section 528 of the NFIRA requires that FEMA develop a standard hazard determination form for recording the determination of whether a structure is located within an identified Special Flood Hazard Area available. Section 528 of the NFIRA also requires the use of this form by regulated lending institutions, Federal agency lending institutions, Federal agency lenders, the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, and the Government National Mortgage Association for any loan made, increased, extended, renewed or purchased by these entities. The form developed to comply with the above requirements is the Standard Flood Hazard Determination form (FEMA Form 83–93, dated October 2002). This form will be completed by federally regulated lending institutions when making, increasing, extending, renewing or purchasing each loan for the purpose of documenting the factors considered as to whether flood insurance is required and available. An estimated 33,000,000 such uses are made each year. This number is entirely driven by the volume of mortgage transactions, of which fluctuations in interest rates is a principal factor.

Affected Public: Business or other for-profit, Federal Government.

Number of Respondents: 33,000,000.

Estimated Time per Respondent: 0.33 hours (20 minutes).

Estimated Total Annual Burden Hours: 10,890,000.

Frequency of Response: Once.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395–7285. Comments must be submitted on or before October 20, 2005.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Section Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov.*

Dated: September 13, 2005.

Darcy Bingham,

Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05–18731 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: Public Assistance Progress Report and Program Forms.

OMB Number: 1660–0017.

Abstract: This collection serves as the mechanism to administer the Public Assistance (PA) Program. The application process contains recordkeeping and reporting requirements via mandatory and optional completion of several forms and timeframes. The Progress Report and related forms ensure that FEMA and the State have up-to-date information on PA program grants. The report describes the status of project completion dates, and circumstances that could delay a project. States are responsible for determining reporting requirements for applicants and must submit reports quarterly to FEMA Regional Directors. The date of the report is determined jointly by the State and the Disaster Recovery Manager.

Affected Public: State, local or tribal government, and Not-for-Profit Organizations.

Number of Respondents: 5,070 respondents from State, local or tribal governments and Not-for Profit Organizations.

Estimated Time per Respondent: 134 hours per respondent allocated as follows: Progress Report = 100 hours, Mandatory Audit = 30 hours; Mandatory forms = 3 hours; and Optional forms = 1 hour.

Estimated Total Annual Burden Hours: 134,562 hours.

Frequency of Response: Quarterly or Yearly.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395–7285. Comments must be submitted on or before October 20, 2005.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov*.

Dated: September 13, 2005.

Darcy Bingham,

Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05–18732 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3237–EM]

Alabama; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Alabama (FEMA–3237–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Alabama, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act). Therefore, I declare that such an emergency exists in the State of Alabama.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Ron Sherman, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Alabama to have been affected adversely by this declared emergency:

All 67 counties in the State of Alabama for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18647 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3241–EM]

Arizona; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Arizona (FEMA–3241–EM), dated September 12, 2005, and related determinations.

EFFECTIVE DATE: September 12, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 12, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Arizona, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act). Therefore, I declare that such an emergency exists in the State of Arizona.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Karen E. Armes, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Arizona to have been affected adversely by this declared emergency:

All 15 counties in the State of Arizona for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public

Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18643 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3226–EM]

District of Columbia; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the District of Columbia (FEMA–3226–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the District of Columbia, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the District of Columbia.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Patricia G. Arcuri, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the District of Columbia to have been affected adversely by this declared emergency:

The District of Columbia for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18638 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3230–EM]

Illinois; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Illinois (FEMA–3230–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Illinois, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Illinois.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Janet M. Odeshoo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Illinois to have been affected adversely by this declared emergency:

All 102 counties in the State of Illinois for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18634 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3238–EM]

Indiana; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Indiana (FEMA–3238–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Indiana, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Indiana.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Janet M. Odeshoo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Indiana to have been affected adversely by this declared emergency:

All 92 counties in the State of Indiana for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18640 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3239–EM]

Iowa; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Iowa (FEMA–3239–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Iowa, resulting from the influx of evacuees from states impacted by Hurricane Katrina, beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Iowa.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Arthur L. Freeman, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Iowa to have been affected adversely by this declared emergency:

All 99 counties in the State of Iowa for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18641 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3236–EM]

Kansas; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Kansas (FEMA–3236–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Kansas, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Kansas.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Arthur L. Freeman, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Kansas to have been affected adversely by this declared emergency:

All 105 counties in the State of Kansas for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18646 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3231–EM]

Kentucky; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Kentucky (FEMA–3231–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the Commonwealth of Kentucky, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act). Therefore, I declare that such an emergency exists in the Commonwealth of Kentucky.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Paul Fay, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the Commonwealth of Kentucky to have been affected adversely by this declared emergency:

All 120 counties in the Commonwealth of Kentucky for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18633 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3225–EM]

Michigan; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Michigan (FEMA–3225–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Michigan, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Michigan.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Janet M. Odeshoo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Michigan to have been affected adversely by this declared emergency:

All 83 counties in the State of Michigan for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18639 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3232–EM]

Missouri; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Missouri (FEMA–3232–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Missouri, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Missouri.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under

Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Arthur L. Freeman, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Missouri to have been affected adversely by this declared emergency:

All 115 counties in the State of Missouri for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18632 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3229–EM]

New Mexico; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New Mexico (FEMA–3229–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of New Mexico, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act). Therefore, I declare that such an emergency exists in the State of New Mexico.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Carlos Mitchell, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of New Mexico to have been affected adversely by this declared emergency:

All 33 counties in the State of New Mexico for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18635 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3228–EM]

Oregon; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Oregon (FEMA–3228–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Oregon, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Oregon.

You are authorized to provide appropriate assistance for required emergency measures,

authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, John E. Pennington, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Oregon to have been affected adversely by this declared emergency:

All 36 counties in the State of Oregon for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18636 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3235–EM]

Pennsylvania; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Pennsylvania (FEMA–3235–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the Commonwealth of Pennsylvania resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the Commonwealth of Pennsylvania.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Patricia G. Arcuri, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the Commonwealth of Pennsylvania to have been affected adversely by this declared emergency:

All 67 counties in the Commonwealth of Pennsylvania for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18645 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3233–EM]

South Carolina; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of South Carolina (FEMA–3233–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of South Carolina, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act). Therefore, I declare that such an emergency exists in the State of South Carolina.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Paul Fay, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of South Carolina to have been affected adversely by this declared emergency:

All 46 counties in the State of South Carolina for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18631 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3234–EM]

South Dakota; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of South Dakota (FEMA–3234–EM), dated September 10, 2005, and related determinations.

EFFECTIVE DATE: September 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of South Dakota, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of South Dakota.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Douglas A. Gore, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of South Dakota to have been affected adversely by this declared emergency:

All 66 counties in the State of South Dakota for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18644 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3240–EM]

Virginia; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Virginia (FEMA–3240–EM), dated September 12, 2005, and related determinations.

EFFECTIVE DATE: September 12, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 12, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the Commonwealth of Virginia resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the Commonwealth of Virginia.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Patricia G. Arcuri, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the Commonwealth of Virginia to have been affected adversely by this declared emergency:

All 95 counties and 40 independent cities in the Commonwealth of Virginia for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18642 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3227–EM]

Washington; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Washington (FEMA–3227–EM), dated September 7, 2005, and related determinations.

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 7, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Washington, resulting from the influx of evacuees from states impacted by Hurricane Katrina beginning on August 29, 2005, and continuing, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Washington.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act to save lives and protect public health and safety, or to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program, at 100 percent Federal funding. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

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 emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration 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 Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, John E. Pennington, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Washington to have been affected adversely by this declared emergency:

All 39 counties in the State of Washington for Public Assistance Category B (emergency protective measures), including direct Federal assistance, at 100 percent Federal funding.

(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 Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–18637 Filed 9–19–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Wildlife and Plants; 5-Year Review of 14 Southeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces a 5-year review of the red wolf (*Canis rufus*), Appalachian elktoe (*Alasmidonta raveneliana*), Cumberland elktoe (*Alasmidonta atropurpurea*), Cumberland monkeyface (*Quadrula intermedia*), Cumberlandian combshell (*Epioblasma brevidens*), green blossom (*Epioblasma torulosa gubernaculum*), oyster mussel (*Epioblasma capsaeformis*), tubercled blossom (*Epioblasma torulosa torulosa*), turgid blossom (*Epioblasma turgidula*), yellow blossom (*Epioblasma florentina florentina*), painted snake coiled forest snail (*Anguispira picta*), dwarf-flowered heartleaf (*Hexastylis naniflora*), Schweinitz's sunflower (*Helianthus schweinitzii*), and seabeach amaranth (*Amaranthus pumilus*) under section 4(c)(2) of the Endangered Species Act of 1973, as amended (Act). The purpose of reviews conducted under this section of the Act is to ensure that the classification of species as threatened or endangered on the List of Endangered and Threatened Wildlife and Plants (50 CFR 17.11 and 17.12) is accurate. The 5-year review is an assessment of the best scientific and commercial data available at the time of the review.

DATES: To allow us adequate time to conduct this review, information submitted for our consideration must be received on or before November 21, 2005. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: Information submitted on the red wolf should be sent to the U.S. Fish and Wildlife Service, Alligator River National Wildlife Refuge, P.O. Box 1969, Manteo, North Carolina 27954. Information submitted on the Appalachian elktoe, Cumberland monkeyface, dwarf-flowered heartleaf, Schweinitz's sunflower, or the tubercled blossom should be sent to the Field Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 160 Zillicoa Street, Asheville, North Carolina 28801. Information submitted on the Cumberland elktoe, Cumberlandian combshell, green blossom, oyster mussel, painted snake coiled forest snail, turgid blossom or the yellow blossom should be sent to the Field Supervisor, Cookeville Field Office, U.S. Fish and Wildlife Service, 446 Neal Street, Cookeville, Tennessee 38501. Information on the seabeach amaranth should be sent to the Field Supervisor, Raleigh Field Office, P. O. Box 33726, Raleigh, North Carolina 27636–3726. Information received in response to this notice of review will be available for public inspection by appointment, during normal business hours, at the same addresses.

FOR FURTHER INFORMATION CONTACT: Buddy Fazio, Alligator River National Wildlife Refuge, North Carolina, address above for the red wolf (telephone (252) 473–1131), John Fridell at the Asheville, North Carolina address above for the Appalachian elktoe (telephone (828) 258–3939), Robert Butler at the Asheville, North Carolina address above for the Cumberland monkeyface or the tubercled blossom (telephone (828) 258–3939), Carolyn Wells at the Asheville, North Carolina address above for dwarf-flowered heartleaf or Schweinitz's sunflower (telephone (828) 258–3939), Tim Merritt at the Cookeville, Tennessee address above for the Cumberland elktoe, Cumberlandian combshell, green blossom, oyster mussel, painted snake coiled forest snail, turgid blossom or the yellow blossom (telephone (931) 528–6481), and Dale Suiter at the Raleigh, North Carolina address above for the seabeach amaranth (telephone (919) 856–4520).

SUPPLEMENTARY INFORMATION: Under the Act (16 U.S.C. 1533 *et seq.*), the Service maintains a list of endangered and threatened wildlife and plant species at 50 CFR 17.11 (for wildlife) and 17.12 (for plants) (collectively referred to as the List). Section 4(c)(2)(A) of the Act requires that we conduct a review of listed species at least once every five years. On the basis of such review, under section 4(c)(2)(B), we determine whether or not species should be removed from the List (delisted), or reclassified from endangered to threatened or from threatened to endangered. Delisting a species must be supported by the best scientific and commercial data available and only considered if such data substantiate that the species is neither endangered nor threatened for one or more of the following reasons: (1) The species is considered extinct; (2) the species is considered to be recovered; and/or (3) the original data available when the species was listed, or the interpretation of such data, were in error. Any change in Federal classification would require a separate rulemaking process. The regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently under active review. This notice announces our active review of the following species that are currently federally listed as endangered: Appalachian elktoe, red wolf, Cumberland monkeyface, Cumberland elktoe, Cumberlandian combshell, green blossom, oyster mussel, tubercled blossom, turgid blossom, yellow blossom, and Schweinitz's sunflower. This notice announces our active review of the following species that are currently federally listed as threatened: painted snake coiled forest snail, dwarf-flowered heartleaf and seabeach amaranth.

The List is found at 50 CFR 17.11 (wildlife) and 17.12 (plants) and is also available on our Internet site at *http://endangered.fws.gov/wildlife.html#Species.* Amendments to the List through final rules are published in the **Federal Register**.

What Information Is Considered in the Review?

A 5-year review considers all new information available at the time of the review. A 5-year review will consider the best scientific and commercial data that have become available since the current listing determination or most recent status review of each species, such as:

A. Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

B. Habitat conditions, including but not limited to amount, distribution, and suitability;

C. Conservation measures that have been implemented to benefit the species;

D. Threat status and trends (see five factors under heading ''How do we determine whether a species is endangered or threatened?''); and

E. 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.

Specific Information Requested for the Green Blossom, Yellow Blossom, and Turgid Blossom

Because collection of live or fresh dead individuals of all three species has not been reported for more than 20 years, we are especially interested in obtaining evidence of extant populations. We specifically request information regarding recent surveys in the following streams:

Virginia (green blossom): Clinch River, Powell River, North Fork Holston River, and North Fork Clinch River.

Tennessee (green blossom): Clinch River, Powell River, Holston River, Nolichucky River, and North Fork Clinch River.

Arkansas (turgid-blossom): Spring Creek, Black River, and White River.

Missouri (turgid-blossom): White River.

Alabama (turgid-blossom): Shoal Creek and Bear Creek.

Tennessee (turgid-blossom): Tennessee River, Elk River, Duck River, Holston River, Clinch River, Emory River, and Cumberland River.

Alabama (yellow-blossom): Flint River, Hurricane Creek, Limestone Creek, Bear Creek, and Cypress Creek.

Tennessee (yellow-blossom): Tennessee River, Elk River, Duck River, Holston River, Little Tennessee River, Citico Creek, Clinch River, and Cumberland River.

We also request information concerning changes in habitat conditions in the above-listed streams since the last reported collection of the green-blossom, yellow-blossom, and turgid-blossom. This information will enable us to determine whether or not populations of the species may still exist in one or more of those streams.

Specific Information Requested for the Cumberland Elktoe, Cumberlandian Combshell, and Oyster Mussel

We are especially interested in information on surviving populations of the Cumberland elktoe, Cumberlandian combshell and oyster mussel. We specifically request any recent information regarding the collection of live or fresh dead shells of these species, as well as information on their location, numbers, habitats and/or threats.

Specific Information Requested for the Painted Snake Coiled Forest Snail

We are especially interested in obtaining any data pertaining to previously known or newly discovered occurrences of the painted snake coiled forest snail or biological studies related to this species. We specifically request information regarding: potential threats arising from commercial, industrial, or residential development, timber harvesting, or other land use activities; conservation activities directed towards this species; and studies related to life history, genetics, and ecology of these animals, including sensitivity to seismic disturbance or limestone dust deposition that could result from quarrying operations.

Specific Information Requested for the Seabeach Amaranth

We are especially interested in information on population trends, distribution and genetics, as well as, the effects of beach nourishment projects on seabeach amaranth individuals, populations and habitat.

Definitions Related to This Notice

The following definitions are provided to assist those persons who contemplate submitting information regarding the species being reviewed:

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.

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.

How Do We Determine Whether a Species Is Endangered or Threatened?

Section 4(a)(1) of the Act establishes that we determine whether a species is endangered or threatened based on one or more of the following five 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. Section 4(a)(1) of the Act requires that our determination be made on the basis of the best scientific and commercial data available.

What Could Happen as a Result of This Review?

If we find that there is new information concerning any of these 14 species indicating that 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 endangered to threatened (downlist); (b) reclassify the species from threatened to endangered (uplist); or (c) delist the species. If we determine that a change in classification is not warranted, then these species will remain on the List under their current status.

Public Solicitation of New Information

We request any new information concerning the status of these 14 species. See ''What information is considered in the review?'' heading for specific criteria. Information submitted should be supported by 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. Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home addresses from the supporting record, which we will honor to the extent allowable by law. There also may be circumstances in which we may withhold from the supporting record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will not consider anonymous comments, however. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Authority: This document is published under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: August 25, 2005.

Jeffrey Fleming,

Acting Regional Director, Southeast Region.

[FR Doc. 05–18688 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Draft Safe Harbor Agreement and Receipt of an Application for an Enhancement of Survival Permit Associated With Proposed Restoration Activities for the Karner Blue Butterfly in the West Gary, Indiana Recovery Unit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The Nature Conservancy (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an Enhancement of Survival Permit Associated with proposed restoration activities for the Karner blue butterfly (*Lycaeides melissa samuelis*) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973 (U.S.C. 1531 *et seq.*), as amended (Act). This permit

application includes a draft Safe Harbor Agreement (SHA) between the Applicant and the Service. The proposed SHA and permit would become effective upon signature of the SHA and issuance of the permit and would remain in effect for 15 years. We are requesting comments on the permit application and on the Service's preliminary determination that the proposed SHA qualifies as a categorical exclusion (516 DM 6 Appendix 1, 1.4C(1)) under the National Environmental Policy Act (NEPA) of 1969, as amended. Further, the Service is specifically soliciting information regarding the adequacy of the SHA as measured against the Service's Safe Harbor Policy and the implementing regulations.

DATES: Written data or comments must be received on or before October 20, 2005.

ADDRESSES: 1. Regional Director, U.S. Fish and Wildlife Service, Ecological Services, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056.

2. U.S. Fish and Wildlife Service, Ecological Services, 620 South Walker Street, Bloomington, Indiana 47403–2121.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Fasbender, (612) 713–5343.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Individuals requesting copies of the enhancement of survival permit application and SHA should contact the Service by telephone at (612) 713–5343 or by letter (see **ADDRESSES**). Copies of the proposed SHA also are available for public inspection during regular business hours at the Bloomington, Indiana, Field Office (see **ADDRESSES**) or at the Service's Regional Web site at: *http://www.fws.gov/midwest/NEPA*. All comments received from individuals become part of the official public record. Requests for such comments will be handled in accordance with the Freedom of Information Act and the Council on Environmental Quality's NEPA regulations [40 CFR 1506.6(f)]. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. If a respondent wishes us to withhold his/her name and/or address, this must be stated prominently at the beginning of the comment.

Background

The Karner blue butterfly was once a locally common species ranging from New England across the Great Lakes Region, extending as far west as eastern Minnesota. In Indiana, the Karner was originally distributed across the northern tier of counties on outwash and lake deposited sands. Currently there are approximately 1,000 acres of dune and swale topography remaining in the West Gary Recovery Unit, of this approximately 650 acres is potential habitat. By 1990, the Karner blue butterfly survived at only two dune and swale remnants: Ivanhoe Nature Preserve and Tolleston Ridges Nature Preserve. At Ivanhoe Nature Preserve, the butterfly was found within scattered openings until it disappeared there in 1998. After several years of habitat restoration effort, the Nature Conservancy began a re-introduction program in 2001. Despite recent success, the Karner blue butterfly continues to persist at limited habitat patches within three relatively isolated natural areas. Ecological fragmentation, combined with complex landownership and land use patterns, has created a difficult landscape for developing and implementing conservation strategies in the West Gary Recovery Unit.

The purpose of the SHA is to allow the Applicant and the Service to address the regional needs of the species by working with individual landowners to develop site specific restoration and management plans for a variety of properties. These plans will be designed to maximize Karner blue butterfly habitat within the constraints of the site's landscape setting and current land use and management needs. In addition they will document baseline conditions, monitoring protocols, timeframes, legal and regulatory responsibilities of participants, and will serve as a framework for coordinating conservation work in the West Gary Recovery Unit.

The SHA will allow willing property owners to enroll private and non-federal governmental lands into a regional program under an umbrella section 10(a)(1)(A) permit issued to the Applicant by means of a Certification of Inclusion. In addition, the Applicant will develop individual restoration and management plans to address the specific conservation benefits that enrolled properties contribute to establishing a viable metapopulation.

The area encompassed by the SHA may contain facilities eligible to be listed on the National Register of Historic Places. Additionally, other historical or archeological resources may be present. The National Historic Preservation Act and other laws require these properties and resources be identified and considered in project planning. The public is requested to inform the Service of concerns about archeological sites, buildings, and structures; historic events; sacred and traditional areas; and other historic preservation concerns.

Dated: August 23, 2005.

Wendi Weber,

Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 05–18682 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Ohio Department of Natural Resources Candidate Conservation Agreement With Assurances and Enhancement of Survival Permit Application for the Eastern Massasauga Rattlesnake

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The Fish and Wildlife Service (Service) has received an application from the Ohio Department of Natural Resources (Applicant) for an enhancement of survival permit (ESP) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973 (U.S.C. 1531 *et seq.*), as amended (Act). The Applicant proposes to implement conservation measures for the Eastern Massasauga rattlesnake (*Sistrurus sistrurus catenatus*) by removing the threats to the survival and protecting and managing its habitat within the Rome State Nature Preserve. The Service announces receipt of the ESP application as well as the availability of a proposed Candidate Conservation Agreement with Assurances (CCAA) intended to facilitate the implementation of conservation measures for the species by the Applicant. Compliance under the National Environmental Policy Act (NEPA) for the proposed action was addressed in an Environmental Assessment (EA) approved July 26, 2005. A copy of the final EA and Finding of No Significant Impact (FONSI) is available at: *http://www.fws.gov/midwest/NEPA.*

DATES: Written data or comments must be received on or before October 20, 2005.

ADDRESSES: 1. Regional Director, U.S. Fish and Wildlife Service, Ecological

Services, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056.

2. U.S. Fish and Wildlife Service, Ecological Services Field Office, 6950 Americana Pkwy, Suite H, Reynoldsburg, Ohio 43068–4127.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Fasbender, (612) 713–5343, or *peter_fasbender@fws.gov.*; or Ms. Angela Zimmerman, telephone: (614) 469–6923.

SUPPLEMENTARY INFORMATION:

Availability of Documents

We provide this notice pursuant to section 10(c) of the Act and pursuant to implementing regulations for the National Environmental Policy Act (NEPA) found at (40 CFR 1506.6). All comments received on the permit application and proposed Agreement, including names and addresses, will become part of the administrative record and may be released to the public. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. All submissions from organizations or companies, or from individuals representing organizations or companies, are available for public inspection in their entirety.

Background

The eastern massasauga rattlesnake, also known as the swamp rattler or black snapper, is a resident of many glaciated areas of Ohio. The massasauga was once common throughout much of the Great Lakes basin, but now is restricted to scattered, often isolated populations. Extensive farming, draining of their wetland habitats, vegetation succession and other forms of habitat fragmentation has contributed to their reduced numbers. Loss of habitat and persecution by humans are thought to be the primary causes of decline. Current records from the Heritage Database (Division of Natural Areas and Preserves) place the snake in only 15 Ohio counties. At least eight of these populations occur on state-owned and/or managed land. The Division of Natural Areas and Preserves (the Division) manages three sites, the Division of Wildlife manages four sites and the Ohio Historical Society manages another. The massasauga was listed as an endangered species in Ohio in 1996. In October 1999, the Service designated it a candidate species for Federal protection by the Endangered Species Act.

The Rome State Nature Preserve is located within Ashtabula County, Ohio. Containing approximately 105 acres, the preserve is located between Rome and Hartsgrove Townships and lies within the Grand River watershed. Under the CCAA, the Applicant has agreed to implement several conservation measures that will reduce and/or eliminate potential threats to the species. The Applicant will: (1) Maintain and manage the Rome State Nature Preserve in a mosaic of habitats essential for the massasauga; (2) control the spread of invasive vegetation species; and (3) implement protective measures to reduce losses from human and natural predators.

Implementation of the CCAA is expected to protect and conserve habitat for the covered species, eliminate unauthorized human disturbances within Rome State Nature Preserve that are believed to impact the covered species, and provide important monitoring data that can be used to develop and/or improve management strategies for the massasauga. These benefits will be obtained through restoration and protection of habitats on the enrolled property.

We will make our final determination after the end of the 30-day comment period and will fully consider all comments received. If the final analysis shows the CCAA to be consistent with our policies and applicable regulations, we will sign the CCAA and issue the ESP. The proposed ESP would, in compliance with the CCAA policy, only become valid on such date as the eastern massasauga rattlesnake is listed as a threatened or endangered species under the Act.

Written data or comments concerning the CCAA or ESP application should be submitted to the Regional Director. (see **ADDRESSES** section). Further, persons wishing to review the CCAA and ESP application may obtain copies by writing to the same address or they can be viewed on the Service's Regional Web site at: *http://www.fws.gov/midwest/NEPA.* Comments must be submitted in writing to be adequately considered in the Service's decision-making process. Please reference permit number TE–101451 in your comments, or in requests of the documents discussed herein. Documents will also be available for public inspection by appointment during normal business hours at the Reynoldsburg, Ohio, Ecological Services Field Office (see **ADDRESSES** section).

Dated: August 29, 2005.

Wendi Weber,

Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 05–18683 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–PB–24 1A]

Extension of Approved Information Collection, OMB Control Number 1004–0185

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is requesting the Office of Management and Budget (OMB) to extend existing approvals to collect certain information from lessees, operators, record title holders, operating rights owners, and the general public on oil and gas and operations on Federal lands.

DATES: You must submit your comments to BLM at the address below on or before November 21, 2005. BLM will not necessarily consider any comments received after the above date.

ADDRESSES: You may mail comments to: Bureau of Land Management, (WO–630), Eastern States Office, 7450 Boston Blvd., Springfield, Virginia 22153.

You may send comments via e-mail to: *comments_washington@blm.gov.* Please include ''Attn: 1004–0185'' and your name and return address in your Internet message.

You may deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620 L Street, NW., Washington, DC.

All comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday except Federal holidays.

FOR FURTHER INFORMATION CONTACT: You may contact Barbara Gamble, on (202) 452–0338 (Commercial or FTS). Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) on 1–800–877–8330, 24 hours a day, seven days a week, to contact Ms. Gamble.

SUPPLEMENTARY INFORMATION: 5 CFR 1320.12(a) requires that we provide a 60-day notice in the **Federal Register** concerning a collection of information to solicit comments on:

(1) Whether the collection of information is necessary for the proper functioning of the agency, including whether the information will have practical utility;

(2) The accuracy of our estimates of the information collection burden, including the validity of the methodology and assumptions we use;

(3) Ways to enhance the quality, utility, and clarity of the information collected; and

(4) Ways to minimize the information collection burden on those who are required to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The Mineral Leasing Act of 1920 (MLA), 30 U.S.C. 191 *et seq.,* gives the Secretary of the Interior responsibility for oil and gas leasing on approximately 570 million acres of public lands and national forests, and private lands where the mineral rights are reserved by the Federal government. The Act of May 21, 1930 (30 U.S.C. 301–306), authorizes the leasing of oil and gas deposits under railroads and other rights-of-way. The Act of August 7, 1947 (Mineral Leasing Act of Acquired Lands), authorizes the Secretary to lease lands acquired by the United States (30 U.S.C. 341–359). The regulations under 43 CFR part 3000 *et al.* authorize BLM to manage the oil and gas leasing and exploration activities. Without the information, BLM would not be able to analyze and approve oil and gas leasing and exploration activities.

BLM collects nonform information on oil and gas leasing and exploration activities when the lessee, record title holder, operating rights owner, or operator files any of the following information for BLM to adjudicate:

43 CFR	Information collection requirements	Number of responses	Reporting hours per respondent	Total hours
3100.3–1	Notice of option holdings	30	1	30
3100.3–3	Option statement	50	1	50
3101.2–4(a)	Excess acreage petition	10	1	10
3101.2–6	Showings statement	10	1.5	15
31.1.3–1	Joinder evidence statement	50	1	50
3103.4–1	Waiver, suspension, reduction of rental, etc.	20	2	40
3105.2	Communitization or drilling agreement	150	2	300
3105.3	Operating, drilling, development contracts interest statement	50	2	100
3105.4	Joint operations; transportation of oil applications	20	1	20
3105.5	Subsurface storage application	50	1	50
3106.8–1	Heirs and devisee statement	40	1	40
3106.8–2	Change of name report	60	1	60
3106.8–3	Corporate merger notice	100	2	200
3107.8	Lease renewal application	30	1	30
3108.1	Relinquishments	150	.5	75
3108.2	Reinstatement petition	500	.5	250
3109.1	Leasing under rights-of-way application	20	1	20
3120.1–1(e)	Lands available for leasing	280	2.5	700
3120.1–3	Protests and appeals	90	1.5	135
3152.1	Oil and gas exploration in Alaska application	20	1	20
3152.6	Data collection	20	1	20
3152.7	Completion of operations report	20	1	20
Totals		1,770		2,235

BLM collects the information in the regulations that address oil and gas drainage and no form is required.

Type of drainage analysis	Number of analyses	Hours
Preliminary	1,000	2,000
Detailed	100	2,400
Additional	10	200
Total	1,110	4,600

Based upon our experience managing oil and gas activities, we estimate for the information collection 2,880 responses per year with an annual information burden of 6,835 hours.

BLM will summarize all responses to this notice and include them in the request for OMB approval. All comments will become a matter of public record.

Dated: September 14, 2005.

Ian Senio,

Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 05–18699 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–025–1232–EA–NV06; Special Recreation Permit # NV–025–05–01]

Notice of Temporary Closure of Public Lands: Pershing, Washoe, & Humboldt Counties, NV

AGENCY: Bureau of Land Management, Winnemucca Field Office, Nevada, Interior.

ACTION: Notice to the public of temporary closures on public lands administered by the Bureau of Land Management, Winnemucca Field Office, Nevada.

SUMMARY: Notice is hereby given that certain lands will be temporarily closed to public use in and around the Paragon Astronautics rocket launch site, located in Pershing, Washoe and Humboldt counties, Nevada, from 0700 to 1200 hours, September 27, 2005–September 30, 2005; October 3, 2005–October 7, 2005; and October 11, 2005–October 14, 2005. These closures are being made in the interest of public safety at and around the location of an amateur high-altitude rocket launch site. This event is expected to attract approximately 50 participants. The lands involved are located northeast of Gerlach, Nevada in the Mount Diablo Meridian.

The following Public Lands are closed to public use: Public land areas north of the Union Pacific Railroad tracks, east of State Highway 34 and County Road 200, and west of the Pahute Peak and Black Rock Desert wilderness boundaries within the following legally described areas:

Unsurveyed T33.5N, R24E

Sec. 25–28, 33–36

Unsurveyed T33N R24E
Sec., 1–5, 8–12, 14–18, 19–22, 29–30
Unsurveyed T33N, R25E
Sec. 3,4
Unsurveyed T34N, R24E
Sec. 1,2, 11,12, 13–15, 22–24, 25–27, 34–36
Unsurveyed T34N, R25E
Sec.1–4, 9–16, 21–28, 33–36
Unsurveyed T34N, R26E
Sec. 1–23, 28–31
Unsurveyed T34N, R27E
Sec. 3–6, 7, 8
Unsurveyed T35.5N, R25E
Sec. 27–29, 32–34
Unsurveyed T35.5N, R26E
Sec. 25–36
Unsurveyed T35N, R24E
Sec. 13, 24–26, 35, 36
Unsurveyed T35N, R25E
Sec. 1–4,9–16, 21–28, 33–36
Unsurveyed T35N, R26E
Unsurveyed T35N R27E
Unsurveyed T36N, R25E
Sec. 1–3, 9–16, 21–28, 32–36
Unsurveyed T36N, R26E
Unsurveyed T36N, R27E
Sec. 4–9, 16–21, 28–33
Unsurveyed T37N, R25E
Sec. 22–27, 34–36
Unsurveyed T37N, R26E
Sec. 19–36
Unsurveyed T37N, R27E
Sec. 19–21, 28–33

To ensure public safety these lands will be closed to public use from 0700–1200 hours during the Paragon Astronautics permit period, with the exception of BLM personnel, law enforcement, emergency medical services, and Paragon Astronautics staff as designated by the BLM authorized officer.

A map showing these temporary closures, restrictions and prohibitions is available from the following BLM offices:

BLM-Winnemucca Field Office, 5100 East Winnemucca Blvd, Winnemucca, Nevada 89445–2921.
BLM-State Office, 1340 Financial Blvd, Reno, Nevada 89520–0006.

DATES: Closure to public use from 0700–1200 hours, September 27–30, 2005; October 3–7, 2005; and October 11–14, 2005.

FOR FURTHER INFORMATION CONTACT: Dave Lefevre, National Conservation Area Outdoor Recreation Planner, Bureau of Land Management, Winnemucca Field Office, 5100 E Winnemucca Blvd, Winnemucca, NV 89445, telephone: (775) 623–1500.

Authority: 43 CFR 8364.1.

Penalty: Any person failing to comply with the closure orders may be subject to imprisonment for not more than 12 months, or a fine in accordance with the applicable provisions of 18 U.S.C. 3571, or both.

Gail G. Givens,
Field Manager.

[FR Doc. 05–18607 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–056–1430–EU; N–61362]

Recreation and Public Purposes Act Classification, Nye County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification for lease or conveyance under the provisions of the Recreation and Public Purposes Act approximately 82.81 acres of public land in Nye County, Nevada. The Nye County School District proposes to use the land for school site purposes.

DATES: Interested parties may submit written comments to the BLM at the address stated below. Comments must be received by not later than November 4, 2005.

ADDRESSES: Please mail your comments to the Las Vegas Field Manager, Bureau of Land Management, Las Vegas Field Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130–2301.

FOR FURTHER INFORMATION CONTACT: Shawna Woods, Realty Specialist at the above address or by telephone at (702) 515–5099.

SUPPLEMENTARY INFORMATION: The following described public land near Pahrump, Nevada in Nye County has been examined and found suitable for classification for lease or conveyance under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended (43 U.S.C. 869 *et seq.*) and is hereby classified accordingly:

Mount Diablo Meridian, Nevada

T. 21 S., R 53 E.,
Sec. 3, Lots 2 and 3.
Containing 82.82 acres, more or less.

In accordance with the R&PP Act, the Nye County School District has filed a petition/application and Plan of Development for an elementary school campus, bus storage, and maintenance yard. The Plan of Development was subsequently amended to add a middle school and high school. The land is not required for any federal purpose. The lease or conveyance is consistent with the Las Vegas Resource Management Plan, dated October 5, 1998, and would be in the public interest. The lease or conveyance, when issued, will be subject to the following terms, conditions, and reservations:

1. Provisions of the Recreation and Public Purposes Act are all applicable regulation of the Secretary of the Interior.

2. Reservation of a right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (26 Stat. 391, 43 U.S.C. 945).

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove such deposits from the same under applicable laws and regulations established by the Secretary of the Interior.

And will be subject to:

Valid existing rights of record, including those documented on the official public land records at the time of lease or patent issuance.

These lands were previously identified for exchange and segregated from mineral entry under case file number N–61968FD, with record notation as of October 1, 2002. The exchange is no longer being pursued, the associated segregation, therefore, will terminate upon the date and time of publication of this Notice of Realty Action in the **Federal Register**, and the lands will thereupon be opened to disposal.

(43 CFR 2201.1–2(c)(2))

Detailed information concerning the proposed action, including but not limited to documentation relating to compliance with applicable environmental and cultural resource laws, is available for review at the BLM, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130, and telephone: (702) 515–5099.

On September 20, 2005, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for leasing or conveyance under the R&PP Act and leasing under the mineral leasing laws.

Interested parties may submit written comments regarding the proposed lease or conveyance or classification of the land to the Field Manager at the address stated above in this notice for that purposes. Comments must be received by not later than November 4, 2005.

Classification Comments: Interested parties may submit comments involving the suitability of the land for an elementary school campus, bus storage,

and maintenance yard. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a school campus and bus storage yard.

Any adverse comments will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, these realty actions will become the final determination of the Department of the Interior. The classification of the land described in this Notice will become effective on November 21, 2005. The lands will not be offered for lease or conveyance until after the classification becomes effective.

(Authority: 43 CFR 2741.5)

Dated: July 29, 2005.

Anna Wharton,

Acting Assistant Field Manager, Division of Lands, Las Vegas, NV.

[FR Doc. 05–18608 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–010–1430–EU, WYW–156332]

Notice of Realty Direct Sale of Public Lands to the Mary A. Clay Revocable Trust in Washakie County, WY, Worland Field Office, WYW–156332

AGENCY: Bureau of Land Management, Interior.

ACTION: Direct sale of public lands.

SUMMARY: The public surface estate has been determined to be suitable for disposal by direct sale under Section 203 of the Federal Land Policy and Management Act (FLPMA) of 1976, (90 STAT. 2750; 43 U.S.C. 1713) and the Federal Land Transaction Facilitation Act of 2000, Pub. L. 106–248, July 25, 2000, to the Mary A. Clay Revocable Trust, the owner of improvements on the property.

FOR FURTHER INFORMATION CONTACT: Victor Trickey, Realty Specialist, BLM Worland Field Office, P.O. Box 119 (101 South 23rd Street), Worland, WY 82401, (307) 347–5106.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management (BLM) will sell the described land at not less than the appraised fair market value of $1,924.00, in accordance with regulations at 43 CFR 2710.0–6(f).

Sixth Principal Meridian

T. 47 N., R. 87 W.,
Sec. 33, N½SE¼SW¼NW¼NE¼, N½S½SE¼NW¼NE¼
Containing approximately 3.75 acres.

The land described is hereby segregated from appropriation under the public land laws pending disposition of this action or 270 days from the date of publication of this notice in the **Federal Register**, whichever occurs first.

This land will not be offered for sale until at least 60 days after the date of this notice. This sale is consistent with BLM policies and the Washakie Resource Management Plan, dated September 2, 1988. This land is being offered by direct sale because a portion of a former girl scout visitor center building was located on land reconveyed to the United States, and the encroachment went unnoticed during the reconveyance. The proposed direct sale of the public land to the owners of the improvements, which is in compliance with an approved land use plan, would recognize the inequities that would be created if the tract were purchased by other than the sale proponent. Direct sale to resolve the unintended occupancy meets the criteria for disposal under the regulations at 43 CFR 2710.0–3(a)(3) and 43 CFR 2711.3–3(a)(5). In accordance with the regulations at 43 CFR 2711.3–3(a)(3) there is a need to recognize the inequitable economic consequences that would be created if the tract were purchased by other than the sale proponent. The authorized officer has determined that the public interest would best be served by direct sale of this parcel. The approved appraisal report, planning document, and environmental assessment covering the proposed sale will be available for review at the Worland Field Office, at the address listed above.

The patent, when issued, will contain a reservation to the United States for ditches and canals and will be subject to rights-of-way of record, as follows:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States pursuant to the Act of August 30, 1890 (43 U.S.C. 945);

2. Those rights for road purposes granted to the Mary A. Clay Revocable Trust, its successors or assigns by Right-of-Way Serial No. WYW–123138, under Title V of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1761–1771;

3. Those rights for telephone purposes granted to Tri-County Telephone, its successors or assigns by Right-of-Way Serial No. WYW–111951, under Title V of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1761–1771; and

4. Those rights for Federal aid highway purposes granted to the Wyoming Department of Transportation, its successors or assigns by Right-of-Way Serial No. WYW–23915, under the Act of August 27, 1958 as amended, Title 23 U.S.C. 317. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the Field Manager, Worland Field Office, P.O. Box 119 (101 South 23rd Street), Worland, Wyoming 82401. In the absence of timely objections, this proposal shall become the final determination of the Department of the Interior. Comments including names and street addresses of respondents will be available for public review at the Worland Field Office during regular business hours (7:45 a.m. to 4:30 p.m.) Monday through Friday, except holidays.

Individual respondents may request confidentiality. If you wish to withhold your name or address from public disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comments. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives of organizations or businesses, will be made available for public inspection in their entirety.

Dated: August 17, 2005.

Mike Roberts,

Acting Worland Field Manager.

[FR Doc. 05–18610 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–926–06–1910–BJ–5REO]

Montana: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plats of survey of the lands described below in the BLM Montana State Office, Billings, Montana, (30) days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Josh Alexander, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, PO Box 36800, Billings, Montana 59107–6800, telephone (406) 896–5123 or (406) 896–5009.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Crow Agency, through the Rocky Mountain Regional Director, Bureau of Indian Affairs and was necessary to determine Trust and Tribal land.

The lands we surveyed are:

Principal Meridian, Montana

T. 5 S., R. 31 E.

The plat, in 1 sheet, representing the dependent resurvey of a portion of the east boundary, a portion of the subdivisional lines, and the adjusted original meanders of the right bank of the Big Horn River, downstream, through section 25, and the subdivision of section 25, and the survey of the meanders of the present right bank of the Big Horn River, downstream, through section 25, and certain division of accretion lines, Township 5 South, Range 31 East, Principal Meridian, Montana, was accepted September 7, 2005.

Principal Meridian, Montana

T. 5 S., R. 32 E.

The plat, in 1 sheet, representing the dependent resurvey of a portion of the west boundary, a portion of the subdivisional lines, the subdivision of section 30, a portion of the adjusted original meanders of the right bank of the Big Horn River, downstream, through section 30, and a certain division of accretion line, and the subdivision of section 30, and the survey of a portion of the meanders of the present right bank of the Big Horn River, downstream, through section 30, and a certain division of accretion line, Township 5 South, Range 32 East, Principal Meridian, Montana, was accepted September 8, 2005.

We will place copies of the plats, in 2 sheets, and related field notes we described in the open files. They will be available to the public as a matter of information.

If BLM receives a protest against these surveys, as shown on these plats, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file these plats, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Dated: September 13, 2005.

Steven G. Schey,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 05–18686 Filed 9–19–05; 8:45 am]

BILLING CODE 4310–$$–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–464 (Second Review)]

Sparklers From China

AGENCY: United States International Trade Commission.

ACTION: Scheduling of an expedited five-year review concerning the antidumping duty order on sparklers from China.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)) (the Act) to determine whether revocation of the antidumping duty order on sparklers from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

EFFECTIVE DATE: September 7, 2005.

FOR FURTHER INFORMATION CONTACT: Debra Baker (202–205–3180), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background. On September 7, 2005, the Commission determined that the domestic interested party group response to its notice of institution (70 FR 31537, June 1, 2005) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act.[2]

Staff report. A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on October 6, 2005, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions. As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[3] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before October 12, 2005 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by October 12, 2005. However, should the Department of Commerce extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II (C) of the Commission's Handbook on Electronic

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's web site.

[2] Commissioner Pearson dissented and Commissioner Aranoff did not participate.

[3] The Commission has found the responses submitted by Diamond Sparkler Manufacturing Co., Inc. and Elkton Sparkler Co., Inc. to be individually adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination. The Commission has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 14, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–18625 Filed 9–19–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–318 and 731–TA–538 and 561 (Second Review)]

Sulfanilic Acid From India and China

AGENCY: United States International Trade Commission.

ACTION: Scheduling of full five-year reviews concerning the countervailing duty and antidumping duty orders on sulfanilic acid from China and India.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) (the Act) to determine whether revocation of the countervailing duty and antidumping duty orders on sulfanilic acid from China and India would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

EFFECTIVE DATE: September 12, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background. On August 5, 2005, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews pursuant to section 751(c)(5) of the Act should proceed (70 FR 48588, August 18, 2005). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

Participation in the review and public service list. Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list. Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report. The prehearing staff report in the reviews will be placed in the nonpublic record on January 5, 2006, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing. The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on January 26, 2006, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before January 17, 2006. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on January 19, 2006, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions. Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is January 17, 2006. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is February 6, 2006; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before February 6, 2006. On March 1, 2006, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before March 3, 2006, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must

conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II (C) of the Commission's Handbook on Electronic Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 14, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–18626 Filed 9–19–05; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: Request for Information Regarding Federal Firearms Dealer's Records (Records of Acquisition and Disposition).

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until November 21, 2005. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact David Adinolfi, Federal Firearms Licensing Center, Room 400, 2600 Century Parkway, West, Atlanta, GA 30044.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Request for Information Regarding Federal Firearms Dealer's Records (Records of Acquisition and Disposition).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* ATF F 5300.3A. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. Firearms licensees are required to keep records of acquisition and disposition. These records remain with the licensee as long as he is in business. When a firearms or ammunition business is discontinued and succeeded by a new licensee, the records required to be kept shall appropriately reflect such facts and shall be delivered to the successor. When discontinuance of the business is absolute, such records shall be delivered within thirty days after the business discontinuance to ATF.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 28,000 respondents will complete a 5 minute form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual total burden hours associated with this collection is 2,380.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530, or by e-mail at *brenda.e.dyer@usdoj.gov.*

Dated: September 15, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–18675 Filed 9–19–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-day notice of information collection under review: Report of Theft or Loss of Explosives.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until November 21, 2005.

This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Anthony Purpura, United States Bomb Data Center, Federal Building, Suite 280, 650 Massachusetts Avenue, NW., Washington, DC 20226.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Report of Theft or Loss of Explosives.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 5400.5. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. Losses or theft of explosives must be reported by the state within 24 hours of the discovery of the loss or theft. This form contains the minimum information necessary for ATF to initiate criminal investigations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 150 respondents will complete the form within 1 hour and 48 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 270 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530, or e-mail to *brenda.e.dyer@usdoj.gov.*

Dated: September 13, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–18676 Filed 9–19–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Proposed Final Judgment and Competitive Impact Statement

United States v. Ecast, Inc. and NSM Music Group, Ltd.

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. section 16(b)–(h), that a Complaint, proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District court for the District of Columbia in *United States* v. *Ecast, Inc. and NSM Music Group, Ltd.,* Civil Case No. 05 CV 1754. The proposed Final Judgment is subject to approval by the Court after compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), including expiration of the statutory 60-day public comment period.

On September 2, 2005, the United States filed a Complaint alleging that Ecast, Inc. and NSM Music Group, Ltd. reached an agreement in February 2003 not to compete in the market for digital jukebox platforms in the United States in violation of Section 1 of the Sherman Act. As a result of the agreement, NSM terminated its plans to release a new digital jukebox with its own platform in the United States.

To restore competition, the proposed Final Judgment filed with the Complaint will terminate the defendants' existing noncompete agreement, and forbid them from entering future noncompete agreements with other digital jukebox platform competitors. A Competitive Impact Statement, filed by the United States, describes the Complaint, the proposed Final Judgment, and the remedies available to private litigants. Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice in Washington, DC in Room 215 North, 325 Seventh Street, NW., 20530 (telephone: 202/514–2692) and at the Office of the Clerk of the United States District Court for the District of Columbia, 333 Constitution Avenue, NW., Washington, DC 2001.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to John Read, Chief, Litigation III Section, Antitrust Division, U.S. Department of Justice, 325 7th Street, NW., Suite 300, Washington, DC 20530 (Telephone (202) 616–5935).

J. Robert Kramer, II

Director of Operations, Antitrust Division.

In the United States District Court for the District of Columbia

United States of America, Department of Justice, Antitrust Division, 325 7th Street, N.W.; Suite 300, Washington, DC 20530, Plaintiff, v. Ecast, Inc., 49 Geary Street, Mezzanine, San Francisco, CA 94108, and NSM Music Group, LTD. 3 Stadium Way, Elland Road, Leeds, West Yorkshire, United Kingdom, LS11 OEW, Defendants; Civil Case Number: 1:05CV01754, Judge: Colleen Kollar-Kotelly, Deck Type: Antitrust, Date Stamp: September 2, 2005.

Complaint

The United States of America, acting under the direction of the Attorney General of the United States, brings the civil antitrust action to obtain equitable relief against defendants Ecast, Inc. (''Ecast'') and NSM Music Group, Ltd. (''NSM''), alleging as follows:

Nature of the Action

1. This action challenges an agreement between Ecast and NSM to not compete in the U.S. market for digital jukebox platforms.

2. A digital jukebox is an Internet-connected device installed in bars and restaurants that is capable of playing digital music files that are either stored on a hard drive inside the jukebox, or are downloaded from a remote server via the Internet. The jukebox consists of two primary components, a physical jukebox and a ''platform,'' which is the term the industry applies to the combination of the software that powers the jukebox and the licensed collection of music that the jukebox is capable of playing at the request of bar or restaurant patrons.

3. At all time relevant to this complaint, defendant Ecast was one of

only two digital jukebox platform providers in the United States. Ecast does not manufacture physical jukeboxes and has instead elected to work with existing jukebox manufacturers. Ecast's manufacturing partners produce digital jukeboxes incorporating Ecast's platform and distribute the jukeboxes through their established distribution networks to ''operators,'' which purchase the jukeboxes and install them in bars and restaurants.

4. In 2002, Ecast was informed by its then manufacturing partner of the manufacturer's plans to terminate its supply relationship with Ecast. Ecast turned to other jukebox manufacturers to avoid an interruption in the flow of digital jukeboxes powered by its platform into the digital jukebox marketplace.

5. At that time, defendant NSM, a jukebox manufacturer, was developing its own distinctive digital jukebox platform, which it planned to incorporate into its physical jukeboxes and release in the United States in competition with Ecast.

6. In the fall of 2002, Ecast initiated negotiations with defendant NSM regarding a possible manufacturing agreement. NSM expressed some interest in manufacturing digital jukeboxes incorporating Ecast's platform, but Ecast and NSM disagreed on how Ecast should compensate NSM in such a relationship. During the negotiations, Ecast requested that NSM agree to abandon its plans to enter the U.S. market in return for an upfront payment. NSM accepted Ecast's condition and entered an agreement with Ecast in February 2003.

7. NSM's agreement to manufacture only Ecast-powered digital jukeboxes caused it to abandon its plan to incorporate its own distinctive digital jukebox platform into its physical jukeboxes and enter the United States market.

8. Defendants' agreement constitutes an unreasonable agreement in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

9. The United States seeks an order to prohibit defendants from enforcing and adhering to any agreement restraining competition between them and to obtain other equitable relief necessary to restore competition, potential or actual, for the benefit of digital jukebox purchasers throughout the United States.

Jurisdiction and Venue

10. The Court has subject matter jurisdiction under section 4 of the Sherman Act, 15 U.S.C. 4, and under 28 U.S.C. 1331 and 1337 to prevent and restrain the defendants from continuing to violate section 1 of the Sherman Act, 15 U.S.C. 1.

11. Venue is proper in this judicial district under section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391(b)(1), (c) because defendants transact or have transacted business here.

Defendants

12. Defendant Ecast, Inc. is a privately held company organized and existing under the laws of the State of Delaware, with is principal place of business in San Francisco, California.

13. Defendant NSM Musical Group, Ltd. is a company incorporated under the laws of the United Kingdom. Since 2002, NSM has offered a digital jukebox powered by an NSM platform in the United Kingdom. NSM's U.S. subsidiary, NSM Music, Inc., is based outside of Chicago, Illinois.

Industry Background

14. Digital jukeboxes emerged in the United States in 1997. Because of the advantages of digital jukeboxes both to consumers and to the ''operators'' that purchase the jukeboxes and install them (along with other coin-operated devices) in bars and restaurants, the pace of conversion from CD jukeboxes to digital jukeboxes is expected to increase rapidly.

15. Digital jukeboxes provide consumers access to a dramatically broader selection of music than they have available to them through CD jukeboxes. Jukeboxes powered by Ecast's platform, for example, allow consumers to choose from among 300 albums stored on each jukebox's hard drive. For an additional fee, consumers can download any of the additional 150,000 songs that Ecast stores on its remote servers. Consumers can also pay an additional fee to have their song choice jump to the front of the song queue. These features are not only popular with consumer users of digital jukeboxes, they also increase the revenue opportunities available to their operator purchasers.

16. After making a one-time payment to a jukebox distributor (the traditional intermediary between the manufacturer and the operator), operators then pay monthly fees to the platform provider to maintain access both to the music collection the platform provider licensed from U.S. copyright holders and to the proprietary software that allows the operator to remotely control the jukebox and the special features associated with it.

17. At all times relevant to the complaint, Ecast had only one other digital jukebox platform competitor, with which it competed on the monthly fee collected from operators. Ecast and its competitor each charged a monthly fee based on a percentage of the revenues generated by the jukebox. Ecast also competed on the special features available through jukeboxes incorporating its platform.

18. Under Ecast's business model, it sought to collaborate closely with and take advantage of the manufacturing expertise and distribution networks maintained by traditional jukebox manufacturers. Ecast believed that by combining the traditional jukebox companies' strengths with Ecast's Internet technology capabilities and the music collection it licensed from U.S. copyright holders, they could provide high-quality, Ecast-powered jukeboxes to the U.S. market more quickly than if Ecast had proceeded on its own.

19. Digital jukebox platforms provide to digital jukebox operators the software that powers digital jukeboxes and the music licensed from U.S. copyright holders that consumers can access through the jukebox. Because of the unique features and the enhanced revenue opportunities that digital jukeboxes offer to operators, if a hypothetical monopolist of digital jukebox platforms were to raise price by a small, but significant amount, digital jukebox manufacturers would not turn to other types of platforms (such as CD libraries). Neither would such a price increase cause operators of digital jukeboxes to switch to possible substitutes (such as CD jukeboxes). Additionally, if such a hypothetical digital jukebox platform monopolist raised its price, digital jukebox manufacturers that sold in the United States and operators that installed jukeboxes in the United States would not switch to platform providers that did not hold the necessary licenses to the U.S. copyrights associated with the music played by the jukebox.

The Illegal Noncompete Agreement

20. In the fall of 2002, defendant NSM was preparing to enter the U.S. digital jukebox market using its own platform in competition with Ecast and the other platform competitor. It had begun obtaining the U.S. copyright licenses necessary to provide a jukebox platform in the United States and had secured a line of credit to pay advances demanded by the copyright holders. NSM had also modified its U.K. jukebox and platform for release in the U.S. market, and it had completed a prototype of its planned

digital jukebox for demonstration at trade shows.

21. NSM saw a significant market opportunity to distinguish itself from Ecast and the other platform competitor by offering a more operator-friendly business model for the digital jukebox platform than the incumbents' revenue-sharing model. NSM's plan was to release a digital jukebox platform at a fixed monthly cost to operators. Operators had expressed interest in NSM's platform and several of them delayed purchases of jukeboxes incorporating Ecast's platform in anticipation of NSM's launch. NSM's commitment to a distinctive business model attractive to operators promised to generate competitive responses from the existing platform providers.

22. At an industry trade show in September 2002, NSM displayed a prototype of a digital jukebox and platform that it intended to release in the U.S. market. Ecast, having learned of its manufacturing partner's plans to terminate Ecast's only manufacturing relationship, approached NSM at the September 2002 trade show and proposed that NSM produce digital jukeboxes that would be powered by Ecast's platform.

23. Given its efforts to introduce a NSM-powered digital jukebox, NSM demanded appropriate compensation from Ecast before it would agree to assist Ecast by producing Ecast-powered digital jukeboxes. During subsequent negotiations, Ecast agreed to make a significant upfront cash payment to NSM in return for NSM's agreement to manufacture only East-powered digital jukeboxes and not compete against Ecast.

24. After those negotiations, Ecast forwarded a letter of intent to NSM. The December 31, 2002, letter of intent contained a provision that stated:

> NSM agrees that it will abandon its attempts to acquire music licenses for the U.S. market (the ''Territory'') and advise all content providers and licensors with which NSM has entered licenses with [sic] that it has abandoned entering the US market with its own digital music platform. NSM also agrees that for as long as Ecast offers the Ecast Platform in the Territory NSM will not produce a competing product in the Territory.

25. Ecast sought through the noncompete provision to prevent NSM from entering and disrupting the digital jukebox platform marketplace. NSM's board thereafter approved the deal with Ecast that included the noncompete provision as quoted above.

26. After agreeing with Ecast to manufacture Ecast-powered jukeboxes exclusively and not to proceed with its own entry into the U.S. platform market, NSM fired the two employees that had been responsible for its planned entry. Upon learning of NSM's action, Ecast reneged on its deal with NSM and refused to make the upfront payment to NSM as previously promised.

27. Ecast and NSM subsequently negotiated a second agreement that also contained a noncompete provision obligating NSM to produce only Ecast-powered digital jukeboxes. The second agreement also called for Ecast to make a smaller upfront payment to NSM and contained a license by NSM to Ecast of a patent relating to digital jukebox technology.

28. NSM did not, and has not, entered the U.S. market with its own digital jukebox using its platform. Its presence in the United States is only as a manufacturer and distributor of CD jukeboxes and digital jukeboxes powered by Ecast's platform.

Cause of Action (Violation of Section 1 of the Sherman Act)

29. The United States hereby incorporates paragraphs 1 through 28.

30. The anticompetitive effects of defendants' noncompete agreement outweigh any procompetitive benefits offered by that agreement.

31. The noncompete agreement prevented NSM from entering the market for digital jukebox platforms and denied to U.S. operators and jukebox users the benefits of competition among NSM and existing participants in the market. The noncompete agreement offered few, if any, procompetitive benefits to weigh against the harm to U.S. consumers.

32. Defendants' agreement unreasonably restrained competition in the digital jukebox platform market in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

Requested Relief

The United States requests that:

(A) The Court adjudge and decree that 6the defendants' agreement not to compete constitutes an illegal restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act;

(B) The defendants be permanently enjoined and restrained from enforcing or adhering to existing contractual provisions that restrict competition between them;

(C) Each defendant be permanently enjoined and restrained from establishing any agreement restricting competition between it and another digital jukebox platform competitor;

(D) The United states be awarded such other relief as the Court may deem just and proper to redress and prevent recurrence of the alleged violation and to dissipate the anticompetitive effects of Ecast's and NSM's illegal agreement; and

(D) The United States be awarded the costs of this action.

Dated: September 2, 2005.

Thomas O. Barnett,

Acting Assistant Attorney General.

J. Robert Kramer II,

Director of Operations.

John R. Read,

Chief.

Nina Hale,

Assistant Chief, Litigation III.

David C. Kully (DC Bar #448763),

Jill A. Beaird,

Attorneys for the United States, United States Department of Justice, Antitrust Division, 325 7th Street, NW; Suite 300, Washington, DC 20530, Telephone: (202) 305–9969, Facsimile: (202) 307–9952.

In the United States District Court for the District of Columbia

United States of America, Plaintiff, v. Ecast, Inc. and NSM Music Group, Ltd., Defendants; Civil No.: 05 1754

Proposed Final Judgment

Whereas, the United States of America filed its Complaint on September 2, 2005, alleging that defendants Ecast, Inc. (''Ecast'') and NSM Music Group, Ltd. (''NSM'') entered into an agreement in violation of Section 1 of the Sherman Act, and plaintiff and defendants, by their respective attorneys, have consent to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against, or any admission by, any party regarding any such issue of fact or law;

And whereas, Ecast and NSM agree to be bound by the provisions of this Final Judgment pending its approval by this Court;

And whereas, the essence of this Final Judgment is the prevention of future conduct by Ecast and NSM that impairs competition in the digital jukebox platform market;

And whereas, the United States requires Ecast and NSM to agree to certain procedures and prohibitions for the purpose of preventing the loss of competition;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged, and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Ecast and NSM under Section 1 of the Sherman Act, as amended, 15 U.S.C. 1.

II. Definitions

As used in this Final Judgment:

A. ''Digital Jukebox'' means a commercial vending device that upon payment plays for public performance digital music files that are delivered electronically from a remote server and stored on any internal or connected data storage medium.

B. ''Digital Jukebox Platform competitor'' means any natural person, corporate entity, partnership, association, or joint venture that has licensed (or that Ecast or NSM knows or has reason to believe has plans to license) a collection of digital music files from U.S. copyright holders for the purpose of supplying music content in the United States to a Digital Jukebox.

C. ''Ecast'' means defendant Ecast, Inc., a privately held company organized and existing under the laws of the State of Delaware, with its principal place of business in San Francisco, California, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their officers, managers, agents, employees, and directors acting or claiming to act on its behalf.

D. ''NSM'' means defendant NSM Music Group, Ltd., a company incorporated under the laws of the United Kingdom, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their officers, managers, agents, employees, and directors acting or claiming to act on its behalf.

III. Applicability

This Final Judgment applies to Ecast and NSM, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

IV. Prohibited and Required Conduct

1. Each defendant, its officers, directors, agents, and employees, acting or claiming to act on its behalf, and successors and all other persons acting or claiming to act on its behalf, are enjoined and restrained from directly or indirectly adhering to or enforcing section 4 (''EXCLUSIVITY'') of defendants' September 2003 ''Manufacturing License, Distribution License and Patent License Agreement,'' or from in any manner, directly or indirectly, entering into, continuing, maintaining, or renewing any contractual provision that prohibits NSM from becoming or limits NSM's ability to become a Digital Jukebox Platform Competitor.

2. Each defendant, its officers, directors, agents, and employees, acting or claiming to act on its behalf, and successors and all other persons acting or claiming to act on its behalf, are enjoined and restrained from, in any manner, directly or indirectly, entering into, continuing, maintaining, or renewing any agreement with any Digital Jukebox Platform Competitor that prohibits such person from supplying or limits the ability of such person to supply music content in the United States to Digital Jukeboxes, provided however, that (a) any merger or acquisition involving either defendant; (b) any valid license of U.S. Patent No. 5,341,350 from either defendant to a nonparty; or (c) any valid license of U.S. patent No. 5,341,350 from NSM to Ecast, which does not in any way prohibit NSM from becoming or limit NSM's ability to become a Digital Jukebox Platform Competitor, will not be considered, by itself, a violation of this paragraph.

V. Compliance Program

1. Each defendant shall establish and maintain an antitrust compliance program which shall include designating, within thirty days of entry of this Final Judgment, an Antitrust Compliance Officer with responsibility for implementing the antitrust compliance program and achieving full compliance with this Final Judgment and the antitrust laws. The Antitrust Compliance Officer shall, on a continuing basis, be responsible for the following:

a. Furnishing a copy of this Final Judgment within thirty days of entry of the Final Judgment to each defendant's officers, directors, and employees;

b. Furnishing within thirty days a copy of this Final Judgment to any person who succeeds to a position described in Section V.1.a;

c. Arranging for an annual briefing to each person designated in Section V.1.a or b on the meaning and requirements of this Final Judgment and the antitrust laws;

d. Obtaining from each person designated in Section V.1.a or b certification that he or she (1) has read and, to the best of his or her ability, understands and agrees to abide by the terms of this Final Judgment; (2) is not aware of any violation of the Final Judgment that has not been reported to the Antitrust Compliance Officer; and (3) understands that any person's failure to comply with this Final Judgment may result in an enforcement action for civil or criminal contempt of court against each defendant and/or any person who violates this Final Judgment;

e. Maintaining (1) a record of certifications received pursuant to this Section; (2) a file of all documents related to any alleged violation of this Final Judgment and the antitrust laws; and (3) a record of all communications related to any such violation, which shall identify the date and place of the communication, the persons involved, the subject matter of the communication, and the results of any related investigation;

f. Reviewing the content of each e-mail, letter, memorandum, or other communication to any Digital Jukebox Platform Competitor written by or on behalf of an officer or director of either defendant that relates to the recipient's supply of music content in the United States to Digital Jukeboxes in order to ensure their adherence with this Final Judgment.

2. If defendant's Antitrust Compliance Officer learns of any violations of any of the terms and conditions contained in this Final Judgment, defendant shall immediately take appropriate action to terminate or modify the activity so as to comply with this Final Judgment.

VI. Compliance Inspection

1. For the purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time duly authorized representatives of the United States Department of Justice, including consultants and other persons retained or designated thereby, shall, upon written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable written notice to defendants, be permitted:

a. Access during defendants' office hours to inspect and copy, or at the United States' option, to require defendants to provide copies of, all books, ledgers, accounts, records, and documents in their possession, custody, or control relating to any matters contained in this Final Judgment; and

b. To interview, either informally or on the record, defendant's officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable

convenience of the interviewee and without restraint or interference by defendants.

2. Upon the written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, defendants shall submit written reports, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

3. No information or documents obtained by the means provided in this section shall be divulged by plaintiffs to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

4. If at the time defendants furnish information or documents to the United States, they represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure,'' then the United States shall use its best efforts to give defendants ten calender days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

VII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

VIII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

IX. Notice

For purposes of this Final Judgment, any notice or other communication shall be given to the persons at the addresses set forth below (or such other addresses as they may specify in writing to Ecast or NSM): John Read, Chief, Litigation III Section, U.S. Department Of Justice, Antitrust Division, 325 Seventh Street, NW., Suite 300, Washington, DC 20530.

X. Public Interest Determination

Entry of this Final Judgment is in the public interest.

Dated: _____

Court approved subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16 *United States District Judge.*

In the United States District Court for the District of Columbia

United States of America, Department of Justice, Antitrust Division, 325 7th Street, NW.; Suite 300, Washington, DC 20530, Plaintiff, v. Ecast, Inc., 49 Geary Street, Mezzanine, San Francisco, CA 94108, and NSM Music Group, Ltd., 3 Stadium Way, Elland Road, Leeds, West Yorkshire, United Kingdom LS11 OWE, Defendants; Civil Case Number 1:05CV01754, Judge: Colleen Kollar-Kotelly, Deck Type: Antitrust, Date Stamp: September 2, 2005.

Competitive Impact Statement

The United States, pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA''), 15 U.S.C. 16(b), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

On September 2, 2005, the United States filed a civil antitrust Complaint pursuant to section 4 of the Sherman Act, as amended, 15 U.S.C. 4, against Ecast, Inc. (''Ecast'') and NSM Music Group, Ltd. (''NSM''). The Complaint alleges that defendants entered into a noncompete agreement that caused NSM not to proceed with its plans to enter the U.S. digital jukebox platform market and compete with Ecast. That agreement, as the Complaint further alleges, is a restraint of interestate trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

The Complaint seeks an order to prohibit defendants from enforcing or adhering to any agreement restraining competition between them, and other equitable relief necessary to prevent a recurrence of the illegal conduct.

The United States filed simultaneously with the Complaint a proposed Final Judgment, which constitutes the parties' settlement. This proposal Final Judgment seeks to prevent defendants' illegal conduct by expressly enjoining them from enforcing or adhering to their existing noncompete agreement, prohibiting them from establishing future noncompete agreements with digital jukebox platform competitors, and requiring each to establish a rigorous antitrust compliance program.

The United States, Ecast, and NSM have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States withdraws its consent. Entry of the proposed Final Judgment would terminate this action, except that this Court would retain jurisdiction to construe, modify, and enforce the proposed Final Judgment and to punish violations thereof.

I. Description of the Events Giving Rise to the Alleged Violation of the Antitrust Laws

A. Defendants

I. Ecast

Ecast is a San Francisco-based, privately held company organized under the laws of the State of Delaware. It developed a digital jukebox platform that supplies the software and music for jukeboxes manufactured by traditional jukebox manufacturers. Ecast refers to jukeboxes that incorporate its platform as ''powered by Ecast.''

2. NSM

NSM is a jukebox manufacturer based in the United Kingdom. It conducts business in the United States through its operating subsidiary, NSM Music, Inc., based outside of Chicago, Illinois.

B. The Digital Jukebox Industry

Digital jukeboxes are Internet-connected devices installed in bars and restaurants that are capable of playing digital music files that are either stored on a hard drive inside each jukebox or are downloaded from a remote server via the Internet. Digital jukeboxes consist of two primary components, a physical jukebox and a ''platform,'' which is the term the industry applies to the combination of the software that powers the jukebox and the licensed collection of music that the jukebox is capable of playing.

As is the case with CD jukeboxes and most other coin-operated devices found in bars and restaurants, digital jukeboxes are purchased, installed, and maintained by 3,000, mostly local businesses called ''operators.'' Operators purchase both CD and digital jukeboxes from distributors, which maintain relationships with jukebox manufacturers.[1] When operators elect to purchase a digital jukebox, they incur—in addition to the one-time, out-of-pocket payment to the distributor—an obligation to make recurring monthly payments to the platform provider to

[1] Operators then negotiate with bars and restaurants for space in their establishments in which to place the digital jukeboxes.

maintain continuous access to the provider's proprietary software and to the music collection that the platform provider licensed from U.S. copyright holders.

There are roughly 15,000 digital jukeboxes in the United States. The popularity of digital jukeboxes to consumers, and their ability to generate greater revenue for the operator than CD jukeboxes, lead many in the industry to predict the pace of digital jukebox adoption to increase in the coming years.

Digital jukeboxes offer consumers a song selection dramatically larger than CD jukeboxes. Ecast, for example, preloads jukeboxes incorporating its platform with 300 albums, but also permits consumers to access, for a higher price, a licensed collection of 150,000 additional songs that it stored on its remote servers. Ecast-powered jukeboxes also allow consumers to pay to jump to the front of the song queue. Because operators can control the song selection on their digital jukeboxes from a remote location over the Internet, digital jukeboxes also relieve operators of the need to visit each their jukeboxes to load new releases or holiday favorites.

Ecast released its platform in the United States in 2001. It did so under an agreement with a jukebox manufacturer, which manufactured and distributed (through the manufacturer's established chain of distributors) digital jukeboxes incorporating the Ecast platform. When the manufacturer notified Ecast in 2002 that it intended to terminate their agreement, Ecast immediately sought to avoid an interruption in the delivery of Ecast-powered digital jukeboxes to the U.S. market by finding another manufacturer partner.

C. The Illegal Noncompete Agreement

At a September 2002 industry trade show, NSM displayed a prototype of a digital jukebox and platform that it intended to release in the U.S. market. By that time, NSM was actively negotiating with U.S. copyright holders to obtain the license it needed to provide music to consumers through its digital jukebox platform, and had secured a line of credit to pay advances typically demanded by the copyright holders. NSM had also modified the digital jukebox and platform it had previously released in the United Kingdom for release in the United States. It had publicly communicated its intention to enter the U.S. market, and it was internally committed to proceeding with those plans.

Ecast approached NSM at the September 2002 industry trade show and proposed that NSM produce digital jukeboxes which would be powered by Ecast's platform. During subsequent negotiations, Ecast agreed to make a significant upfront payment to NSM, provided that NSM abandon its entry plans in the U.S. and agree not to compete against Ecast. After further negotiations on those terms, Ecast submitted to NSM a letter of intent calling for an upfront payment by Ecast of $700,000, and containing the following noncompete agreement:

> NSM agrees that it will abandon its attempts to acquire music licenses for the U.S. market (the ''Territory'') and advise all content providers and licensors with which NSM has entered licenses with [sic] that it has abandoned entering the US market with its own digital music platform. NSM also agrees that for as long as Ecast offers the Ecast Platform in the Territory NSM will not produce a competing product in the Territory.

To Ecast, the principal motivation for requesting the noncompete provision was to prevent NSM from entering and disrupting the digital jukebox platform market. NSM went ahead and approved the deal with Ecast that included the above-quoted noncompete provision.

Pursuant to the agreement, NSM thereafter ceased all efforts to enter the U.S. market with its own digital jukebox platform. NSM also fired the two employees responsible for its planned entry. Those employees were the only NSM representatives involved in its copyright license negotiations, its successful efforts to obtain financing necessary to pay advances to copyright holders, and its communications with U.S. operators and distributors concerning NSM's impending U.S. entry.

Ecast recognized that without those employees, NSM no longer possessed the ability to enter quickly with its own platform. Ecast then refused to pay NSM the full $700,000 as agreed. Ecast and NSM subsequently renegotiated the terms of their agreement such that NSM would remain prohibited from entering the U.S. market with its own digital jukebox platform with smaller payments from Ecast. The revised agreement also included a license by NSM to Ecast of a patent concerning digital jukebox technology.

D. Defendants' Noncompete Agreement Is an Unreasonable Restraint of Trade

Noncompete agreements between competitors can violate Section 1 of the Sherman Act. In this case, the noncompete agreement was entered into in conjunction with an agreement to jointly produce and distribute a product. The Department analyzed this noncompete agreement pursuant to the rule of reason because it was reasonably related to the venture and enhanced its efficiency. Under the rule of reason, the Department considers ''all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.'' *Chicago Bd. of Trade* v. *United States*, 246 U.S. 231, 238 (1918). After consideration of the circumstances in this case, the Department concluded that the noncompete agreement significantly suppressed competition and that harm to competition outweighed the procompetitive benefits of the agreement.

The noncompete agreement between Ecast and NSM forced NSM to abandon its efforts to enter the U.S. market with its own digital jukebox platform. Many operators had expressed great interest in NSM's entry because NSM intended to utilize a more attractive pricing model for its jukebox platform (a flat-price model as opposed to a percentage-or-revenue model) than either Ecast or its only U.S. platform competitor. This and other significant potential benefits to consumers were eliminated by the noncompete provision. The procompetitive benefits of the venture were very limited. Accordingly, the Department concluded that the anticompetitive effects of the noncompete agreement outweighed the procompetitive effects.

II. Explanation of the Proposed Final Judgment

The Antitrust Division typically seeks, through an enforcement action, to restore the competitive conditions that existed prior to defendants' establishment of their illegal agreement. The Antitrust Division cannon require NSM to enter the U.S. digital jukebox platform market, but believes it is important to eliminate the artificial impediments to NSM's ability to do so in the future. The proposed Final Judgment thus enjoins defendants from enforcing or adhering to this or any other noncompete agreement that restricts NSM's entry into the U.S. digital jukebox platform market. The proposed Final Judgment also prohibits defendants from establishing noncompete agreements with other digital jukebox platform competitors and imposes a rigorous antitrust compliance program upon each defendant.

III. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in a federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorney's fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent lawsuit that any private party may bring against the defendants.

IV. Procedures Available for Modification of the Proposed Final Judgment

The United States and the defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this competitive Impact Statement in the **Federal Register**. The United States will evaluate and respond to the comments. All comments will be given due consideration by the United States, through the Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to entry. The comments and the response of the United States will be filed with the Court and published in the **Federal Register**. Written comments should be submitted to John Read, Chief, Litigation III Section, Antitrust Division, United States Department of Justice, 325 Seventh Street, NW., Suite 300, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

V. Alternative to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits of its Complaint against the defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Ecast and NSM. However, the United States is satisfied that the relief provided in the proposed Final Judgment will prevent a recurrence of conduct that restricted competition in the digital jukebox platform market. Thus, the proposed Final Judgment would achieve substantially all the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VI. Standard of Review Under the APPA for the Proposed Final Judgment

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court shall consider:

> (1) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (2) The impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1). As the United States Court of Appeals for the D.C. Circuit has held, the APPA permits a court to consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See United States* v. *Microsoft*, 56 F.3d 1448, 1461–62 (D.C. Cir. 1995).

''Nothing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). Thus, in conducting this inquiry, ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney).[2] Rather,

> [a]bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

United States v. *Mid-Am. Dairymen, Inc.,* 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. May 17, 1977).

Accordingly, with respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 5.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see* also Microsoft, 56 F.3d at 1460–62. Case law requires that

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is *''within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[3]

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[2] *See also United States* v. *Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (recognizing it was not the court's duty to settle; rather, the court must only answer ''whether the settlement achieved [was] within the reaches of the public interest''). A ''public interest'' determination can be made properly on the basis of the Competitive Impact Statement and Response to Comments filed pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. *See* H.R. Rep. No. 93–1463, 93rd Cong., 2d Sess. 8–9 (1974), reprinted in 1974 U.S.C.C.A.N. 6535, 6538.

[3] Cf. BNS, 858 F.2d at 463 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *Gillette,* 406 F. Supp. at 716 (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a

Continued

The proposed Final Judgment, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a particular practice or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls with the range of acceptability or is 'within the reaches of public interest.''' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting Gillette, 406 F. Supp. at 716), aff'd sub nom. *Maryland* v. *United States,* 460 U.S. 1001 (1983); *see* also *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Compliant, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the compliant'' to inquire into other matters that the United States might have but did not pursue. *Id.* at 1459–60.

VII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: September 2, 2005.

Respectfully submitted,

David C. Kully (DC Bar #448763),

Jill A. Beaird,

Attorneys for the United States, U.S. Department of Justice, Antitrust Division, Litigation III Section, 325 Seventh Street, NW., Suite 300, Washington, DC 20530, (202) 305–9969 (telephone), (202) 307–9952 (facsimile), David.Kully@usdoj.gov.

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microscope, but with an artist's reducing glass''). *See* generally *Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charges as to fall outside of the 'reaches of the public interest' '').

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of existing safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Kingwood Mining Company, LLC

[Docket No. M–2005–062–C]

Kingwood Mining Company, LLC, Route 1 Box 294C, Newburg, West Virginia 26410 has filed a petition to modify the application of 30 CFR 75.364(b)(1) (Weekly examination) to its Whitetail K-Mine (MSHA I.D. No. 46–08751) located in Preston County, West Virginia. The petitioner requests a modification of the existing standard to permit monitoring stations to be established for the left side entries (looking inby) from the belt entry over of South Mains #2 at #8 crosscut to South Mains #4 at #9 crosscut due to deteriorating roof conditions. The petitioner proposes to establish monitoring stations (MS–S1, S2, S3, & S4) at inlet entries (MS–S3 and S4) at South #4 between #9–#10 crosscut and the outlet entries (MS–S1 and S2) at South #2 between #6–#7 crosscut. The petitioner will have a certified person examine the monitoring stations on a weekly basis for air quantity, quality, and direction, and record the results of the examination in a book. The petitioner will also examine the stopping line between the belt entry and the intake air entry area in question from the South Mains #2 at #4 crosscut to South Mains #4 at #9 crosscut each production day for integrity, and record the results in the daily belt examiners book. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

2. Mach Mining, LLC

[Docket No. M–2005–063–C]

Mach Mining, LLC, P.O. Box 300, Johnston City, Illinois 62951 has filed a petition to modify the application of 30 CFR 75.1909(b)(6) (Nonpermissible diesel-powered equipment; design and performance requirements) to its Mach #1 Mine (MSHA I.D. No. 11–03141) located in Williamson County, Illinois. The petitioner proposes to operate the Getman Roadbuilder as it was originally designed without front brakes. The petitioner will provide training to the grader operators on lowering the moldboard for additional stopping capability in emergency situations; train operators to recognize the appropriate speeds to use on different roadway conditions; and limit the maximum speed of the Roadbuilder to 10 miles per hour. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

Request for Comments

Persons interested in these petitions are encouraged to submit comments via Federal eRulemaking Portal: *http://www.regulations.gov*; E-mail: *zzMSHA-Comments@dol.gov;* Fax: (202) 693–9441; or Regular Mail/Hand Delivery/Courier: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. All comments must be postmarked or received in that office on or before October 20, 2005. Copies of these petitions are available for inspection at that address.

Dated at Arlington, Virginia, this 15th day of September 2005.

Rebecca J. Smith,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. 05–18738 Filed 9–19–05; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Extend an Information Collection

AGENCY: National Science Foundation (NSF).

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than three years.

DATES: Written comments on this notice must be received by November 21, 2005 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230; telephone (703) 292–7556; or send e-mail to

splimpto@nsf.gov. Individuals who use a telecommunications device 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. You also may obtain a copy of the data collection instrument and instructions from Ms. Plimpton.

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for Science and Technology Centers (STC): Integrative Partnerships.

OMB Number: 3145–0194.

Expiration Date of Approval: January 31, 2006.

Type of Request: Intent to seek approval to extend an information collection.

Abstract: The National Science Foundation (NSF) requests extension of data collection (annual reports) called ''Grantee Reporting Requirements for Science and Technology Centers (STC): Integrative Partnerships''. The current data collection, designed to measure the Science and Technology Centers' progress and plans, had been approved for use through January 2006. The annual reports have proven an effective means for efficiently gathering data from Centers. The data gathered through the annual reports under the current OMB approval has been used in making decisions about continued funding of individual Centers. In addition, a database of Centers' characteristics, activities, and outcomes has been created using data from these annual reports.

The Science and Technology Centers (STC): Integrative Partnerships Program supports innovation in the integrative conduct of research, education and knowledge transfer. Science and Technology Centers build intellectual and physical infrastructure within and between disciplines, weaving together knowledge creation, knowledge integration, and knowledge transfer. STCs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. Thus, new knowledge created is meaningfully linked to society.

In addition, STCs enable and foster excellence in education, the integration of research and education, and the creation of bonds between learning and inquiry so that discovery and creativity more fully support the learning process. STCs capitalize on diversity through participation in Center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

All Centers will be required to submit annual reports on progress and plans that are used as a basis for performance review and determining the level of continued funding. This continues the practice established under the previously approved data collection. To support this review and the management of a Center, new STCs are required to develop a set of management and performance indicators (continuing Centers have already developed these indicators). These indicators are submitted annually to NSF via FastLane. These indicators are both quantitative and descriptive and include, for example, the characteristics of Center personnel and students; sources of financial support and in-kind support; expenditures by operational component; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents and licenses; publications; degrees granted to students involved in Center activities; descriptions of significant advances and other outcomes of the STCs' efforts. The reporting will be added to the STC program database that has been compiled by an NSF evaluation technical assistance contractor to support decisions for continued funding of the Centers and will be made available for the 2007 program evaluation. This database captures specific information that demonstrates progress towards achieving the goals of the individual Centers and the goals of the program. Such reporting requirements are included in the cooperative agreement that is binding between the academic institution and the NSF.

Each Center's annual report provides information about the following categories of activities: (1) Research, (2) education, (3) knowledge transfer, (4) partnerships, (5) diversity, (6) management, and (7) budget issues.

For each of the categories the report describes overall objectives for the year, problems the Center has encountered in making progress towards goals for the year, specific outputs and outcomes for the year, and expected accomplishments and anticipated problems in the coming year.

Use of the Information: NSF will use the information to make decisions on continued funding for the Centers, to evaluate the yearly progress of the program and to inform the upcoming 2007 Program Evaluation. The data will be analyzed to evaluate progress towards specific goals of the STC program.

Estimate of Burden: For the first year of this data collection, the time estimate for the 11 continuing Centers is a total of 550 hours. The time estimate for the 2 newly funded Centers and the anticipated 4 additional Centers is a total of 600 hours. In subsequent years of the data collection, the time estimate is a total of 850 hours for the 17 Centers (the 11 established Centers, the 2 newly funded Centers, and the anticipated 4 additional Centers).

Respondents: Non-profit institutions; Federal Government.

Estimated Number of Responses per Report: One from each of the 13 funded Centers and 4 anticipated Centers.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: September 15, 2005.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 05–18680 Filed 9–19–05; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–331]

Nuclear Management Company, Duane Arnold Energy Center; Notice of Consideration of Approval of Transfer of Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of an order under 10 CFR 50.80 approving the transfer of Facility Operating License No. DPR–49 for the Duane Arnold Energy Center (DAEC) to the extent currently held by Interstate Power and Light Company (IPL) as owner, and Nuclear Management Company, LLC (NMC) as licensed operator of DAEC. The transfer would be to FPL Energy

Duane Arnold, LLC (FPLE Duane Arnold). The Commission is also considering amending the license for administrative purposes to reflect the proposed transfer.

According to an application for approval filed by DAEC, FPLE Duane Arnold, an indirect, wholly owned subsidiary of FPL Group, Inc., would assume title to IPL's 70 percent ownership of the facility following approval of the proposed license transfer, and would be responsible for the operation, maintenance, and eventual decommissioning of DAEC. FPLE Duane Arnold will also take title to the general license for the independent spent fuel storage installation. No physical changes to the DAEC facility or operational changes are being proposed in the application.

The proposed amendment would replace references to IPL and NMC in the license with references to FPLE Duane Arnold, to reflect the proposed transfer.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility which does no more than conform the license to reflect the transfer action involves no significant hazards consideration. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person whose interest may be affected by the Commission's action on the application may request a hearing and, if not the applicant, may petition for leave to intervene in a hearing proceeding on the Commission's action. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)–(viii).

Requests for a hearing and petitions for leave to intervene should be served upon Robert E. Helfrich, Senior Attorney, FPL Energy, LLC, 700 Universe Blvd., Juno Beach, Florida 33408, (561) 304–5288, facsimile: (561) 691–7135, e-mail: *robert_helfrich@fpl.com,* Sam Behrends, LeBoeuf, Lamb, Greene & MacRae, 1875 Connecticut Ave., NW, Suite 1200, Washington, DC 20009, (202) 986–8108, facsimile: (202) 986–8102, e-mail: *Sbehrend@llgm.com,* Kent M. Ragsdale, Managing Attorney—Regulatory Alliant Energy Corporate Services, Inc., PO Box 351, 2100 First Street, SE., Cedar Rapids, IA 52406–0351, 319–786–7765, facsimile: (319) 786–4533, e-mail: *kentragsdale@alliantenergy.com,* Jonathan Rogoff, Vice President, General Counsel and Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016, (715) 377–3316, facsimile: (715) 386–1013, e-mail: *jonathan.rogoff@nmcco.com*; the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 (e-mail address for filings regarding license transfer cases only: *OGCLT@NRC.gov*); and the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, in accordance with 10 CFR 2.302 and 2.305.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

As an alternative to requests for hearing and petitions to intervene, within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this action, see the application dated August 1, 2005, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland this 12th day of September 2005.

For the Nuclear Regulatory Commission.

Deirdre W. Spaulding,

Project Manager, Section 1, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 05–18661 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–02286]

Issuance of Environmental Assessment and Finding of No Significant Impact Regarding a Proposed License No. 24–00889–01 Amendment for Saint Luke's Hospital of Kansas City, Kansas City, MO

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Issuance of environmental assessment and finding of no significant impact.

FOR FURTHER INFORMATION CONTACT: Gene Bonano, Health Physicist, Decommissioning Branch, Division of Nuclear Material Safety, Region III, U.S. Nuclear Regulatory Commission, 2443 Warrenville Road, Lisle, Illinois 60532; Telephone: (630) 829–9826; fax number: (630) 515–1259; e-mail: *gab1@nrc.gov*.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to Material License No. 24–00889–01 to authorize Saint Luke's Hospital of Kansas City, Kansas City, Missouri (the licensee), to release from its license the Medical Plaza I Building at 4320 Wornall Road, and the Dickson-Diveley Laboratory at 4312 J.C. Nichols Parkway, Kansas City, Missouri for unrestricted use. The NRC has prepared this Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of 10 CFR Part 51. Based on this EA, the NRC has determined that a Finding of No Significant Impact (FONSI) is appropriate.

I. Environmental Assessment

Identification of the Proposed Action

The proposed action would approve the licensee's request to amend its license to release the Medical Plaza I Building and the Dickson-Diveley Laboratory from its license for unrestricted use in accordance with 10 CFR part 20, subpart E. The proposed action is in accordance with the licensee's December 1, 2004 (ML052510691) and June 21, 2005 (ML052510686) request to release its Medical Plaza I Building and Dickson-Diveley Laboratory for unrestricted use. Both facilities are listed under Saint Luke's Material License Number 24–00889–01. Saint Luke's Hospital is authorized to use byproduct material for medical research. The licensee transferred all licensed material from the Medical Plaza I Building and the Dickson-Diveley Laboratory to its radioactive waste storage area in the main hospital building. The main hospital building is under the same radioactive materials license. The licensee also transferred materials to the Mayo Clinic Rochester [License No. 22–00519–03], and shipped material for disposal through Adco Services, Inc. [IL–01347–01], and GTS Duratek [R–73008–E94]. The licensee identified two isotopes, which are listed in the license, with half-lives greater than 120 days (hydrogen–3, and carbon–14), which had been used at the Medical Plaza I Building and Dickson-Diveley Laboratory facilities. The licensee conducted surveys of the facilities and provided information to the NRC to demonstrate that the radiological condition of the buildings is consistent with criteria specified in 10 CFR part 20, subpart E for unrestricted use. No radiological remediation activities are required to complete the proposed action.

Need for the Proposed Action

The licensee is requesting this license amendment because it no longer plans to conduct NRC-licensed activities at the Medical Plaza I Building and the Dickson-Diveley Laboratory. The NRC is fulfilling its responsibilities under the Atomic Energy Act to make a decision on the proposed action for decommissioning that ensures that residual radioactivity is reduced to a level that is protective of the public health and safety and the environment.

Environmental Impacts of the Proposed Action

The NRC staff reviewed the information provided and surveys performed by Saint Luke's Hospital of Kansas City to demonstrate that the release of the Medical Plaza I Building, 4320 Wornall Road, and the Dickson-Diveley Laboratory, 4312 J.C. Nichols Parkway, Kansas City, Missouri facilities comply with radiological criteria for unrestricted use in 10 CFR 20.1402. Based on its review, the staff has determined that the radiological environmental impacts from the proposed action are bounded by the ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities'' (NUREG–1496). Additionally, no non-radiological or cumulative impacts were identified. Therefore, the NRC has determined that the proposed action will not have a significant effect on the quality of the human environment.

Alternatives to the Proposed Action

The only alternative to the proposed action of releasing the facilities for unrestricted use is to take no action. Under the no-action alternative, the Medical Plaza I Building and the Dickson-Diveley Laboratory facilities would remain under an NRC license and would not be released for unrestricted use. Denial of the license amendment request would result in no change to current conditions at the facilities. The no-action alternative is not acceptable because it is inconsistent with the NRC's Timeliness Rule, 10 CFR Part 30.36, ''Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas,'' which requires licensees who have ceased licensed activities to request termination of their radioactive materials license. This alternative also would impose an unnecessary regulatory burden and limit potential benefits from future uses of the facilities.

Conclusion

The NRC staff concluded that the proposed action is consistent with the NRC's unrestricted use specified in 10 CFR part 20, subpart E. Since the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

The NRC staff has determined that the proposed action will not affect listed species or critical habitats. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. Likewise, the NRC staff has determined that the proposed action is not a type of activity that has potential to cause effect on historic properties. Therefore, consultation under Section 106 of the National Historic Preservation Act is not required. The NRC consulted with the Missouri Section for Environmental Public Health, Department of Health and Senior Services. The Missouri Section for Environmental Public Health was provided with the draft EA for comment on September 6, 2005. The State reviewed the EA and responded back to the NRC on September 7, 2005, and did not have any additional comments.

II. Finding of No Significant Impact

On the basis of the EA in support of the proposed license amendment to release the facilities for unrestricted use, the NRC has determined that the proposed action will not have a significant effect on the quality of the

human environment. Thus, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Further Information

1. McPhee, Mark, M.D., Chief Operating Officer, Saint Luke's Hospital of Kansas City, letter to U.S. Nuclear Regulatory Commission, December 1, 2004 (ML052510691).
2. Decommissioning Report (Final Status Survey Report), Saint Luke's Hospital of Kansas City, Medical Plaza I Building, 4320 Wornall Road, and the Dickson-Diveley Laboratory, 4312 J.C. Nichols Parkway, Kansas City, Missouri facilities, June 21, 2005 (ML052510686).
3. Saint Luke's Hospital of Kansas City Conversation Record, dated September 2, 2005 (ML052510698).
4. U.S. Nuclear Regulatory Commission, ''Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,'' NUREG–1748, August 2003.
5. U.S. Nuclear Regulatory Commission, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities,'' NUREG–1496, August 1994.
6. NRC, NUREG–1757, ''Consolidated NMSS Decommissioning Guidance,'' Volumes 1–3, September 2003.

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at (800) 397–4209, (301)415–4737 or by e-mail to *pdr@nrc.gov*. Documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Lisle, Illinois, this 12th day of September 2005.

Jamnes L. Cameron,

Chief, Decommissioning Branch, Division of Nuclear Materials Safety, RIII.

[FR Doc. 05–18664 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 25 and 26, 2005. A sample of agenda items to be discussed during the public sessions includes: (1) Discussion of the Energy policy Act of 2005, which provides for NRC regulation of accelerator-produced radioactive material and discrete sources of Ra–226; (2) Status of Specialty Board applications for NRC recognition; (3) Electronic signature in written directives; (4) Revision of NRC Form 313A; (5) RIS on dose control and assessment; (6) Review of the medical events definition commission paper. To review the agenda, see *http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda/* or contact, via e-mail *MSS@nrc.gov*.

Purpose: Discuss issues related to 10 CFR part 35, Medical Use of Byproduct Material.

Date and Time for Closed Session Meeting: October 25, 2005, from 8 a.m. to 10 a.m. This session will be closed so that NRC staff can brief the ACMUI on discussing information relating solely to internal personnel rules.

Dates and Times for Public Meetings: October 25, 2005, from 10 a.m. to 5 p.m.; and October 26, 2005, from 8 a.m. to 5 p.m.

Address for Public Meetings: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Room T2B3, 11545 Rockville Pike, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION CONTACT: Mohammad S. Saba, telephone (301) 415–7608; e-mail *MSS@nrc.gov* of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Conduct of the Meeting

Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Mohammad S. Saba, U.S. Nuclear Regulatory Commission, Mail Stop T8F03, Washington, DC 20555. Submittals must be postmarked by October 3, 2005 and must pertain to the topics on the agenda for the meeting.
2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.
3. The transcript and written comments will be available for inspection on NRC's Web site (*http://www.nrc.gov*) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852–2738, telephone (800) 397–4209, on or about January 26, 2006. This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, Part 7.
4. Attendees are requested to notify Mohammad S. Saba at (301) 415–7608 of their planned attendance if special services, such as for the hearing impaired, are necessary.

Dated at Rockville, Maryland, this 14th day of September, 2005.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 05–18652 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meetings

DATES: Weeks of September 19, 26, October 3, 10, 17, 24, 2005.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of September 19, 2005

There are no meetings scheduled for the Week of September 19, 2005.

Week of September 26, 2005—Tentative

There are no meetings scheduled for the Week of September 26, 2005.

Week of October 3, 2005—Tentative

There are no meetings scheduled for the Week of October 3, 2005.

Week of October 10, 2005—Tentative

There are no meetings scheduled for the Week of October 10, 2005.

Week of October 17, 2005—Tentative

Tuesday, October 18, 2005

9:30 a.m. Briefing on Decommissioning Activities and Status (Public Meeting)
This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Week of October 25, 2005—Tentative

Wednesday, October 26, 2005

1:30 p.m. Discussion of Security Issues (Closed—Ex. 1)

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html*.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301–415–7080, TDD: 301–415–2100, or by e-mail at *aks@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: September 15, 2005.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 05–18784 Filed 9–16–05; 10:14 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Form N–8b–4; SEC File No. 270–180; OMB Control No. 3235–0247.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') requests for extension of the previously approved collection of information discussed below.

- Form N–8b–4—Registration Statement of Face-Amount Certificate Companies

Form N–8b–4 is the form used by face-amount certificate companies to comply with the filing and disclosure requirements imposed by Section 8(b) of the Investment Company Act of 1940 [15 U.S.C. 80a–8(b)]. Form N–8b–4 requires disclosure about the organization of a face-amount certificate company, its business and policies, its investment in securities, its certificates issued, the personnel and affiliated persons of the depositor, the distribution and redemption of securities, and financial statements. The Commission uses the information provided in the collection of information to determine compliance with Section 8(b) of the Investment Company Act of 1940.

Based on the Commission's industry statistics, the Commission estimates that there would be approximately 1 annual filing on Form N–8b–4. The Commission estimates that each registrant filing a Form N–8b–4 would spend 171 hours in preparing and filing the Form and that the total hour burden for all Form N–8b–4 filings would be 171 hours. Estimates of the burden hours are made solely for the purposes of the PRA, and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms.

The information provided on Form N–8b–4 is mandatory. The information provided on Form N–8b–4 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

General comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: September 12, 2005.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18613 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. SR–NASD–2005–093]

Securities Exchange Act of 1934; Release No. 52426/September 14, 2005; In the Matter of: The National Association of Securities Dealers, Incorporated; Order of Summary Abrogation

Notice is hereby given that the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(3)(C) of the Securities Exchange Act of 1934 (''Exchange Act''),[1] is summarily abrogating a proposed rule change of The National Association of Securities Dealers, Incorporated (''NASD'').

On July 20, 2005, the NASD filed SR–NASD–2005–093.[2] The NASD submitted the rule change for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Exchange Act.[3] The proposed rule change amended NASD Rule 3370 to clarify that members must make an affirmative determination and document compliance when effecting long sale orders. In the proposal, the NASD stated that it proposed to amend Rule 3370, ''to re-adopt expressly the affirmative determination requirements as they now relate to member obligations with respect to long sales under Regulation SHO''.[4] The NASD designated the rule change proposal as ''non-controversial'' under paragraph (f)(6) of Rule 19b–4 under the Exchange Act,[5] which renders the proposal effective upon filing with the Commission.

Pursuant to Section 19(b)(3)(C) of the Exchange Act,[6] at any time within 60 days of the date of filing a proposed rule change pursuant to Section 19(b)(1) of

[1] 15 U.S.C. 78s(b)(3)(C).

[2] *See* Securities Exchange Act Release No. 52131 (Jul. 27, 2005), 70 FR 44707 (Aug. 3, 2005).

[3] 15 U.S.C. 78s(b)(3)(A).

[4] *See* Securities Exchange Act Release No. 52131, 70 FR at 44708.

[5] A proposed rule filing may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A) if it is properly designated by the self-regulatory organization as effecting a change that: ''(i) Does not significantly affect the protection of investors or the public interest; (ii) Does not impose any significant burden on competition; and (iii) By its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate * * *.'' 17 CFR 240.19b–4(f)(6).

[6] 15 U.S.C. 78s(b)(3)(C).

the Exchange Act,[7] the Commission may summarily abrogate the change in the rules of the self-regulatory organization and require that the proposed rule change be re-filed in accordance with the provisions of Section 19(b)(1) of the Exchange Act[8] and reviewed in accordance with Section 19(b)(2) of the Exchange Act,[9] 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 Exchange Act.

The Commission has received three comment letters in response to the proposed rule change.[10] The substance of the comment letters calls into question the ''non-controversial'' designation of the proposal.

Accordingly, the Commission believes that the procedures provided by Section 19(b)(2) of the Exchange Act[11] will provide a more appropriate mechanism for determining whether the proposed rule change is consistent with the Exchange Act. Therefore, the Commission finds that it is appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Exchange Act, to abrogate the proposed rule change.

It is therefore ordered, pursuant to Section 19(b)(3)(C) of the Exchange Act,[12] that File No. SR–NASD–2005–093 be, and it hereby is, summarily abrogated. If the NASD chooses to re-file the proposed rule change, it must do so pursuant to Sections 19(b)(1)[13] and 19(b)(2) of the Exchange Act.[14]

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18667 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[7] 15 U.S.C. 78s(b)(1).

[8] *Id.*

[9] 15 U.S.C. 78s(b)(2).

[10] *See* letter from Ira D. Hammerman, Senior Vice President and General Counsel, Securities Industry Association, to Jonathan G. Katz, Secretary, Commission, dated Aug. 24, 2005; letter from Julian Rainero, Bingham McCutchen LLP, to Jonathan G. Katz, Secretary, Commission, dated Aug. 24, 2005; letter from Shane E. Swanson, General Counsel, Automated Trading Desk, LLC, to Jonathan Katz, Secretary, Commission, dated Aug. 24, 2005.

[11] *Id.*

[12] 15 U.S.C. 78s(b)(3)(C).

[13] 15 U.S.C. 78s(b)(1).

[14] 15 U.S.C. 78s(b)(2).

[15] 17 CFR 200.30–3(a)(58).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27064; 812–12868]

Applied Materials, Inc.; Notice of Application

September 13, 2005.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application under section 3(b)(2) of the Investment Company Act of 1940 (the ''Act'').

SUMMARY OF APPLICATION: Applied Materials, Inc. (''Applied'') seeks an order under section 3(b)(2) of the Act declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Applied, directly and through its wholly-owned subsidiaries, develops, manufactures, markets and services integrated circuit fabrication equipment.

FILING DATES: The application was filed on August 14, 2002, and amended on February 28, 2005, May 31, 2005 and September 6, 2005.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 11, 2005, 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 20549–9303. Applicant, 3050 Bowers Ave., P.O. Box 58039, Santa Clara, CA 95054.

FOR FURTHER INFORMATION CONTACT: Julia Kim Gilmer, Senior Counsel, at (202) 551–6871, or Janet M. Grossnickle, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Desk, 100 F Street, NE., Washington, DC 20549–0102 (tel. 202–551–5850).

Applicant's Representations

1. Applied, a Delaware corporation, is in the business of developing, manufacturing, marketing and servicing integrated circuit fabrication equipment. Customers for Applied's products include semiconductor wafer manufacturers and semiconductor integrated circuit, or ''chip'' manufacturers such as Intel, Texas Instruments and IBM. Applied represents that these chips are key components in most advanced electronic devices and that the push to make these devices more powerful, portable and affordable spurs a rapid pace of technological change in the semiconductor industry. Applied states that in the past 23 years, it has introduced over 100 major products.

2. Applied states that it requires substantial liquid capital to fund its global infrastructure, manufacturing and service activities, and to continue its research, development and engineering programs. Applied also intends to use its liquid capital to support other business and strategic objectives by acquiring and investing in businesses with complementary products, services and/or technologies. In addition to being capital intensive, Applied states that the integrated circuit fabrication equipment industry is subject to volatile business cycles due to the rapid pace of technological developments and changes in global and regional economic conditions. Applied seeks to preserve its capital and maintain liquidity, pending the use of such capital for its current and future operations, by investing in short-term investment grade and liquid fixed income and money market investments that earn competitive market returns and provide a low level of credit risk (''Capital Preservation Investments''). Applied's board of directors oversees Applied's investment practices and defines the parameters for investment activities. Applied states that it does not invest in securities for short-term speculative purposes.

Applicant's Legal Analysis

1. Applied seeks an order under section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore not an investment company as defined in the Act.

2. Under section 3(a)(1)(C) of the Act, an issuer is an investment company if it is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in

securities, and owns or proposes to acquire investment securities having a value in excess of 40 percent of the value of the issuer's total assets (exclusive of government securities and cash items) on an unconsolidated basis. Section 3(a)(2) of the Act defines ''investment securities'' to include all securities except government securities, securities issued by employees' securities companies, and securities issued by majority-owned subsidiaries of the owner which (a) are not investment companies, and (b) are not relying on the exclusions from the definition of investment company in section 3(c)(1) or 3(c)(7) of the Act. Applied states that as of January 30, 2005, approximately 50% of its total assets (exclusive of government securities and cash items), on an unconsolidated basis, consisted of investment securities as defined in section 3(a)(2) of the Act.

3. Rule 3a–1 provides an exemption from the definition of investment company if no more than 45% of a company's total assets consist of, and not more than 45% of its net income over the last four quarters is derived from, securities other than government securities, securities of majority-owned subsidiaries and primarily controlled companies. Applied states that it cannot rely upon rule 3a–1 under the Act because as of January 30, 2005, such other securities exceeded 45% of its total assets. Applied further states that it cannot rely on rule 3a–1 because the percentage of its net income derived from investment securities fluctuates unpredictably with the cycles of the semiconductor industry. The cyclical nature of the industry, rather than any change in Applied's business or financial management policies, has led to significant variations in the ratio of Applied's income from investment securities relative to net operating income.

4. Rule 3a–8 under the Act provides an exemption from the definition of investment company if, among other factors, a company's research and development expenses are a substantial percentage of its total expenses for the last four fiscal quarters combined. While Applied believes it could satisfy the other factors in the rule, Applied's research and development expenses have fluctuated from year to year due to the cyclical nature of the industry. During the 2000 through 2004 fiscal years, Applied's research and development expenses have varied, ranging from approximately 16% to 22% of its total expenses, including cost of goods sold. Applied's ratio of research and development expenses to total expenses thus may be deemed a ''substantial percentage'' in certain years, but not others. Applied presently cannot rely on rule 3a–8 because its research and development expenses for the last four fiscal quarters ended on January 30, 2005 represented approximately 16% of its total expenses, including cost of goods sold.

5. Section 3(b)(2) of the Act provides that, notwithstanding section 3(a)(1)(C) of the Act, the Commission may issue an order declaring an issuer to be primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities either directly, through majority-owned subsidiaries. Applied requests an order under section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore not an investment company as defined in the Act.

6. In determining whether a company is primarily engaged in a non-investment company business under section 3(b)(2), the Commission considers: (a) the issuer's historical development; (b) its public representations of policy; (c) the activities of its officers and directors; (d) the nature of its present assets; and (e) the sources of its present income.[1]

a. *Historical Development.* Applied states that since its inception in 1967 it has, directly and through its wholly-owned subsidiaries, developed into the largest supplier of products and services to the global semiconductor industry. Applied states that it currently manufactures systems that perform a majority of the steps in the semiconductor integrated circuit fabrication process and also provides products and services that enhance manufacturing yields. Customers for Applied's products include semiconductor wafer manufacturers and semiconductor integrated circuit, or ''chip'' manufacturers such as Intel, Texas Instruments and IBM. Applied further states that in the past 23 years, it has introduced over 100 major products. Applied states that it has not sold any of its subsidiaries in over 20 years and that these sales were conducted for reasons related to its business as a supplier of integrated circuit fabrication equipment and services.

b. *Public Representations of Policy.* Applied states that it has never represented that it is involved in any business other than developing, manufacturing, marketing and servicing integrated circuit fabrication equipment. Applied asserts that it has consistently stated in its annual reports, stockholder letter, prospectuses, filings with the Commission, press releases, marketing materials and website that it is the largest supplier of products and services to the global semiconductor industry. Applied states that it generally does not make public representations regarding its investment securities except as required by its obligation to file periodic reports to comply with federal securities laws. Applied further states that it has emphasized operating results and has never emphasized either its investment income or the possibility of significant appreciation from its cash management investment strategies as a material factor in its business or future growth.

c. *Activities of Officers and Directors.* Applied states that its directors and officers spend substantially all of their time managing Applied's business of developing, manufacturing, marketing and servicing integrated circuit fabrication equipment. Nine out of Applied's ten directors have extensive experience in the semiconductor or electronics industries. The remaining director is experienced in government and academia. Applied's directors spend less than 1% of their time on investment-related matters. Applied's chief financial officer spends less than 10% of her time monitoring Applied's cash balances and managing short-term investment securities in accordance with Applied's investment policies. Out of Applied's approximately thirty senior officers, only two (other than the chief financial officer) spend time monitoring cash balances and managing short-term investment securities; the treasurer spends less than 30% of his time and the corporate controller spends less than 5% of her time on such activities. Applied has approximately 13,000 full-time employees in approximately 80 locations throughout the world. In addition to the officers discussed above, only three other employees spend their time on matters relating to the management of Applied's investment securities; the rest of Applied's employees are involved in product design and engineering, manufacturing, customer technical support, supplier and materials management, sales and marketing, finance and corporate services, human resources, environmental, health and safety issues, global security, information technology, transactional and corporate legal services and protection and enforcement of intellectual property rights.

d. *Nature of Assets.* Applied states that as of January 30, 2005 its

[1] Tonopah Mining Company of Nevada, 26 SEC 426, 427 (1947).

investment securities (as defined in Section 3(a)(2) of the Act) of $5.1 billion constituted approximately 48% of Applied's total assets (excluding Government securities and cash items), consolidated with its wholly-owned subsidiaries.[2] More than 99% of Applied's investment securities consisted of Capital Preservation Investments. Applied's remaining investment securities consisted of investments in businesses with complementary products, services and/or technologies and an interest in a limited partnership that invests in early-stage companies involving nanotechnology and/or communications technology. Applied anticipates that its investment securities other than Capital Preservation Investments will not exceed 10% of Applied's total consolidated assets (excluding Government securities and cash items) in the future. Applied further states that a significant portion of its assets consist of intangible assets such as internally-developed intellectual property that are not included in the value of Applied's total assets for purposes of determining Applied's status under the Act. Applied states that the asset tests used in connection with sections 3(a)(1)(c) and 3(b) of the Act therefore significantly understate the relative value of Applied's non-investment security assets.

e. Sources of Income and Revenue. Applied states that for the four quarters ended January 30, 2005, its operating activities produced 94% of its net income after taxes, while its investment securities produced 6% of its net income on a tax-equivalent basis. However, for the fiscal year ended October 26, 2003, Applied had operating losses while deriving net income from its investment securities. Applied states that its net income does not always accurately reflect its operating activities since its net income fluctuates unpredictably with the cycles of the semiconductor industry. Applied thus believes that its activities as an operating company are more appropriately analyzed by looking at its revenues. Applied states that, for the four quarters ending January 30, 2005, its revenues from operations[3] represented approximately 99% of its total revenues, and its revenues from investments, or net investment income, represented approximately 1% of its total revenues. Applied expects that as its business continues in the future, the percentage of its total revenues derived from operating activities will ordinarily be over 90% and the percentage derived from investments will ordinarily be under 10%.

7. Applied thus asserts that it satisfies the standards for an order under section 3(b)(2) of the Act.

Applicant's Conditions

1. Applied will continue to allocate and use its accumulated cash and investment securities for bona fide business purposes.

2. Applied will refrain from investing or trading in securities for short-term speculative purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18614 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[2] Applied states that consolidation provides a more accurate picture of its primary business of developing, manufacturing, marketing and servicing integrated circuit fabrication equipment because Applied does not have any independent business operations separate from the activities of its wholly-owned subsidiaries. Applied has not sold any subsidiaries in over 20 years, and those sales were related to its business as a supplier of integrated circuit fabrication equipment and services. Since the subsidiaries being consolidated are all wholly-owned, consolidation will not result in the type of distortions that could result from consolidating other types of subsidiaries. Applied also has a 50% owned subsidiary that is dormant, has no operations and has not been consolidated for purposes of determining Applied's status under the Act.

[3] For the reasons stated above, revenues of Applied's wholly-owned subsidiaries were consolidated for purposes of this discussion. Applied consolidates its wholly-owned subsidiaries when preparing its financial statements in accordance with Generally Accepted Accounting Principles.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27066; 813–357]

Peter Kiewit Sons', Inc. and Kiewit Investment Fund LLLP; Notice of Application

September 14, 2005.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(b) of the Investment Company Act of 1940 (the ''Act'') granting an exemption from section 15(a) of the Act and the rules and regulations thereunder.

SUMMARY OF THE APPLICATION: Applicants request an order to permit the board of directors of an ''employees'' securities company'' as defined in section 2(a)(13) of the Act to enter into and materially amend investment advisory contracts without the approval of holders of the company's outstanding voting securities.

APPLICANTS: Peter Kiewit Sons'', Inc. (''Kiewit'') and Kiewit Investment Fund LLLP (the ''Fund'').

FILING DATES: The application was filed on July 25, 2005 and amended on August 29, 2005 and September 13, 2005.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 11, 2005, 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, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303. Applicants, Tobin A. Schropp, Peter Kiewit Sons', Inc., Kiewit Plaza, Omaha, Nebraska, 68131 and Robert A. Giles, Jr., Kiewit Investment Fund LLLP, 73 Tremont Street, Boston Massachusetts 02108.

FOR FURTHER INFORMATION CONTACT: Shannon Conaty, Senior Counsel, at (202) 551–6827 or Janet M. Grossnickle, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Desk, 100 F Street, NE., Washington, DC, 20549–0102 (tel. (202) 551–5850).

Applicants' Representations

1. Kiewit, a Delaware corporation, is a large construction contractor operating primarily in the North American market. Through various subsidiaries, joint ventures and partnerships, Kiewit provides construction services to a broad range of public and private customers. It also owns and operates several coal mining operations. Pursuant to the terms of its organizational documents, Kiewit's common stock (''Kiewit Stock'')

generally may only be owned by directors and full-time employees of Kiewit and its current or former subsidiaries, joint ventures and partnerships.

2. The Fund, a Delaware limited liability limited partnership, is registered under the Act as a non-diversified, closed-end management investment company, and will at all times operate as an ''employees'' securities company'' within the meaning of section 2(a)(13) of the Act. Kiewit, or a wholly-owned subsidiary, will be the general partner of the Fund (the ''General Partner''). To the fullest extent permitted under the Delaware Revised Uniform Limited Partnership Act (''DRULPA''), the General Partner pursuant to the Fund's amended and restated limited partnership agreement (''Partnership Agreement'') will irrevocably delegate management, control and operation of the Fund and its business and affairs to the Fund's Board of Directors (''Fund Board'', and each member thereof a ''Director'') pursuant to section 17–403 of the DRULPA.[1] All but two of the five current Directors are directors, officers or employees of Kiewit and Directors that are officers, directors or employees of Kiewit will comprise a majority of the Fund Board in the future.

3. The Fund is designed as a long-term investment vehicle for key employees and former key employees of Kiewit and its affiliated companies and their immediate family members. Units of limited partnership interests of the Fund (''Units'') will be offered pursuant to offerings registered under the Securities Act of 1933, as amended (''Securities Act'') and will be sold only to Eligible Holders.[2] Eligible Holders consist of (i) current and former employees or persons on retainer of the Kiewit Group,[3] within the meaning of section 2(a)(13) of the Act (''Eligible Employees''); (ii) Directors retained by the Fund; (iii) immediate family members, within the meaning of section 2(a)(13) of the Act, of such Directors or Eligible Employees; or (iv) members of the Kiewit Group.[4] After the initial offering, the Fund intends to offer Units continuously and accept applications to purchase Units at the end of the second and fourth calendar quarters of each year. Units will not be transferable except with the prior written consent of the Fund and then only to Eligible Holders. Units are not redeemable at the option of a holder of Units (''Unitholder'').[5]

4. Applicants believe that the Fund will provide a cost-effective opportunity to access types of investments and professional investment management that otherwise may not be available to key employees of the Kiewit Group on an individual basis. The Fund's investment objective is long-term capital growth with consideration given to consistency of returns. Under normal market conditions, the Fund's assets will be invested in a variety of securities, including U.S. and non-U.S. equities and fixed-income instruments and other investment funds that are registered investment companies or private investment funds excepted from the definition of ''investment company'' pursuant to section 3(c)(1) or 3(c)(7) of the Act (''Private Portfolio Funds''), including Private Portfolio Funds that are commonly referred to as hedge funds.[6]

5. The Fund will retain a primary investment adviser and it may determine to retain other investment advisers in the future (each, a ''Fund Adviser''). Any Fund Adviser will be registered under the Advisers Act. The Fund's primary Fund Adviser will make recommendations to the Fund Board regarding the allocation of portions of the Fund's assets to the management of other Fund Advisers. Within the framework of the investment policies set forth in the Fund's registration statement, and subject to supervision and oversight by the Fund Board, a Fund Adviser will develop an investment program with respect to its allocated assets. Each investment advisory contract or material amendment to such a contract will be approved by the Fund Board, including a majority of the Directors that are not interested persons of the Fund within the meaning of section 2(a)(19) of the Act, in accordance with section 15(c) of the Act.[7] All Fund Advisers will be subject to removal by the Fund Board at any time, without penalty, on not more than sixty days' written notice.

6. There will be no sales load or any other distribution fee charged to Eligible Holders during the initial sale of Units or any subsequent sale of Units. The Fund will not issue senior securities or borrow money for investment purposes. The Fund also will not invest in securities issued by Kiewit, any affiliated person of Kiewit or any investment company, Private Portfolio Fund or alternative investment vehicle sponsored by or affiliated with Kiewit or any of its affiliated persons; provided that the Fund may invest in an investment company, Private Portfolio Fund or alternative investment vehicle that is an affiliated person of an employee or former employee of Kiewit or its affiliated companies (that is not a current or former director or officer of Kiewit or its affiliated companies) solely by virtue of such person holding a limited partnership interest in such entity.

Applicants' Legal Analysis

1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the company should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, the disposition of the proceeds of any sales of the company's securities,

[1] Applicants represent that the delegation of duties by the General Partner to the Fund Board will be substantially identical to the delegation described in Federated Core Trust II, SEC No-Action Letter (Feb. 6, 2002).

[2] The Fund has filed a registration statement in connection with a proposed public offering of Units. The registration statement was declared effective and the Fund commenced a public offering on July 26, 2005.

[3] The term ''Kiewit Group'' refers to Kiewit and any affiliated company of Kiewit of which Kiewit is an affiliated company, as defined in section 2(a)(2) of the Act.

[4] Applicants are not asking the Commission to decide, nor is the Commission deciding, whether any particular person (or group of persons) would be considered an ''employee'' or ''person on retainer'' within the meaning of section 2(a)(13) of the Act.

[5] The Fund, subject to approval by the Fund Board, will conduct tender offers for 5% to 25% of the Fund's outstanding Units at least semi-annually commencing in January 2006. No repurchase, redemption or other fee will be assessed by the Fund on any repurchase of Units.

[6] As discussed more fully in the application, the Fund, at Kiewit's expense, will make available to each offeree that does not meet the standard of an ''accredited investor'' as set forth in rule 501(a) under the Securities Act (a ''Non-Accredited Offeree'') an investment adviser registered under the Investment Advisers Act of 1940, as amended (''Advisers Act'') that meets the requirements set forth in rule 501(h) under the Securities Act and is independent from Kiewit, the Fund and the Fund Advisers (the ''Investment Professional''). Prior to an investment in the Fund whether during the initial sale of Units or any subsequent sale of Units, each Non-Accredited Offeree will be given the opportunity to consult on a one-on-one basis with such Investment Professional for the purpose of assisting the Non-Accredited Offeree in evaluating the merits and risks of a prospective investment in the Fund and the appropriateness of an investment in the Fund in light of his or her particular circumstances.

[7] The Fund Board will consider the following factors, among others, prior to any such approval: the nature and quality of services to be rendered, the expected total revenue and profit of a Fund Adviser as a result of its relationship with the Fund, any economies of scale that a Fund Adviser may experience as the Fund grows, and the competitiveness of fees, costs and expense ratios.

how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by the vote of a majority of the company's outstanding voting securities. Applicants request an order under section 6(b) of the Act exempting the Fund from section 15(a) of the Act and the rules and regulations thereunder solely to the extent necessary to permit the Fund to enter into and materially amend investment advisory contracts with Fund Advisers without approval by Unitholders holding a majority of the outstanding voting securities of the Fund. Each investment advisory contract with any Fund Adviser will comply with all other requirements of the Act and the Advisers Act, including that the renewal of the contract is subject to annual review by the Fund Board after its initial term. For the reasons discussed below, applicants believe that the requested exemption from section 15(a) is consistent with the protection of investors and the purposes of the Act.

3. Applicants state that, because the Fund may engage multiple Fund Advisers, it is important that the Fund Board have the capability to quickly reallocate assets among Fund Advisers and retain a new Fund Adviser in the event that any such Fund Adviser performs poorly or the Fund Board determines that Fund assets should be reallocated to asset classes, strategies or styles for which existing Fund Advisers are not able to manage most efficiently. Unitholder approval each time that a new Fund Adviser is retained or an existing contract with a Fund Adviser is materially amended or assigned would impose a substantial burden on the Fund. Applicants assert that the requested relief will result in substantial cost-savings to the Fund and other efficiencies.

4. Applicants state that Kiewit (not any Fund Adviser or any affiliated person of any Fund Adviser) is the sponsor of the Fund and no member of the Kiewit Group will receive any compensation from the Fund. No Director will be an interested person of any Fund Adviser within the meaning of section 2(a)(19) of the Act and it is expected that all Directors will be Unitholders in the Fund.[8] Further, applicants state that most of the Directors are directors, officers and employees of Kiewit who share an essential community of interest with key employees and their immediate family members and have a considerable interest in seeing that the Fund is managed consistent with the interests of such key employees and their immediate family members. Applicants believe that the arms-length relationship between the Fund Board and any Fund Adviser, the community of interest that will exist among Unitholders and Directors and the Directors' fiduciary duties will reduce the risk of abuses that section 15(a) of the Act is designed to prevent.[9]

5. Applicants further believe that Unitholders will expect the Fund Board to select and monitor Fund Advisers. The Fund will disclose in its prospectus the existence, substance, and effect of the relief requested in the application and it will hold itself out to Eligible Holders as employing the management structure described in the application. The prospectus also will prominently disclose that the Fund Board has ultimate responsibility to oversee Fund Advisers and recommend their hiring, termination, and replacement.

6. Key employees of the Kiewit Group have historically invested significant portions of their personal financial assets in Kiewit Stock, which effectively results in Kiewit directors, officers and other senior management being responsible for such employees' financial well being through their management of Kiewit. Because of this historical and ongoing relationship between Kiewit's stockholders and senior management of Kiewit and the disclosure discussed above,[10] Applicants believe that key employees of the Kiewit Group that invest in the Fund would expect the Fund Board to exercise overall supervisory responsibility for the management and investment of the Fund's assets on an ongoing basis.[11]

7. Applicants further represent that the following additional safeguards exist to protect Unitholders: (i) The Fund's financial statements will be audited by a nationally recognized independent certified public accounting firm; (ii) each Fund Adviser will be registered with the Commission and will be retained pursuant to an arms-length negotiation; (iii) participation in the Fund is entirely voluntary; (iv) Unitholders will not be charged a sales load or any other distribution fee; and (v) the Fund will not invest, directly or indirectly, in securities issued by any member of the Kiewit Group.

Applicants' Condition

The applicants agree that any order granting the requested relief will be subject to the following condition:

The Fund will operate in compliance with the Act pending final determination of the application, provided that the Fund may rely on rule 6b–1 under the Act solely to implement the relief specifically requested in the application from section 15(a) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18612 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[8] Applicants state that the Fund Board's sole obligation with respect to the Fund is managing the Fund in the Fund's and Unitholders' best interests and that the Fund Board and the Directors will not have any obligation to any person or entity that benefits from the Fund.

[9] Unitholders also will be able to elect Directors in accordance with section 16(a) of the Act and, under the Partnership Agreement, Unitholders that own, in the aggregate, 10% of outstanding Units may call a special meeting of Unitholders for the purpose of electing Directors. As a result, Unitholders have the ability to replace the Fund Board if a sufficient amount of Unitholders so desire.

[10] Applicants also note that the Fund's method of operation, including its proposed investment strategy, is analogous to the operation of certain employee benefit plans, where employers or their delegates have the discretion to replace and retain advisers or terminate investment options and reinvest the assets without employee consent.

[11] This overall supervisory responsibility includes: (i) Evaluating and selecting Fund Advisers to manage all or a part of the Fund's assets; (ii) negotiating and approving contracts with Fund Advisers; (iii) when appropriate, approving the allocation and reallocation of the Fund's assets among multiple Fund Advisers; (iv) monitoring and evaluating the performance of the Fund Advisers; and (v) approving and monitoring the implementation of procedures reasonably designed to ensure that the Fund Advisers comply with the Fund's investment objective, policies and restrictions and with the Act.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52413; File No. 4–429]

Joint Industry Plan; Order Approving Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage Relating to a ''Trade and Ship'' Exception to the Definition of ''Trade-Through'' and a ''Book and Ship'' Exception to the Locked Markets Provision

September 13, 2005.

I. Introduction

On April 13, 2005, April 22, 2005, April 26, 2005, April 27, 2005, May 5, 2005, and June 2, 2005, the International Securities Exchange (''ISE''), the American Stock Exchange LLC (''Amex''), the Chicago Board Options Exchange, Incorporated (''CBOE''), the Pacific Exchange, Inc. (''PCX''), the Boston Stock Exchange, Inc. (''BSE''), and the Philadelphia Stock Exchange, Inc. (''Phlx'') (collectively, ''Participants''), respectively, filed with the Securities and Exchange Commission (''Commission'') an amendment (''Joint Amendment No. 15'') to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (''Linkage Plan'').[1] In Joint Amendment No. 15, the Participants propose to add a ''trade and ship'' exception to the definition of ''Trade-Through''[2] and a ''book and ship'' exception to the locked markets provision of the Linkage Plan.[3] The proposed amendment to the Linkage Plan was published in the **Federal Register** on August 9, 2005.[4] No comments were received on the proposed amendment. This order approves the proposed amendment to the Linkage Plan.

II. Description and Purpose of the Proposed Amendment

The purpose of Joint Amendment No. 15 is to provide that: (i) A Participant may trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order[5] is sent contemporaneously to each Participant disseminating the NBBO to satisfy all interest at the NBBO price; and (ii) a Participant may book an order that would otherwise lock another Participant if a Linkage Order is sent contemporaneously to such other Participant to satisfy all interest at the lock price and only the remaining portion of the order is booked. Under the proposed trade and ship provision, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order underlying the Linkage Order that would be sent to trade with the market disseminating the NBBO.

III. Discussion

After careful consideration, the Commission finds that the proposed amendment to the Linkage Plan seeking to add a trade and ship exception to the definition of Trade-Through and a book and ship exception to the locked markets provision of the Linkage Plan is consistent with the requirements of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the proposed amendment to the Linkage Plan is consistent with Section 11A of the Act[6] and Rule 11Aa3–2 thereunder,[7] in that the proposed amendment should facilitate the ability of Participants' members to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets in the options market.

IV. Conclusion

It is therefore ordered, pursuant to Section 11A of the Act[8] and Rule 11Aa3–2 thereunder,[9] that the proposed Joint Amendment No. 15 is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18620 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[1] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the Amex, the CBOE, and the ISE. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Phlx, the PCX, and the BSE, the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[2] *See* Section 2(29) of the Linkage Plan.

[3] Specified in Section 7(a)(i)(C) of the Linkage Plan.

[4] *See* Securities Exchange Act Release No. 52167 (July 29, 2005), 70 FR 46224.

[5] *See* Section 2(16) of the Linkage Plan.

[6] 15 U.S.C. 78k–1.

[7] 17 CFR 240.11Aa3–2.

[8] 15 U.S.C. 78k–1.

[9] 17 CFR 240.11Aa3–2.

[10] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting Federal Register Citation of Previous Announcement: [To Be Published]

STATUS: Open Meeting.

PLACE: 100 F Street, NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Wednesday, September 21, 2005.

CHANGE IN THE MEETING: Additional item.

The following item has been added to the Open Meeting scheduled for Wednesday, September 21, 2005:

In addition, the Commission will consider whether to propose interpretive guidance and solicit comment regarding the scope of ''brokerage and research services'' within Section 28(e) of the Securities Exchange Act of 1934. The interpretive release is designed to provide guidance to securities industry participants on money managers' use of client commission dollars to pay for research and brokerage services under Section 28(e). The release also reminds industry participants of the statutory requirements for client commission arrangements under Section 28(e).

For further information, please contact Jo Anne Swindler, Assistant Director, at (202) 551–5750; Patrick M. Joyce, Special Counsel, at (202) 551–5758; Stanley C. Macel, IV, Special Counsel, at (202) 551–5755; or Marlon Quintanilla Paz, Special Counsel, at (202) 551–5756, at the Office of Enforcement Liaison and Institutional Trading, Division of Market Regulation.

Commissioner Glassman, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: September 15, 2005.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18816 Filed 9–16–05; 12:04 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52414; File No. SR–Amex–2005–046]

Self-Regulatory Organizations; American Stock Exchange LLC; Order Approving a Proposed Rule Change and Amendment No. 1 Thereto To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On April 28, 2005, the American Stock Exchange LLC (''Amex''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage [3] by amending Amex Rules 940 and 943 to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. On July 6, 2005, the Amex filed Amendment No. 1 to the proposed rule change.[4] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 5, 2005.[5] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

Under the proposed rule change, an Amex member could trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order [6] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest at the NBBO price. The proposed rule change also would provide that an Amex member may book an order that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The Amex proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [7] and the rules and regulations thereunder applicable to a national securities exchange.[8] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[9] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of Amex's members to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (SR-Amex-2005–046) as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18617 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the Amex, the Chicago Board Options Exchange, Incorporated, and the International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., the Pacific Exchange, Inc., and the Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] In Amendment No. 1, the Amex revised the rule text to use terms consistent with Amex's current rules and made clarifying changes in the purpose, statutory basis, and burdens sections.

[5] *See* Securities Exchange Act Release No. 52172 (July 29, 2005), 70 FR 45449.

[6] *See* Amex Rule 940(b)(10).

[7] 15 U.S.C. 78f.

[8] 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).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52428; File No. SR–Amex–2005–047]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto Relating to the Definition of Firm Customer Quote Size and the Removal of Certain Restrictions on Sending Principal Acting as Agent (P/A) Orders Through the Linkage

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 28, 2005, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Amex. On September 12, 2005, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the operation of the intermarket option linkage to conform with a proposed amendment [4] to the Plan for the Purpose of Creating and Operating an Intermarket Linkage (''Linkage Plan'').[5] Accordingly, the Exchange is proposing to amend Amex Rules 940 and 941 to modify the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange made clarifying changes to the proposed rule text relating to the availability of Participant exchanges' automatic execution system.

[4] *See* Securities Exchange Act Release No. 34–52401 (September 9, 2005) (File No. 4–429) (''Amendment No. 16'').

[5] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option market linkage proposed by the Amex, Chicago Board Options Exchange, Incorporated, and International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., Pacific Exchange, Inc. and Boston Stock Exchange, Inc. the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000), 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000) and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

definition of ''Firm Customer Quote Size'' (''FCQS'')[6] to provide automatic executions of the Principal Acting as Agent Orders (''P/A Orders'')[7] up to the full size of the Exchange's disseminated quotation and to eliminate the 15-second waiting period between the sending of P/A Orders.

The text of the proposed rule change is available on the Amex's Web site at *http://www.amex.com,* the Office of the Secretary, the Amex and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex 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 this proposed rule change is to conform Amex's rules to proposed Amendment No. 16. Amendment No. 16, together with this proposed rule change, would change the definition of FCQS and eliminate the 15-second limitation in connection with the sending of P/A Orders. The change to the definition of FCQS is intended to reflect current practices of the Linkage Plan participants (''Participants'') relating to disseminated size not in existence at the time the Plan was originally adopted. At the time of the Linkage Plan's adoption, options quote sizes were generally not disseminated through the Options Price Reporting Authority, and most Participants employed automatic execution systems that guaranteed automatic executions on orders under a certain contract size. Accordingly, the FCQS was calculated based on the number of contracts the sending and receiving exchange guaranteed they would automatically execute. Now that all the Participants disseminate dynamic quotes with size, the Exchange believes it is appropriate to calculate the FCQS based on the size of the disseminated quotation of the Participant receiving the P/A Order. Therefore, the Exchange proposes to amend Amex Rule 940(b)(7) to define FCQS as the size of the disseminated quotation of the Participant receiving the P/A Order.

This proposal also seeks to eliminate the 15-second wait period for sending a second P/A Order. Specifically, Amex Rule 941(b)(2), which governs the manner in which a P/A Order larger than the FCQS can be broken into smaller P/A Orders. Currently, Amex Rule 941(b)(2) provides that an initial P/A Order may be sent to a Participant for execution at the FCQS and, if the same Participant continues to disseminate the same price 15 seconds after the execution of the initial P/A Order, the specialist may send a second P/A Order, subject to certain restrictions. The Exchange proposes to eliminate the 15-second wait period because the Participants now employ dynamic quotes with size, obviating the need for a manual quote refresh period for P/A Orders. The Exchange also proposes to amend Amex Rule 941 to clarify that an automatic execution of a P/A Order is not required if the P/A Order is larger than the FCQS.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, 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 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.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Amex does not believe that the proposed rule change, as amended, would 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the Amex consents, the Commission will:

A. By order approve such proposed rule change, as amended; or

B. Institute proceedings to determine whether the proposed rule change, as amended, should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Amex–2005–47 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–Amex–2005–047. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. 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

[6] *See* Exchange Rule 940(b)(7).

[7] *See* Section 2(16)(a) of the Linkage Plan and Exchange Rule 940(b)(10)(i).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–Amex–2005–047 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18671 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52404; File No. SR–BSE–2005–21]

Self-Regulatory Organizations; Boston Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to a Proposal To Transfer a Portion of Its Ownership Interest in Boston Options Exchange Facility

September 9, 2005.

On July 27, 2005, the Boston Stock Exchange (''BSE'' 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 announcing BSE's intention to transfer a portion of its ownership interest in BOX LLC, the operator of its Boston Options Exchange facility (''BOX''), such that its aggregate percentage interest will fall below 20%.[3] The purpose of the transfer would be to assist BSE in funding its equities-related business interests and initiatives related thereto.

The proposed rule change was published for comment in the **Federal Register** on August 5, 2005.[4] The Commission received no comments on the proposed rule change. This order approves the proposed rule change.

The Commission has reviewed carefully BSE's proposed rule change and finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[5] and with the requirements of Section 6(b).[6] In particular, the Commission finds that the proposal furthers the objectives of Section 6(b)(1),[7] in that it will help ensure that the Exchange is so organized and has the capacity to carry out the purposes of the Act and to comply and to enforce compliance by the Exchange's members with the Act, the rules and regulations of the Act, and the rules of the Exchange; and Section 6(b)(5),[8] in that it is designed to facilitate transactions in securities; to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities; to remove impediments to and perfect the mechanism of a free and open market and a national market system; and in general, to protect investors and the public interest.

Although BSE does not presently have a transferee designated, BSE represented in its proposed rule change that: (1) Any transferee will need to sign and be bound by the provisions of the LLC Agreement; and (2) any Transfer,[9] including a Transfer that will result in BSE's Percentage Interest falling below the 20% threshold, will be subject to the various limitations set forth in the LLC Agreement, throughout Article 8 and elsewhere, regarding suitability and other regulatory and business requirements.[10]

Further, the BSE represented that its proposed transfer of Units will not affect additional provisions of the LLC Agreement that make special accommodations for BSE as the SRO of the BOX facility. For example, Section 4.1(b) of the LLC Agreement provides that, with its present ownership interest, BSE is entitled to maintain two seats on the BOX LLC Board. Because BSE is not proposing to make any transfers that would result in BSE's percentage interest in BOX LLC going below 8.00%, which is the threshold amount established in Section 4.1(b) for BSE to maintain two directors on the Board, this entitlement will remain. In addition, pursuant to Section 4.1 of the LLC Agreement, BSE has an absolute right to designate at least one director on the BOX LLC Board regardless of whether it maintains any ownership interest in BOX LLC.

BSE also noted that, as a facility of an exchange, BOX is an integral part of a self-regulatory organization registered pursuant to the Act and is subject to the requirements of the Act. Although BOX LLC itself will not carry out any regulatory functions, all of its activities must be consistent with the Act. These obligations continue as long as BOX is a facility of BSE, regardless of the size of BSE's ownership interest in BOX LLC. BSE also represented that because the Exchange is the SRO for the BOX facility, it will, independent of its ownership interest, ensure that BOX LLC conducts the facility's business in a manner consistent with the regulatory and oversight responsibilities of the BSE and with the Act.

Finally, BSE represented that neither its proposal nor the actual transfer of any BSE units will alter or modify the terms or the enforcement of the LLC Agreement.

The Commission believes that because the proposed transfer of Units by the BSE pursuant to the proposed rule change and the terms of the LLC Agreement will not affect BOX's responsibilities as a facility of BSE, or the Exchange's rights and obligations as the SRO for the BOX facility, including the Exchange's right to designate at least one director on the Board of BOX LLC, the proposed transfer of Units is consistent with the requirements of the Act and the rules and regulations

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In the proposed rule change, BSE acknowledged that pursuant to Section 8.4(f) of the operating agreement of BOX LLC (the ''LLC Agreement''), any transfer that would result in a reduction of BSE's aggregate Percentage Interest in BOX LLC to below 20% is subject to the rule filing process pursuant to Section 19(b)(1) of the Act (15 U.S.C. 78s(b)(1)) and Rule 19b–4 thereunder (17 CFR 240–19b–4).

[4] *See* Securities Exchange Act Release No. 52169 (July 29, 2005), 70 FR 45451.

[5] In approving this proposed rule change, the Commission notes that it has also considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(1).

[8] 15 U.S.C. 78f(b)(5).

[9] Under the terms of the LLC Agreement, a ''Transfer'' occurs when any LLC Member would ''dispose of, sell, alienate, assign, exchange, participate, subparticipate, encumber, or otherwise transfer in any manner * * * all or any part or portion of its Units'' (ownership interest).

[10] For example, BSE would be prohibited, under Section 8.1(d), from Transferring any of its Units to anyone other than a Member, an affiliate of a Member, or Interactive Brokers Group LLC (''IB'') (according to the terms set forth in Section 8.6(d)), until the earlier of the second anniversary of the Launch Date of BOX or the date on which IB's percentage interest has been reduced to no more than 8.00%. Further, pursuant to Section 8.1(a) of the LLC Agreement, except for: (i) Transfers among Members; (ii) certain transfers by IB; and (iii) transfers to Affiliates of a Member, prior to any transfer, the proposed transferee must be approved by the BOX LLC Board. To be eligible for approval, the proposed transferee must: (i) Be of high professional and financial standing; (ii) be able to carry out their duties as a Member; and (iii) be under no regulatory or governmental bar or disqualification. In addition, pursuant to Section 8.4(e) of the LLC Agreement, BOX would be required to provide the Commission with notice ten days prior to the closing date of any acquisition that results in a BOX Member's ownership percentage interest meeting or crossing the threshold level of 5%, or the successive 5% percentage interest levels of 10% and 15%.

thereunder applicable to a national securities exchange.

The Commission expects, and BSE has represented, that should there be any changes in the terms of the LLC Agreement between the date of the publication of this proposal and the proposed transfer of BSE's Units that would result in the BSE's Percentage Interest falling below the 20% threshold, the Exchange will submit a new proposed rule change in order for the Commission to consider the transfer of Units in light of any changes made to the LLC Agreement.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–BSE–2005–21) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18615 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52415; File No. SR–BSE–2005–29]

Self-Regulatory Organizations; Boston Stock Exchange, Inc.; Order Approving a Proposed Rule Change To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On August 1, 2005, the Boston Stock Exchange, Inc. (''BSE''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 10(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage[3] by amending Sections 1 and 4 of chapter XII of the Boston Options Exchange Facility (''BOX'') Rules to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. The proposed rule change was published for comment in the **Federal Register** on August 10, 2005.[4] The Commission received no comments on the proposal. This order approves the proposed rule change.

Under the proposed rule change, a BOX Options Participant could trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order[5] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest of the NBBO price. The proposed rule change also would provide that a BOX Options Participant may book an order on BOX that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The BSE proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act[6] and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of BOX Options Participants to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (SR–BSE–2005–29) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18618 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–M

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the American Stock Exchange LLC, the Chicago Board Options Exchange, Incorporated, and the International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., the Pacific Exchange, Inc., and the BSE, the Commission issued order to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 40198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] *See* Securities Exchange Act Release No. 52205 (August 4, 2005), 70 FR 46551.

[5] *See* Section 1, subsection (j) of Chapter XII of the BOX Rules.

[6] 15 U.S.C. 78f.

[7] 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).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52412; File No. SR–BSE–2005–38]

Self-Regulatory Organizations; Boston Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto Relating to the Exchange's Transaction Fees and Tape a Revenue Sharing Program for Electronically Routed Cross Trades

September 13, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 19, 2005, the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The BSE filed the proposal pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] as one establishing or changing a due, fee or other charge imposed by the BSE, which renders the proposal effective upon filing with the Commission. On September 9, 2005, the Exchange filed Amendment No. 1 to the proposed rule change.[5] On September 12, 2005, the Exchange filed Amendment No. 2 to the proposed rule change.[6] The Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The BSE withdrew Amendment No. 1 on August 12, 2005 for technical and formatting reasons.

[6] In Amendment No. 2, the Exchange: (1) provided additional detail about the Exchange's

Continued

is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Transaction Fee Schedule in relation to electronically routed cross trade executions. The text of the proposed rule change is available on the Exchange's Web site (*http://www.bostonstock.com*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, 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 BSE proposes to amend its Transaction Fee Schedule by eliminating all fees for cross trades delivered electronically to the Exchange.[7] Specifically, the Exchange proposes to waive all Value Charges and Trade Recording Fees on cross trades that are electronically routed to the BSE for execution. The current fee structure for Automated Portfolio Crosses will also be eliminated. The category of Automated Portfolio Crosses was created in the Transaction Fee Schedule several years ago for a specific type of business related only to cross trades that would be routed to the Exchange as part of a larger basket of trades. The BSE no longer receives this type of specialized cross trade. Therefore, the separate category of fees for Automated Portfolio Crosses is no longer required. The BSE believes that these changes to its Transaction Fee Schedule will allow the Exchange to attract a new segment of business to the Exchange, which will, in turn, allow the Exchange to remain competitive in the overall marketplace.

The BSE is now proposing to eliminate all fees for all electronically delivered cross trades. Since the Exchange requires that all orders submitted to a BSE specialist by members be transmitted through the BEACON trading system, all cross trades submitted to BSE specialists for execution would be considered to be electronically routed, with the exception of those entered by a BSE Floor Broker. While floor brokered orders must also be entered into the BEACON trading system for transmission to a BSE specialist, the Exchange does not consider floor brokered orders to be electronically routed cross trades, due to the intervention of and handling by the floor broker. Thus, the proposed fee waiver would not apply to floor broker entered cross trades, even though such cross trades are entered through the BEACON trading system, but would apply to all other cross trades submitted to BSE specialists through BEACON.

The Exchange also proposes to amend its Tape A revenue sharing program to further encourage its member firms to electronically route cross trades to the BSE. Under this proposal, electronically routed cross trades would be excluded from the current Tape A revenue sharing program, which requires that a pre-determined Exchange-wide Tape A revenue target be achieved, and requires that a member firm generate a minimum of $50,000 in overall monthly transaction fees before being eligible to participate in a 50% revenue share for Tape A business. The BSE is proposing that member firms that electronically route cross trades to the BSE for execution be permitted to receive 50% of the Tape A revenue generated by such electronically routed cross trades, regardless of whether the Exchange has met its pre-determined Tape A revenue target, and regardless of the amount of the firm's overall monthly transaction fees. The 50% revenue sharing would be a flat rate, calculated on a trade-by-trade basis. Thus, a BSE member would receive 50% of the Tape A revenue generated by each electronically routed cross trade that the member routes to the BSE for execution.

The Exchange is cognizant of its surveillance and compliance responsibilities as a self-regulatory organization. Although this proposal involves the waiver of certain fees and amendments to the Tape A revenue sharing program, which could result in a reduction of revenue to the BSE, the Exchange represents that its responsibilities as a self-regulatory organization will in no way be compromised by the implementation of the changes proposed herein.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(4) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act[10] and subparagraph (f)(2) of Rule 19b–4 thereunder,[11] because it establishes or changes a due, fee or other charge

rules and procedures regarding electronically routed cross trades; (2) clarified that the proposed changes will not adversely affect the BSE's regulatory responsibilities; and (3) amended the proposed rule text regarding the Exchange's Tape A revenue sharing program to clarify how the revenue sharing will be calculated. The effective date of the original proposed rule change is August 19, 2005, and the effective date of Amendment No. 2 is September 12, 2005. For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, the Commission considers the period to commence on September 12, 2005, the date on which the Exchange filed Amendment No. 2. *See* 15 U.S.C. 78s(b)(3)(C).

[7] Upon entry into the BEACON trading system, all orders are transmitted to a BSE specialist. Depending on factors such as order size and type, the orders are either automatically or manually executed. Cross trades would automatically execute, provided that no customer orders existed on the book which held priority over either side of the cross and could ''break up'' the cross. *See* Chapter II, ''Dealings on the Exchange,'' Section 6, ''Bids and Offer for Stocks,'' and Section 18, ''Orders to Buy and Sell the Same Security'' of the Rules of the Board of Governors of the BSE (''BSE Rules''). Additionally, cross trades of 5,000 shares or more are considered, under Chapter II, Section 18 of the BSE Rules, to be ''clean crosses,'' which can execute within the prevailing bid and offer given a set of qualifying conditions.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

imposed by the BSE. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[12]

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–BSE–2005–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR-BSE–2005–38. 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 inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BSE–2005–38 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18619 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[12] *See supra* note 6.

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52429; File No. SR–BSE–2005–39]

Self-Regulatory Organizations; Boston Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change Relating to the Definition of Firm Customer Quote Size and Limitations on Sending of Multiple P/A Orders on the Boston Options Exchange

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 13, 2005, the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the BSE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its rules governing the operation of the intermarket option linkage (''Linkage'') on the Boston Options Exchange (''BOX'') to conform with a proposed amendment[3] to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (''Linkage Plan'').[4] The Exchange is proposing: (i) To amend the definition of ''Firm Customer Quote Size'' (''FCQS'')[5] to provide automatic executions for Principal Acting as Agent Orders (''P/A Orders'')[6] sent via Linkage up to the full size of a Participant's disseminated quotation; and (ii) to eliminate a 15-second waiting period between the sending of P/A Orders.

The text of the proposed rule amendment is available on BSE's Web site at *http://www.bostonstock.com,* at the BSE's Office of the Secretary, and at the Commission's public reference room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules governing Linkage in two areas: the definition of FCQS and limitations on sending multiple P/A Orders.

The Linkage Plan participants (''Participants'') provide automatic execution to P/A Orders up to the FCQS, if automatic execution is available. At the time the Participants adopted the Linkage Plan, options quote sizes were not disseminated through the Options Price Reporting Authority, and the floor-based Participants employed automatic execution systems that guaranteed automatic fills on orders under a certain contract size (which generally was a static number). As such, the FCQS was calculated based on the number of contracts the sending and receiving Participants guaranteed they would automatically execute. Now that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 52401 (September 9, 2005) (File No. 4–429) (''Amendment No. 16'').

[4] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option market linkage proposed by the American Stock Exchange, LLC, Chicago Board Options Exchange, Incorporated, and International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., Pacific Exchange, Inc., and BSE, the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000), 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000) and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[5] *See* Section 2(11) of the Linkage Plan and Chapter XII, Section 1(g) of BOX's Rules.

[6] *See* Section 2(16)(a) of the Linkage Plan and Chapter XII, Section 1(j)(i) of BOX's Rules.

all Participants disseminate dynamic quotes with size, the Participants believe that it is appropriate to calculate the FCQS based on the size of the disseminated quotation of the Participant receiving the P/A Order. Accordingly, the Participant Exchanges submitted Amendment No. 16 to the Linkage Plan, and the Exchange proposes to amend the definition of FCQS to Chapter XII, Section 1(g) of BOX Rules. As such, upon implementation of the proposed rule change and Amendment No. 16, a Participant will provide incoming P/A Orders with executions up to the full size of a Participant's disseminated quotation.

The proposed rule change will eliminate a 15-second period Participants must wait before sending a second P/A Order. Specifically, Chapter XII, Section 2(c) of BOX's Rules governs the manner in which P/A Orders larger than the FCQS are handled. It provides that an initial P/A Order may be sent to a Participant for execution at the FCQS; if the same Participant continues to disseminate the same price 15 seconds after the execution of the initial P/A Order, the market maker can send a second P/A Order, subject to certain restrictions. The Exchange proposes to eliminate the 15-second wait period because the Participants now employ dynamic quotes with size, obviating the need for a manual quote refresh period for P/A Orders.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [7] in general, and furthers the objectives of Section 6(b)(5) of the Act [8] 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes the proposed rule change will help promote the Linkage Plan by providing greater automatic execution of Linkage orders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the BSE consents, the Commission will:

A. By order approve such proposed rule change; or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml); or*
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–BSE–2005–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–BSE–2005–39. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section Room. 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 publicly available. All submissions should refer to File Number SR–BSE–2005–39 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18669 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52419; File No. SR–CBOE–2005–51]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving a Proposed Rule Change and Amendment No. 1 Thereto To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On June 30, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage [3] by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the American Stock Exchange LLC, the CBOE, and the International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., the Pacific Exchange, Inc., and the Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities

amending CBOE Rules 6.80 and 6.84 to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. On July 26, 2005, the CBOE filed Amendment No. 1 to the proposed rule change.[4] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 5, 2005.[5] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

Under the proposed rule change, an order could be traded at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order[6] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest at the NBBO price. The proposed rule change also would provide that an order may be booked that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The CBOE proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of section 6 of the Act[7] and the rules and regulations thereunder applicable to a national securities exchange.[8] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[9] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of CBOE's members to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (SR–CBOE–2005–51) as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18623 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] In Amendment No. 1, the CBOE revised the rule text to use terms consistent with CBOE's current rules and made certain clarifying changes to the purpose section.

[5] *See* Securities Exchange Act Release No. 52173 (July 29, 2005), 70 FR 45452.

[6] *See* CBOE Rule 6.80(12).

[7] 15 U.S.C. 78f.

[8] 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).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52424; File No. SR–CBOE–2005–68]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of Proposed Rule Change Relating to the Definition of Firm Customer Quote Size in the Linkage Plan

September 14, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 29, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the operation of the intermarket option linkage (''Linkage'') to conform with a proposed amendment[3] to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (''Linkage Plan'').[4] The Exchange is proposing: (i) To amend the definition of ''Firm Customer Quote Size'' (''FCQS'')[5] to provide automatic executions for Linkage Principal Acting as Agent Orders (''P/A Orders'')[6] up to the full size of the Exchange's disseminated quotation; and (ii) to eliminate a 15-second waiting period between the sending of P/A Orders.

The text of the proposed rule change is available on CBOE's Web site (*www.cboe.com*), at the CBOE's Office of the Secretary, and at the Commission's public reference room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of 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 modernize the definition of FCQS in CBOE rules related to the operation of the Linkage rules. At the time the Linkage commenced, options quote sizes were not disseminated through the Options Price Reporting Authority and most participants in the Linkage Plan employed automatic execution systems that guaranteed automatic fills on orders under a certain contract size (which was generally a static number). As such, the FCQS was

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 52401 (September 9, 2005) (File No. 4–429) (''Amendment No. 16'').

[4] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option market linkage proposed by the American Stock Exchange, LLC, CBOE, and International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., Pacific Exchange, Inc. and Boston Stock Exchange, Inc. the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000), 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000) and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[5] *See* Exchange Rule 6.80(9).

[6] *See* Section 2(16)(a) of the Linkage Plan and Exchange Rule 6.80(12)(i).

calculated based on the number of contracts the sending and receiving Linkage Plan participants (''Participants'') guaranteed they would automatically execute. Now that all Participants disseminate dynamic quotes with size, the Participants believe that it is appropriate to calculate the FCQS based on the size of the disseminated quotation of the Participant receiving the P/A Order. Accordingly, the Exchange proposes to amend CBOE Rule 6.80 to effect this change.[7]

The other purpose of the proposed rule change is to eliminate a 15-second wait period for sending a secondary P/A Order currently provided in Exchange Rule 6.81(b)(2). Exchange Rule 6.81(b)(2) governs the manner in which a P/A Order larger than the FCQS can be broken into smaller P/A Orders. Currently, Exchange Rule 6.81(b)(2) provides that an initial P/A Order can be sent to the Participant disseminating the National Best Bid or Offer for the FCQS, and if that Participant continues to disseminate the same price after 15 seconds from the execution of the initial P/A Order, a subsequent P/A Order can be sent for at least the lesser of (i) the size of the disseminated quote; (ii) 100 contracts; or (iii) the remainder of the customer order underlying the P/A Orders. The Exchange proposes to eliminate the 15-second waiting period because the dynamic quotes with size now employed by the Participants obviate the need for a manual quote refresh period for P/A Orders. This proposed rule change would conform the CBOE rules to the pending Amendment No. 16 to the Linkage Plan.[8]

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act[9] in general, and furthers the objectives of section 6(b)(5) of the Act[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

[7] The Commission added to this sentence pursuant to a telephone conversation with CBOE, as noted herein. Telephone call between Tim Fox, Special Counsel, Commission, and Patrick Sexton, Assistant General Counsel, CBOE on September 12, 2005.

[8] *See Supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change would 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the CBOE consents, the Commission will:

A. By order approve such proposed rule change; or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2005–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–CBOE–2005–68. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. 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 publicly available. All submissions should refer to File Number SR–CBOE–2005–68 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18670 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52423; File No. SR–CBOE–2005–76]

Self-Regulatory Organizations; Chicago Board Options Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Duration of CBOE Rule 6.45A(b) Pertaining to Orders Represented in Open Outcry

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 13, 2005, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') 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 CBOE. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to extend the duration of CBOE Rule 6.45A(b) (the ''Rule''), relating to the allocation of orders represented in open outcry in equity option classes designated by the Exchange to be traded on the CBOE Hybrid Trading System (''Hybrid''), through December 14, 2005. No other substantive changes are being made to the Rule. The text of the proposed rule change is available on the CBOE's Web site (*http://www.cboe.com*), at the CBOE'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 CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

In March 2005, the Commission approved revisions to CBOE Rule 6.45A related to the introduction of Remote Market-Makers.[5] Among other things, the Rule, pertaining to the allocation of orders represented in open outcry in equity options classes traded on Hybrid, was amended to clarify that only in-crowd market participants would be eligible to participate in open outcry trade allocations. In addition, the Rule was amended to limit its duration until September 14, 2005, unless otherwise extended. As the duration period expires on September 14, 2005, the Exchange proposes to extend the effectiveness of the Rule through December 14, 2005.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for thirty 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[9] and Rule 19b–4(f)(6)[10] thereunder.

A proposed rule change filed under Commission Rule 19b–4(f)(6)[11] normally does not become operative prior to thirty days after the date of filing. The CBOE requests that the Commission waive the 30-day operative delay, as specified in Rule 19b–4(f)(6)(iii), and designate the proposed rule change to become operative immediately to allow the Exchange to continue to operate under the existing allocation parameters for orders represented in open outcry in Hybrid on an uninterrupted basis. The Commission hereby grants the request. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will allow the CBOE to continue to operate under the Rule without interruption. For these reasons, the Commission designates the proposed rule change as effective and operative immediately.[12]

At any time within 60 days of the filing of the proposed rule change the Commission may summarily abrogate such proposed rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2005–76 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–CBOE–2005–76. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your

[5] *See* Securities Exchange Act Release No. 51366 (March 14, 2005), 70 FR 13217 (March 18, 2005) (SR–CBOE–2004–75).

[6] In order to effect proprietary transactions on the floor of the Exchange, in addition to complying with the requirements of the Rule, members are also required to comply with the requirements of Section 11(a)(1) of the Act, 15 U.S.C. 78k(a)(1), or qualify for an exemption. Section 11(a)(1) restricts securities transactions of a member of any national securities exchange effected on that 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. The Exchange will issue a regulatory circular to members reminding them of the applicability of these Section 11(a)(1) requirements.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] *Id.*

[12] For the purposes only of waiving the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2005–76 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18674 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52422; No. SR–DTC–2005–11]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish an Insurance Program as Part of the Profile Modification System Feature of Its Direct Registration System

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on August 22, 2005, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') and on August 22, 2005, amended [2] the rule change described in Items I, II, and III below, which items have been prepared primarily by DTC. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

[1] 15 U.S.C. 78s(b)(1).

[2] The amendment corrected a pagination error in the original filing.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The rule change establishes an insurance program as part of DTC's Profile Modification System (''Profile'') of its Direct Registration System (''DRS'').

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC included statements concerning the purpose of and basis for the rule change and discussed any comments it received on the rule change. The text of these statements may be examined at the places specified in Item IV below. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Currently, Profile allows a DTC participant to submit electronically to a transfer agent that is a DRS limited participant an investor's instruction that its share positions be moved from the investor's DRS account with the DRS limited participant to the investor's broker-dealer's participant account at DTC. Similarly, a DRS limited participant may submit an investor's instruction for the movement of its share positions from the investor's broker-dealer's participant account at DTC to an account maintained by the DRS limited participant.

Currently, all Profile users must agree to a Participant Terminal System (''PTS'') screen indemnity as part of their use of Profile and must procure a surety bond relating to their obligations under such indemnity (''Surety Program''). Participation in the Surety Program requires the payment of an annual premium of $3,150 to a surety provider and a DTC administration fee of $250. The Surety Program provides for a coverage limit of $3 million per occurrence and an annual aggregate limit of $6 million.

DTC believes the cost of the annual surety and the coverage limit may be a disincentive for some to use Profile. In order to encourage greater participation in the service, DTC proposes the implementation of the DTC Profile Modification System Indemnity Insurance Program (''Insurance Program''). Under the Insurance Program, Profile users will have the option to procure indemnity insurance with higher coverage limits ($25 million per occurrence per policy with an annual aggregate limit of $100 million) than the surety bond under the Surety Program provides, which will allow larger transactions to be covered under one policy. Furthermore, Profile users will have the option to procure indemnity insurance at an annual fee that is less than the premium for the Surety Program. In addition to any pass-through fee from the insurer, DTC will charge users participating in the Insurance Program an annual administration fee of $250 and a $2.50 per transaction fee. Users will be able to participate in both the Surety Program and the Insurance Program but would be required and permitted to use only one provider per Profile transaction.

The issuing insurance company will be either a company selected by DTC as the administrator of such insurance or an insurance company selected by the user procuring the insurance, provided the insurance company will issue insurance subject to the terms and conditions established by DTC for the Insurance Program.

DTC believes the rule change is consistent with Section 17A of the Act,[4] as amended, because it is a modification of a DTC service that enhances the safeguards for transactions processed in the service. As such it is a change to an existing service that will not adversely affect the safeguarding of securities and funds in DTC's custody or control.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the rule change have not yet been solicited or received. DTC will notify the Commission of any written comments it receives.

[3] The Commission has modified the text of the summaries prepared by DTC.

[4] 15 U.S.C. 78q–1.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii) of the Act [5] and Rule 19b–4(f)(4) [6] thereunder because it does not adversely affect the safeguarding of securities or funds in the custody or control of DTC or for which it is responsible and does not significantly affect the respective rights or obligations of the clearing agency or persons using the service. At any time within sixty days of the filing of the rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the 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–DTC–2005–11 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–DTC–2005–11. 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 rule change that are filed with the Commission, and all written communications relating to the rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549. Copies of such filings also will be available for inspection and copying at the principal office of DTC and on DTC's Web site at *https://login.dtcc.com/dtcorg/.* 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–DTC–2005–11 and should be submitted on or before October 11, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18668 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[5] 15 U.S.C. 78s(b)(3)(A)(iii).

[6] 17 CFR 240.19b–4(f)(4).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52418; File No. SR–ISE–2005–33]

Self-Regulatory Organizations; International Securities Exchange, Inc.; Order Approving a Proposed Rule Change To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On July 8, 2005, the International Securities Exchange, Inc. (''ISE''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage [3] by amending ISE Rules 1900 and 1903 to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. The proposed rule change was published for comment in the **Federal Register** on August 5, 2005.[4] The Commission received no comments on the proposal. This order approves the proposed rule change.

Under the proposed rule change, an ISE member could trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order [5] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest at the NBBO price. The proposed rule change also would provide that an ISE member may enter an order on the ISE that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The ISE proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [6] and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of ISE's members to execute their customer

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the American Stock Exchange LLC, the Chicago Board Options Exchange, Incorporated, and the ISE. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., the Pacific Exchange, Inc., and the Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] *See* Securities Exchange Act Release No. 52174 (July 29, 2005), 70 FR 45455.

[5] *See* ISE Rule 1900(10).

[6] 15 U.S.C. 78f.

[7] 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).

[8] 15 U.S.C. 78f(b)(5).

orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (SR–ISE–2005–33) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18616 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52410; File No. SR–ISE–2005–42]

Self-Regulatory Organizations; International Securities Exchange, Inc.; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto Relating to the Definition of Firm Customer Quote Size in the Linkage Plan

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 31, 2005, the International Securities Exchange, Inc. (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the ISE. On September 7, 2005, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the operation of the intermarket option linkage (''Linkage'') to conform with a proposed amendment[4] to the Plan for the Purpose of Creating and Operating an Intermarket Linkage (''Linkage Plan'').[5] The Exchange is proposing: (i) to amend the definition of ''Firm Customer Quote Size'' (''FCQS'')[6] to provide automatic executions for Principal Acting as Agent Orders (''P/A Orders'')[7] sent via Linkage up to the full size of the receiving exchange's disseminated quotation; and (ii) to eliminate a 15-second waiting period between the sending of P/A Orders.

The text of the proposed rule change is available on ISE's Web site (*http://www.iseoptions.com*), at the ISE's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the ISE included statements concerning the purpose of, and basis for, the proposed rule change, as amended, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules governing Linkage trading in two areas: the definition of FCQS; and limitations on sending multiple P/A Orders. As to the definition of FCQS, the participants in the Linkage Plan (''Participants'') provide automatic execution to P/A Orders up to the FCQS. At the time the Participants adopted the Linkage Plan, options quote sizes were not disseminated through the Options Price Reporting Authority, and the floor-based exchanges employed automatic execution systems that guaranteed automatic fills on orders under a certain contract size (which was generally a static number). As such, the FCQS was calculated based on the number of contracts the sending and receiving exchanges guaranteed they would automatically execute. Now that all the Participants disseminate dynamic quotes with size, the Participants believe that it is appropriate to calculate the FCQS based on the size of the disseminated quotation of the exchange receiving the P/A Order. As such, upon implementation of the proposed rule change, the ISE will provide incoming P/A Orders with executions up to the full size of the ISE's disseminated quotation.

With respect to multiple P/A Orders, the proposed rule change will eliminate a 15-second period members must wait before sending a second P/A Order. Specifically, ISE Rule 1901(c)(2)(ii) governs the manner in which the Participants will execute P/A Orders larger than the FCQS. ISE Rule 1901(c)(2)(ii) provides that an initial P/A Order may be sent to a Participant for execution at the FCQS; if the same Participant continues to disseminate the same price 15 seconds after the execution of the initial P/A Order, the market maker can send a second P/A Order, subject to certain restrictions. The Exchange proposes to eliminate the 15-second wait period because the Participants now employ dynamic quotes with size, obviating the need for a manual quote refresh period for P/A Orders.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, 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 regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. In particular, the proposed rule change will help implement the Linkage Plan by providing greater automatic execution of Linkage Orders.

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[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 made technical corrections to the proposed rule change.

[4] *See* Securities Exchange Act Release No. 52401 (September 9, 2005) (File No. 4–429).

[5] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option market linkage proposed by the American Stock Exchange, LLC, Chicago Board Options Exchange, Incorporated, and ISE. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., Pacific Exchange, Inc. and Boston Stock Exchange, Inc. the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000), 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000) and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[6] *See* Exchange Rule 1900(7).

[7] *See* Section 2(16)(a) of the Linkage Plan and Exchange Rule 1900(10)(i).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The ISE does not believe that the proposed rule change, as amended, would 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the ISE consents, the Commission will:

A. By order approve such proposed rule change, as amended; or

B. Institute proceedings to determine whether the proposed rule change, as amended, should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, 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–ISE–2005–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–ISE–2005–42. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. 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 publicly available. All submissions should refer to File Number SR–ISE–2005–42 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18672 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52421; File No. SR–NYSE–2005–54]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Granting Accelerated Approval of a Proposed Rule Change To Amend NYSE Rule 123C (Market on the Close Policy and Expiration Procedures) To Eliminate the Requirement To Publish Pre-Opening Market Order Imbalances on Expiration Fridays

September 14, 2005.

I. Introduction

On July 26, 2005, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposal to amend NYSE Rule 123C (Market on the Close Policy and Expiration Procedures) to eliminate the requirement to publish pre-opening market order imbalances on expiration Fridays. The proposed rule change was published for comment in the **Federal Register** on August 19, 2005.[3] The Commission received no comments regarding the proposal. This order approves the proposed rule change on an accelerated basis.

II. Description of the Proposal

NYSE Rule 123C contains requirements with respect to operation of the Exchange's market concerning market-on-close (''MOC'') and limit-on-close (''LOC'') orders as well as order entry and imbalance publication requirements for use on expiration days.[4] Under NYSE Rule 123C(6), the Exchange currently publishes information order imbalances, as promptly as possible after 9 a.m., only with respect to the imbalance of buy and sell market orders, and does not include buy and sell limit orders entered up to that time for execution at the opening. The NYSE proposes to eliminate the publication of pre-opening market order imbalances on expiration Fridays. The NYSE believes that the publication of only market order imbalances does not provide useful information, especially with respect to stocks which are part of an expiring index whose settlement is based on NYSE opening prices on one of those days.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[5] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[6] which requires, among other things, that the rules of a national securities exchange be 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

[10] 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. 52255 (August 15, 2005), 70 FR 48792.

[4] NYSE Rule 123C defines an ''expiration day'' as ''a trading day prior to the expiration of index-related derivative products (futures, options or options on futures), whose settlement pricing is based upon opening or closing prices on the Exchange, as identified by a qualified clearing corporation (e.g., the Options Clearing Corporation). The twelve expiration days are 'expiration Fridays' which fall on the third Friday in every month.'' On these expiration days, the Exchange has specific requirements governing the entry of orders in stocks relating to index contracts whose settlement prices are based on the opening prices on the Exchange of the stocks comprising the indices.

[5] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f(b)(5).

open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that by amending NYSE Rule 123C to eliminate the publication of pre-opening market order imbalances which do not include limit orders, the NYSE will no longer disseminate information that may have been misleading to investors.

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[7] for approving the proposed rule change prior to the 30th day after the date of publication of notice in the **Federal Register**. The Commission does not believe that the proposed rule change raises novel regulatory issues. Granting accelerated approval of the proposed rule change allows the NYSE to implement the proposed rule change by the next expiration Friday. Consequently, the Commission believes that it is appropriate to grant accelerated approval to permit the Exchange to eliminate the publication of pre-opening market order imbalances on expiration Fridays as soon as possible. Accordingly, the Commission finds that there is good cause, consistent with the reasons herein, to approve the proposal on an accelerated basis.

IV. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[8] that the proposed rule change (SR–NYSE–2005–54) be, and hereby is approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18666 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[7] 15 U.S.C. 78s(b)(2).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52417; File No. SR–PCX–2005–59]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Order Approving a Proposed Rule Change and Amendments No. 1 and 3 Thereto To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On April 27, 2005, the Pacific Exchange, Inc. (''PCX''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage[3] by amending PCX Rules 6.92 and 6.95 to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. On July 8, 2005, the PCX filed Amendment No. 1 to the proposed rule change.[4] The PCX filed Amendment No. 2 to the proposed rule change on July 29, 2005 and withdrew Amendment No. 2 on August 1, 2005. The PCX filed Amendment No. 3 to the proposed rule change on August 1, 2005.[5] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 11, 2005.[6] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

Under the proposed rule change, a Participant Exchange[7] could trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order[8] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest at the NBBO price. The proposed rule change also would provide that an OTP Holder, OTP Firm, or Eligible Market Maker may book an order that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The PCX proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act[9] and the rules and regulations thereunder applicable to a national securities exchange.[10] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[11] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of PCX's participants to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–PCX–2005–59) as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18622 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the American Stock Exchange LLC, the Chicago Board Options Exchange, Incorporated, and the International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., the PCX, and the Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] In Amendment No. 1, the PCX revised the rule text to use terms consistent with PCX's current rules and made clarifying changes in the purpose and statutory basis sections.

[5] In Amendment No. 3, the PCX made clarifying changes to the rule text and the purpose section.

[6] *See* Securities Exchange Act Release No. 52206 (August 4, 2005), 70 FR 46898.

[7] *See* PCX Rule 6.92(a)(16).

[8] *See* PCX Rule 6.92(a)(12).

[9] 15 U.S.C. 78f.

[10] 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).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52427; File No. SR–PCX–2005–104]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Notice of Filing of Proposed Rule Change Relating to the Definition of Firm Customer Quote Size and the Removal of Certain Restrictions on Sending Secondary Principal Acting as Agent Orders Pursuant to the Linkage Plan

September 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 7, 2005, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the PCX. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the operation of the intermarket option linkage (''Linkage'') to conform with a proposed amendment[3] to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (''Linkage Plan'').[4] The Exchange is proposing to modify the definition of ''Firm Customer Quote Size'' (''FCQS'')[5] to provide automatic executions for Linkage Principal Acting as Agent Orders (''P/A Orders'')[6] up to the full size of the Exchange's disseminated quotation; and (ii) to eliminate a 15-second waiting period between the sending of P/A Orders.

The text of the proposed rule change is available on PCX's Web site at *http://www.pacificex.com*, at the PCX's Office of the Secretary, and at the Commission's public reference room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PCX 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 modernize the definition of FCQS. At the time the Linkage commenced, options quote sizes were not disseminated through the Options Price Reporting Authority and most Linkage Plan participants (''Participants'') employed automatic execution systems that guaranteed automatic fills on orders under a certain contract size (which was generally a static number). As such, the FCQS was calculated based on the number of contracts the sending and receiving Participants guaranteed they would automatically execute. Now that all Participants disseminate dynamic quotes with size, the Participants believe that it is appropriate to calculate the FCQS based on the size of the disseminated quotation of the Participant receiving the P/A Order. Accordingly, the Participants submitted Amendment No. 16, and the Exchange is submitting herein a proposed rule change to amend the definition of FCQS, provided in PCX Rule 6.92(a)(9).[7]

The other purpose of the proposed rule change is to eliminate a 15-second wait period for sending a secondary P/A Order pursuant to Exchange Rule 6.93. That Exchange Rule governs the manner in which a P/A Order larger than the FCQS can be broken into smaller P/A Orders. It provides that an initial P/A Order can be sent to the National Best Bid or Offer (''NBBO'') market for the FCQS, and that if the NBBO market continues to disseminate the same price after 15 seconds from the execution of the initial P/A Order, a secondary P/A Order can be sent (for at least the lesser of (i) the size of the disseminated quote; (ii) 100 contracts; or (iii) the remainder of the customer order underlying the P/A Orders). The 15-second wait period is being eliminated because the dynamic quotes with size now employed by the Participants obviate the need for a manual quote refresh period for P/A Orders.

2. Statutory Basis

The Exchange believes that the proposed rule change 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 mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PCX does not believe that the proposed rule change would 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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the PCX consents, the Commission will:

A. By order approve such proposed rule change; or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–52401 (September 9, 2005) (File No. 4–429) (''Amendment No. 16'').

[4] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option market linkage proposed by the American Stock Exchange, LLC, Chicago Board Options Exchange, Incorporated, and International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Philadelphia Stock Exchange, Inc., PCX and Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000), 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000) and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[5] *See* Exchange Rule 6.92(a)(10).

[6] *See* Section 2(16)(a) of the Linkage Plan and Exchange Rule 6.92(a)(12)(i).

[7] The Commission added to this sentence pursuant to a telephone conversation with PCX, as noted herein. Telephone call between Steven Matlin, Senior Counsel, PCX, and Tim Fox, Special Counsel, Commission on September 12, 2005.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–PCX–2005–104 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–PCX–2005–104. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. 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 publicly available. All submissions should refer to File Number SR–PCX–2005–104 and should be submitted on or before October 11, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18673 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–52416; File No. SR–Phlx–2005–26]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving a Proposed Rule Change and Amendment No. 1 Thereto To Amend the Exchange's Trade-Through and Locked Markets Rules

September 13, 2005.

On April 26, 2005, the Philadelphia Stock Exchange, Inc. (''Phlx''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] to implement Amendment No. 15 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage[3] by amending Phlx Rules 1083 and 1086 to add a ''trade and ship'' exception to the definition of ''Trade-Through'' and add a ''book and ship'' exception to the provision relating to locked markets, respectively. On July 21, 2005, the Phlx filed Amendment No. 1 to the proposed rule change.[4] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 5, 2005.[5] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

Under the proposed rule change, a Participant Exchange[6] could trade an order at a price that is one minimum quoting increment inferior to the national best bid or offer (''NBBO'') if a Linkage Order[7] is sent contemporaneously to the market(s) disseminating the NBBO to satisfy all interest at the NBBO price. The proposed rule change also would provide that an Eligible Market Maker or other member may book an order that would otherwise lock another market if a Linkage Order is sent contemporaneously to such other market to satisfy all interest at the lock price and only the remaining portion of the order is booked. The Phlx proposes that, under trade and ship, any execution received from the market disseminating the NBBO must (pursuant to agency obligations) be reassigned to the customer order that is underlying the Linkage Order that was sent to trade with the market disseminating the NBBO.

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act[8] and the rules and regulations thereunder applicable to a national securities exchange.[9] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[10] which requires, among other things, that the rules of an 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. The Commission believes that the proposed rule change should help to implement the Linkage Plan by facilitating the ability of Phlx's members to execute their customer orders in a timely manner and potentially could decrease the incidence of Trade-Throughs and locked markets.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–Phlx–2005–26) as amended, is approved.

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[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket option linkage proposed by the American Stock Exchange LLC, the Chicago Board Options Exchange, Incorporated, and the International Securities Exchange, Inc. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (''Linkage Plan''). Subsequently, upon separate requests by the Phlx, the Pacific Exchange, Inc., and the Boston Stock Exchange, Inc., the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70851 (November 28, 2000); 43574 (November 16, 2000), 65 FR 70850 (November 28, 2000); and 49198 (February 5, 2004), 69 FR 7029 (February 12, 2004).

[4] In Amendment No. 1, the Phlx revised the rule text to use terms consistent with Phlx's current rules and the Linkage Plan, and made clarifying changes in the description of the substance of the proposed rule change and the purpose and statutory basis sections.

[5] *See* Securities Exchange Act Release No. 52175 (July 29, 2005), 70 FR 45480.

[6] *See* Phlx Rule 1083(o).

[7] *See* Phlx Rule 1083(k).

[8] 15 U.S.C. 78f.

[9] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–18621 Filed 9–19–05; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF STATE

[Public Notice 5190]

Meeting of the U.S.-Chile Environment Affairs Council

ACTION: Notice and request for comments.

SUMMARY: The Department of State and the Office of the United States Trade Representative (USTR) are providing notice that, as set forth in Chapter 19 (Environment) of the U.S.-Chile Free Trade Agreement (FTA), the tow governments intend to hold the second meeting of the Environment Affairs Council (the ''Council'') in Washington, DC on October 24, 2005. U.S. Deputy Assistant Secretary Claudia McMurray and Chilean Under Secretary Rodrigo Egana will jointly chair the Council meeting. The purpose of this meeting is detailed below under **SUPPLEMENTARY INFORMATION.**

In this notice, the Department of state and USTR are requesting: (1) Written comments from the public regarding agenda items for the Council meeting; (2) written comments regarding the implementation of the eight cooperative projects listed in Annex 19.3 of Chapter 19 (Environment) of the FTA, particularly Reducing Mining Pollution and Sharing Private Sector Expertise (in the initial implementation stages); (3) written comments regarding implementation of Chapter 19's framework for public participation; and (4) written suggestions for future bilateral environmental cooperation between the United States and the Republic of Chile. A joint public session will be held immediately following the Council meeting. The purpose of this public session is detailed below under **SUPPLEMENTARY INFORMATION.** In preparing comments, the public is encouraged to refer to:

- The environment chapter of the U.S.-Chile Free Trade Agreement and Annex 19.3, available at:*http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/asset_upload_file482_401.3.pdf;*
- The U.S.-Chile Environmental Cooperation Agreement, available at:*http://www.state.gov/goes/rls/or/22185.html* and
- The Final Environment Review of the U.S.-Chile Free Trade Agreement, available at: *http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Chile_FTA/asset_upload_file 411_5109.pdf.*

DATES: To guarantee receipt in proper time for consideration prior to the meeting, comments are requested no later than October 20, 2005.

ADDRESSES: Comments may be sent by fax to (202) 647–5947 or (202) 647–1052. by e-mail to *OES–ENV–Mail@state.gov.*

FOR FURTHER INFORMATION CONTACT: Lawrence Sperling, Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Policy Coordination and Initiatives, Telephone (202) 647–2061.

SUPPLEMENTARY INFORMATION: The U.S.-Chile Free Trade Agreement (FTA) entered into force on January 1, 2004. Article 3 of Chapter 19 (Environment) of the FTA establishes an Environment Affairs Council (the ''Council''), which is required to meet once a year, or more often if agreed by the two governments, to discuss the implementation of, and progress under, Chapter 19. Chapter 19 requires that meetings of the Council include a public session, unless otherwise agreed by the two governments. The first meeting of the Council was held on July 22, 2004, in Santiago, Chile, to discuss issues of mutual concern related to Chapter 19 of the FTA, including matters related to the eight cooperation projects listed in Annex 19.3 of the FTA. The Council Agenda for this second meeting will include discussion of the progress in implementing the eight cooperation projects under Chapter 19 of the FTA. This meeting will also consider how to further implement the provisions of Chapter 19, including public participation, and recommendations for future bilateral cooperation. Written comments from the public regarding agenda items for the Council meeting, as well as written comments regarding the eight cooperative projects and future bilateral cooperation, may be submitted to the contact addresses listed above.

The public session will take place in Washington, DC after the Council meeting, on October 24, 2005 starting time and place to be announced, in order to explain the provision in Chapter 19 of the FTA and the role of the Council, as well as discuss the cooperative projects identified in the annex of Chapter 19. The public is advised to refer to the State Department Web site at *http://www.state.gov/g/oes/env/* for further information related to this meeting.

Dated: September 15, 2005.

David E. Brown,

Director, Office of Environmental Policy Department of State.

[FR Doc. 05–18723 Filed 9–19–05; 8:45 am]

BILLING CODE 4710–09–M

TENNESSEE VALLEY AUTHORITY

Paperwork Reduction Act of 1995, as amended by Pub. L. 104–13; Submission for OMB Review; Comment Request

AGENCY: Tennessee Valley Authority.

ACTION: Submission for OMB review; comment request.

SUMMARY: The proposed information collection described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). The Tennessee Valley Authority is soliciting public comments on this proposed collection as provided by 5 CFR 1320.8(d)(1). Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Agency Clearance Officer: Alice D. Witt, Tennessee Valley Authority, 1101 Market Street (EB 5B), Chattanooga, Tennessee 37402–2801; (423) 751–6832. (SC: 0001JTJ) Comments should be sent to the OMB Office of Information and Regulatory Affairs, Attention: Desk Officer for the Tennessee Valley Authority by October 20, 2005.

SUPPLEMENTARY INFORMATION:

Type of Request: Regular submission; proposal for a new collection.

Title of Information Collection: Confirmation of TVA-Owned Cash.

Frequency of Use: One time.

Type of Affected Public: Business.

Small Businesses or Organizations Affected: No.

Estimated Number of Annual Responses: 629.

Estimated Total Annual Burden Hours: 345.50.

Estimated Average Burden Hours Per Response: 0.55 hours.

Need For and Use of Information: We are requesting the information from the financial institutions located near TVA operating plants and offices to determine whether those financial institutions have TVA-owned cash on deposit. We will use the information obtained to confirm the amount of cash

[12] 17 CFR 200.30–3(a)(12).

included in TVA's financial statement report.

Jacklyn J. Stephenson,

Senior Manager, Enterprise Operations, Information Services.

[FR Doc. 05–18684 Filed 9–19–05; 8:45 am]

BILLING CODE 8120–08–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Public Comment With Respect to the Annual National Trade Estimate Report on Foreign Trade Barriers

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: Pursuant to section 303 of the Trade and Tariff Act of 1984, as amended, USTR is required to publish annually the National Trade Estimate Report on Foreign Trade Barriers (NTE). With this notice, the Trade Policy Staff Committee (TPSC) is requesting interested parties to assist it in identifying significant barriers to U.S. exports of goods, services and overseas direct investment for inclusion in the NTE. Particularly important are impediments materially affecting the actual and potential financial performance of an industry sector. The TPSC invites written comments that provide views relevant to the issues to be examined in preparing the NTE.

DATES: Public comments are due not later than Wednesday, November 16, 2005.

ADDRESSES: Submissions by electronic mail: *FR0508@USTR.EOP.GOV.* Submissions by facsimile: Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the United States Trade Representative, (202) 395–6143. The public is strongly encouraged to submit documents electronically rather than by facsimile. (See requirements for submissions below.)

FOR FURTHER INFORMATION CONTACT: Questions regarding the report, its subject matter or procedural questions concerning submissions should be directed to Ms. Gloria Blue, Office of Policy Coordination, Office of the United States Trade Representative (202) 395–3475.

SUPPLEMENTARY INFORMATION: Last year's report may be found on USTR's Internet Home Page (*http://www.ustr.gov*) in the Document Library under the section on Reports/Publications. In order to ensure compliance with the statutory mandate for reporting foreign trade barriers that are significant, we will focus particularly on those restrictions where there has been active private sector interest.

The information submitted should relate to one or more of the following ten categories of foreign trade barriers:

(1) Import policies (*e.g.*, tariffs and other import charges, quantitative restrictions, import licensing, and customs barriers);

(2) Standards, testing, labeling, and certification (including unnecessarily restrictive application of phytosanitary standards, refusal to accept U.S. manufacturers' self-certification of conformance to foreign product standards, and environmental restrictions);

(3) Government procurement (*e.g.*, ''buy national'' policies and closed bidding);

(4) Export subsidies (*e.g.*, export financing on preferential terms and agricultural export subsidies that displace U.S. exports in third country markets);

(5) Lack of intellectual property protection (*e.g.*, inadequate patent, copyright, and trademark regimes);

(6) Services barriers (*e.g.*, limits on the range of financial services offered by foreign financial institutions, regulation of international data flows, restrictions on the use of data processing, quotas on imports of foreign films, and barriers to the provision of services by professionals (*e.g.*, lawyers, doctors, accountants, engineers, nurses, etc.);

(7) Investment barriers (*e.g.*, limitations on foreign equity participation and on access to foreign government-funded R&D consortia, local content, technology transfer and export performance requirements, and restrictions on repatriation of earnings, capital, fees and royalties);

(8) Anticompetitive practices with trade effects tolerated by foreign governments (including anticompetitive activities of both state-owned and private firms that apply to services or to goods and that restrict the sale of U.S. products to any firm, not just to foreign firms that perpetuate the practices);

(9) Trade restrictions affecting electronic commerce (*e.g.*, tariff and non-tariff measures, burdensome and discriminatory regulations and standards, and discriminatory taxation); and

(10) Other barriers (*i.e.*, barriers that encompass more than one category, *e.g.*, bribery and corruption, or that affect a single sector).

As in the case of last year's NTE, we are asking that particular emphasis be placed on any practices that may violate U.S. trade agreements. We are also interested in receiving any new or updated information pertinent to the barriers covered in last year's report as well as new information. Please note that the information not used in the NTE will be maintained for use in future negotiations.

It is most important that your submission contain estimates of the potential increase in exports that would result from the removal of the barrier, as well as a clear discussion of the method(s) by which the estimates were computed. Estimates should fall within the following value ranges: Less than $5 million; $5 to $25 million; $25 million to $50 million; $50 million to $100 million; $100 million to $500 million; or over $500 million. Such assessments enhance USTR's ability to conduct meaningful comparative analyses of a barrier's effect over a range of industries.

Please note that interested parties discussing barriers in more than one country should provide a separate submission (*i.e.*, one that is self-contained) for each country.

Requirements for Submissions: In order to facilitate prompt processing of submissions, USTR strongly urge and prefers electronic (e-mail) submissions in response to this notice. In the event an e-mail submission is impossible, submissions should be made by facsimile. Facsimile submissions should not exceed a maximum of 20 pages.

E-mail submissions should be single copy transmissions in English. Submissions should use the following subject line: ''2006 National Trade Estimate Report—Submission by (sector, company, association). Documents must be submitted as either WordPerfect (''WPD''), MSWord (''DOC''), or text (''TXT'') file. Documents should not be submitted as electronic image files or contain imbedded images (for example, ''JPG'', ''PDF'' ''BMP'', or ''GIF''), as these type of files are generally excessively large. Supporting Documentation submitted as spreadsheets are acceptable as Quattro Pro or Excel, pre-formatted for printing on 8½ x 11 inch paper. To the extent possible, any data attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Petitions will be available for public inspection by appointment with the staff of the USTR Public Reading Room, except for information granted ''business confidential'' status pursuant to 15 CFR 2003.6. If the submission contains business confidential information, a non-confidential version of the submission must also be submitted that indicates where

confidential information was redacted by inserting asterisks where material was deleted. In addition, the confidential submission must be clearly marked ''Business Confidential'' in large, bold letters at the top and bottom of every page of the documents. The public version that does not contain business confidential information must be clearly marked either ''Public Version'' or ''Non-Confidential'' in large, bold letters at the top and bottom of every page. The file name of any documents containing business confidential information attached to an e-mail transmission should begin with the characters ''BC-'', and the file name of the public version should begin with the characters ''P-''. The ''P-'' or ''BC-'' should be followed by the name of the person or party submitting the petition. Submissions by e-mail should not include separate cover letters or messages in the message area of the e-mail; information that might appear in any cover letter should be included directly in the submission. The e-mail address for submissions is *FR0508@ustr.eop.gov*. Public versions of all documents relating to this review will be available for review shortly after the due date by appointment in the USTR Public Reading Room, 1724 F Street, NW., Washington, DC. Availability of documents may be ascertained and appointments may be made from 9:30 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, by calling (202) 395–6186.

Carmen Suro-Bredie,

Chair, Trade Policy Staff Committee.

[FR Doc. 05–18701 Filed 9–19–05; 8:45 am]

BILLING CODE 3190–W5–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Multiple Counties, Alabama

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project that will traverse the west central section of the State of Alabama.

FOR FURTHER INFORMATION CONTACT: Mr. Joe D. Wilkerson, Division Administrator, Federal Highway Administration, 500 Eastern Boulevard, Suite 200, Montgomery, Alabama 36117–2018, Telephone (334) 223–7370.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the State of Alabama Department of Transportation, will prepare an Environmental Impact Statement (EIS) for Project NCPD–PE02(910). The proposed action is to construct a multi-lane, limited-access roadway to provide a connecting link in the freeway/Interstate system between I–59/I–20 near the Mississippi State line and I–85 in Montgomery, Alabama. The highway will have an approximate length of 140 miles. The study area includes large parts of six Black Belt Counties (Dallas, Hale, Lowndes, Marengo, Perry, and Sumter), as well as Autauga and Montgomery Counties. A new Interstate connector will improve system linkage, provide a safe and efficient transportation corridor, and enhance economic opportunities for the Black Belt and other areas in the region.

Alternatives under consideration include: (1) alternate route locations and (2) a no-action or no-build alternative.

The Alabama Department of Transportation and the Alabama Division Office of the Federal Highway Administration have begun a corridor study. Letters describing the proposed action and soliciting comments were sent to appropriate Federal, State, and local agencies and to private organizations and citizens who previously expressed or were known to have interest in this proposal.

In addition to the early coordination already accomplished, additional meetings will be held as appropriate, and formal public hearings will be held. Public notice will be given of the time and place for the meetings and hearings. The Draft Environmental Impact Statement will be available for public and agency review and comment prior to the public hearings.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues are identified, comments and suggestions are invited from all interested parties. An interagency scoping meeting was scheduled for September 22, 2005, in Selma, Alabama. 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 Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: September 8, 2005.

Joe D. Wilkerson,

Division Administrator, Montgomery.

[FR Doc. 05–18627 Filed 9–19–05; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 658]

The 25th Anniversary of the Staggers Rail Act of 1980: A Review and Look Ahead

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of public hearing.

SUMMARY: The Surface Transportation Board will hold a public hearing beginning at 10 a.m. on Wednesday, October 19, 2005, at its offices in Washington, DC. The purpose of the public hearing will be to examine the impact, the effectiveness, and the future of the Staggers Rail Act of 1980 (Staggers Act). Persons wishing to speak at the hearing should notify the Board in writing.

DATES: The public hearing will take place on Wednesday, October 19, 2005. Any person wishing to speak at the hearing should file with the Board a written notice of intent to participate, and should identify the party, the proposed speaker, the time requested, and the topic(s) to be covered, as soon as possible but no later than October 7, 2005. Each speaker should also file with the Board his/her written testimony by October 12, 2005. Written submissions by interested persons who do not wish to appear at the hearing will also be due by October 12, 2005. A list of speakers and time will be published by October 14, 2005.

ADDRESSES: All notices of intent to participate and testimony may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should comply with the Board's *''www.stb.dot.gov''* Web site, at the ''E-FILING'' link. Any person submitting a filing in the traditional paper format should send an original and 10 copies of the filing to: Surface Transportation Board, Attn: STB Ex Parte No. 658, 1925 K Street, NW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1609. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at: (800) 877–8339.]

SUPPLEMENTARY INFORMATION: The Board will hold a public hearing to provide a forum for the expression of views on the impact, effectiveness, and future of the Staggers Act. Interested persons, including large and small rail customers, large and small railroad companies, representatives of local communities, and State and Federal government officials, are invited to participate. The hearing is not intended to offer a forum for discussion of pending cases, but rather is intended as an opportunity for interested persons to address broader issues regarding the Staggers Act generally.

Date of Hearing. The hearing will begin at 10 am on Wednesday, October 19, 2005, in the 7th floor hearing room at the Board's headquarters in Washington, DC, and will continue, with short breaks if necessary, until every person scheduled to speak has been heard.

Notice of Intent To Participate. Any person wishing to speak at the hearing should file with the Board a written notice of intent to participate, and should identify the party, the proposed speaker, the time requested, and topic(s) to be covered, as soon as possible, but no later than October 7, 2005.

Testimony. Each speaker should file with the Board his/her written testimony by October 12, 2005. Also, any interested person who wishes to submit a written statement without appearing at the October 19 hearing should file that statement by October 12, 2005.

Board Releases and Live Audio Available Via the Internet. Decisions and notices of the Board, including this notice, are available on the Board's Web site at *''http://www.stb.dot.gov.''* This hearing will be available on the Board's Web site by live audio streaming. To access the hearing, click on the ''Live Audio'' link under ''Information Center'' at the left side of the Home page beginning at 10 a.m. on October 19, 2005.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Dated: September 14, 2005.

Vernon A. Williams,

Secretary.

[FR Doc. 05–18681 Filed 9–19–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–43 (Sub-No. 176X)]

Illinois Central Railroad Company—Abandonment Exemption—in Rankin County, MS

Illinois Central Railroad Company (IC) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 1.52-mile line of railroad, on its Flowood Trackage, between milepost 70.20 and milepost 71.72, in Flowood, Rankin County, MS. The line traverses United States Postal Service Zip Code 39232.

IC 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 or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on October 20, 2005, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by September 30, 2005. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by October 11, 2005, with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to IC's representative: Michael J. Barron, Jr., Illinois Central Railroad Company, c/o CN, 17641 S. Ashland Avenue, Homewood, IL 60430.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

IC has filed environmental and historic reports which address the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by September 23, 2005. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 565–1539. [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), IC 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 IC's filing of a notice of consummation by September 20, 2006, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: September 14, 2005.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–18746 Filed 9–19–05; 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 Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,200. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34750]

Browns, Grayville & Poseyville Railway Company—Acquisition and Operation Exemption—Owensville Terminal Company, Inc.

Browns, Grayville & Poseyville Railway Company (BG&P), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire and operate approximately 22.5 miles of rail line owned by Owensville Terminal Company, Inc. (OTC) in Edwards and White Counties, IL, and Gibson and Posey Counties, IN. The line runs between milepost 205.0 at or near Browns, IL, and milepost 227.5 at or near Poseyville, IN.

On February 25, 1998, a decision and notice of interim trail use or abandonment (NITU) was served in *Owensville Terminal Company, Inc.—Abandonment Exemption—In Edwards and White Counties, IL and Gibson and Posey Counties, IN*, STB Docket No. AB–477 (Sub No. 3X), establishing a 180-day period under the National Trails System Act, 16 U.S.C. 1247(d), for OTC to negotiate an interim trail use/rail banking agreement for the line. Trail negotiations were successful and an agreement was reached between OTC and Indiana Trails Fund, Inc. within the prescribed period. OTC has subsequently entered into an agreement with BG&P whereby, for value, OTC has conveyed its right to reinstitute rail service on the line to BG&P. BG&P now wishes to reactivate service over the line.[1]

BG&P certifies that its projected revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier, and that its annual revenues will not exceed $5 million.

The transaction was expected to be consummated on or after September 1, 2005, the effective date of the exemption (7 days after the exemption was filed).

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

[1] BG&P simultaneously filed a petition to vacate the NITU issued in *Owensville Terminal Company, Inc.—Abandonment Exemption—in Edwards and White Counties, IL and Gibson and Poseyville Counties, IN*, STB Docket No. AB–477 (Sub. No. 3X) (STB served Feb. 25, 1998). The petition will be addressed by the Board in a separate decision.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34750, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Thomas F. McFarland, 208 South La Salle Street, Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at *http://www.Stb.Dot.Gov*.

Decided: September 9, 2005.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–18571 Filed 9–19–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of amendment to system of records.

SUMMARY: As required by the Privacy Act of 1974, 5 U.S.C. 552a(e), notice is hereby given that the Department of Veterans Affairs (VA) is amending the system of records currently entitled ''The Revenue Program—Billing and Collections Records-VA'' (114VA16) as set forth in the **Federal Register** 69 FR 4205. VA is amending the system of records by revising the Categories of Records in the System, Purpose and Routine Uses of Records Maintained in the System. VA is republishing the system notice in its entirety.

DATES: Comments on the amendment of this system of records must be received no later than October 20, 2005. If no public comment is received, the amended system will become effective October 20, 2005.

ADDRESSES: Written comments concerning the proposed amended system of records may be submitted by: mail or hand-delivery to Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or e-mail to *VAregulations@mail.va.gov*. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273–9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration (VHA) Privacy Act Officer, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; telephone (727) 320–1839.

SUPPLEMENTARY INFORMATION: VA is amending ''The Revenue Program—Billing and Collections Records-VA'' (114VA16) to allow for the collection of the National Provider Identifier (NPI) of healthcare providers in order for the NPI to be submitted on claims for payment of healthcare services provided by VA. The Categories of Records in the System is amended to add the NPI to the other demographic data collected on healthcare providers. Purpose(s) is amended to reflect how the data may be used to make application for a NPI, as required under the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Rule on Standard Unique Health Identifier for Healthcare Providers which includes participation in pilot testing of NPI enumeration system by the Centers for Medicare and Medicaid Services (CMS).

We are proposing to amend and establish the following Routine Use disclosure of information maintained in the system:

Routine Use ten (10) is amended to add NPI to the list of healthcare provider demographic data that may be disclosed to a third party where the third party requires the Department provide that information before it will pay for medical care provided by VA.

Routine Use thirteen (13) is amended to replace ''Patient identifying information may be disclosed'' to ''Relevant information may be disclosed.'' Identifying information on a spouse sometimes must be disclosed to a third party payer in order for VA to be reimbursed for services.

A new Routine Use seventeen (17) is added. Provider identifying information may be disclosed from this System of Records to CMS to test the enumeration system for the NPI and, once the system is operational, to obtain a NPI for any eligible healthcare professional providing examination or treatment within VA healthcare facilities.

VA needs the NPI to be able to bill for services provided by the healthcare provider.

The Privacy Act permits VA to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which we collected the

information. In all of the routine use disclosures described above, the recipient of the information will use the information in connection with a matter relating to one of VA's programs, will use the information to provide a benefit to VA, or disclosure is required by law.

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: September 1, 2005.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

114VA16

SYSTEM NAME:

The Revenue Program—Billing and Collections Records-VA.

SYSTEM LOCATION:

Records are maintained at each VA healthcare facility. In most cases, back-up computer tape information is stored at off-site locations. Address locations for VA facilities are listed in VA Appendix 1 of the biennial publication of VA Privacy Act Issuances. In addition, information from these records or copies of records may be maintained at the Department of Veterans Affairs (VA), 810 Vermont Avenue, NW, Washington, DC; the VA Austin Automation Center (AAC), Austin, Texas; Veterans Integrated Service Network (VISN) Offices; VA Allocation Resource Center (ARC), Boston, Massachusetts, and contractor facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

1. Veterans who have applied for healthcare services under Title 38, United States Code, Chapter 17, and in certain cases members of their immediate families.
2. Beneficiaries of other Federal agencies.
3. Individuals examined or treated under contract or resource sharing agreements.
4. Individuals examined or treated for research or donor purposes.
5. Individuals who have applied for Title 38 benefits but who do not meet the requirements under Title 38 to receive such benefits.
6. Individuals who were provided medical care under emergency conditions for humanitarian reasons.
7. Pensioned members of allied forces (Allied Beneficiaries) who are provided healthcare services under Title 38, United States Code, Chapter 1.
8. Healthcare professionals providing examination or treatment to any individuals within VA healthcare facilities.
9. Healthcare professionals providing examination or treatment to individuals under contract or resource sharing agreements.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include information related to:

1. The social security number and insurance policy number of the veteran and/or veteran's spouse. The record may include other identifying information (*e.g.*, name, date of birth, age, sex, marital status) and address information (*e.g.*, home and/or mailing address, home telephone number).
2. Insurance company information specific to coverage of the veteran and/or spouse to include annual deductibles and benefits.
3. Diagnostic codes (ICD9–CM, CPT–4, and any other coding system) pertaining to the individual's medical, surgical, psychiatric, dental and/or psychological examination or treatment.
4. Charges claimed to a third party payer, including insurance companies, other Federal agencies, or foreign governments, based on treatment/services provided to the patient.
5. Charges billed to those veterans who are required to meet co-payment obligations for treatment/services rendered by VA.
6. The name, social security number, universal personal identification number, National Provider Identifier (NPI) and credentials including provider's degree, licensure, certification, registration or occupation of healthcare providers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code (U.S.C.), sections 1710 and 1729.

PURPOSE(S):

The records and information are used for the billing of, and collections from, a third-party payer, including insurance companies, other Federal agencies, or foreign governments, for medical care or services received by a veteran for a nonservice-connected condition or from a first party veteran required to make co-payments. The records and information are also used for the billing of and collections from other Federal agencies for medical care or services received by an eligible beneficiary. The data may be used to identify and/or verify insurance coverage of a veteran or veteran's spouse prior to submitting claims for medical care or services. The data may be used to support appeals for non-reimbursement of claims for medical care or services provided to a veteran. The data may be used to enroll healthcare providers with health plans and VA's healthcare clearinghouse in order to electronically file third-party claims. For the purposes of healthcare billing and payment activities to and from third party payers, VA will disclose information in accordance with the legislatively-mandated transaction standard and code sets promulgated by the United States Department of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act (HIPAA). The records and information may be used for statistical analyses to produce various management, tracking and follow-up reports, to track and trend the reimbursement practices of insurance carriers, and to track billing and collection information.

The data may be used to enroll healthcare providers with health plans and VA's healthcare clearinghouse in order to electronically file third party claims. The data may be used to make application for a NPI, as required HIPAA Administrative Simplification Rule on Standard Unique Health Identifier for Healthcare Providers, 45 CFR Part 162, for all healthcare professionals providing examination or treatment within VA healthcare facilities, including participation in pilot test of NPI enumeration system by the Centers of Medicare and Medicaid Services (CMS). The records and information may be used for statistical analyses to produce various management, tracking and follow-up reports, to track and trend the reimbursement practices of insurance carriers, and to track billing and collection information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164, *i.e.*, individually-identifiable health information, and 38 U.S.C. 7332; *i.e.*, medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority in 38 U.S.C. 7332 and regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

1. On its own initiative, VA may disclose information, except for the names and home address of veterans

and their dependents, to a Federal, state, local, tribal or foreign agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. On its own initiative, VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

2. Disclosure may be made to an agency in the executive, legislative, or judicial branch, or the District of Columbia government in response to its request or at the initiation of VA, in connection with the letting of a contract, other benefits by the requesting agency, or the lawful statutory, administrative, or investigative purpose of the agency to the extent that the information is relevant and necessary to the requesting agency's decision. However, names and addresses of veterans and their dependents will be released only to Federal entities.

3. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

4. Disclosure may be made to National Archives and Records Administration (NARA) in records management inspections conducted under authority of Title 44 U.S.C.

5. Disclosure may be made to the Department of Justice and United States attorneys in defense or prosecution of litigation involving the United States, and to Federal agencies upon their request in connection with review of administrative tort claims filed under the Federal Tort Claims Act, 28 U.S.C. 2672.

6. Any information in this system of records, including personal information obtained from other Federal agencies through computer-matching programs, may be disclosed for the purposes identified below to any third party, except consumer reporting agencies, in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any benefit program administered by VA. Information may be disclosed under this routine use only to the extent that it is reasonably necessary for the following purposes: (a) To assist VA in collection of Title 38 overpayments, overdue indebtedness, and/or costs of services provided individuals not entitled to such services; and (b) to initiate civil or criminal legal actions for collecting amounts owed to the United States and/or for prosecuting individuals who willfully or fraudulently obtain Title 38 benefits without entitlement. This disclosure is consistent with 38 U.S.C. 5701(b)(6).

7. The name and address of a veteran, other information as is reasonably necessary to identify such veteran, including personal information obtained from other Federal agencies through computer matching programs, and any information concerning the veteran's indebtedness to the United States by virtue of the person's participation in a benefits program administered by VA may be disclosed to a consumer reporting agency for purposes of assisting in the collection of such indebtedness, provided that the provisions of 38 U.S.C. 5701(g)(4) have been met.

8. The name of a veteran, or other beneficiary, other information as is reasonably necessary to identify such individual, and any information concerning the individual's indebtedness by virtue of a person's participation in a medical care and treatment program administered by VA, may be disclosed to the Treasury Department, Internal Revenue Service, for the collection of indebtedness arising from such program by the withholding of all or a portion of the person's Federal income tax refund. These records may be disclosed as part of a computer-matching program to accomplish these purposes.

9. Relevant information (excluding medical treatment information related to drug or alcohol abuse, infection with the human immunodeficiency virus or sickle cell anemia) may be disclosed to HHS for the purpose of identifying improper duplicate payments made by Medicare fiscal intermediaries where VA was authorized and was responsible for payment for medical services obtained at non-VA healthcare facilities.

10. The social security number, universal personal identification number, NPI, credentials, and other identifying information of a healthcare provider may be disclosed to a third party where the third party requires the Department provide that information before it will pay for medical care provided by VA.

11. Relevant information may be disclosed to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practical for the purposes of laws administered by VA, in order for the contractor and/or subcontractor to perform the services of the contract or agreement.

12. Relevant information from this system of records may be disclosed to the National Practitioner Data Bank and/or State Licensing Board in the State(s) in which a practitioner is licensed, in which the VA facility is located, and/or in which an act or omission occurred upon which a medical malpractice claim was based when VA reports information concerning: (a) Any payment for the benefit of a physician, dentist, or other licensed healthcare practitioner which was made as the result of a settlement or judgment of a claim of medical malpractice if an appropriate determination is made in accordance with agency policy that payment was related to substandard care, professional incompetence or professional misconduct on the part of the individual; (b) a final decision which relates to possible incompetence or improper professional conduct that adversely affects the clinical privileges of a physician, dentist or other licensed healthcare practitioner for a period longer than 30 days; or, (c) the acceptance of the surrender of clinical privileges, or any restriction of such privileges by a physician, dentist, or other licensed healthcare practitioner either while under investigation by the healthcare entity relating to possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding. These records may also be disclosed as part of a computer-matching program to accomplish these purposes.

13. Relevant information may be disclosed from this system of records to any third party or Federal agency such as the Department of Defense, Office of Personnel Management, HHS and government-wide third-party insurers responsible for payment of the cost of medical care for the identified patients, in order for VA to seek recovery of the medical care costs. These records may also be disclosed as part of a computer-matching program to accomplish these purposes.

14. Relevant information, including the nature and amount of a financial obligation, may be disclosed in order to assist VA in the collection of unpaid financial obligations owed VA, to a debtor's employing agency or commanding officer, so that the debtor-employee may be counseled by his or her Federal employer or commanding officer. This purpose is consistent with 5 U.S.C. 5514, 4 CFR 102.5, and section 206 of Executive Order 11222 of May 8, 1965 (30 FR 6469).

15. Identifying information such as name, address, social security number and other information as is reasonably necessary to identify such individual, may be disclosed to the National Practitioner Data Bank at the time of hiring and/or clinical privileging/re-privileging of healthcare practitioners, and at other times as deemed necessary by VA, in order for VA to obtain information relevant to a Department decision concerning the hiring, privileging/re-privileging, retention or termination of the applicant or employee.

16. Disclosure of individually-identifiable health information including billing information for the payment of care may be made by appropriate VA personnel, to the extent necessary and on a need-to-know basis consistent with good medical-ethical practices, to family members and/or the person(s) with whom the patient has a meaningful relationship.

17. Provider identifying information may be disclosed from this System of Records to CMS to test the enumeration system for the NPI and once the system is operational, to obtain an NPI for any eligible healthcare professional providing examination or treatment with VA healthcare facilities.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Pursuant to 5 U.S.C. 552a(b)(12), VA may disclose records from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper or electronic media.

RETRIEVABILITY:

Records are retrieved by name, social security number or other assigned identifier of the individuals on whom they are maintained, or by specific bill number assigned to the claim of the individuals on whom they are maintained.

SAFEGUARDS:

1. Access to VA working and storage areas is restricted to VA employees on a ''need-to-know'' basis; strict control measures are enforced to ensure that disclosure to these individuals is also based on this same principle. Generally, VA file areas are locked after normal duty hours and the facilities are protected from outside access by the Federal Protective Service or other security personnel.

2. Information in VistA may only be accessed by authorized VA personnel. Access to file information is controlled at two levels. The systems recognize authorized personnel by series of individually unique passwords/codes as a part of each data message, and personnel are limited to only that information in the file, which is needed in the performance of their official duties. Information that is downloaded from VistA and maintained on personal computers is afforded similar storage and access protections as the data that is maintained in the original files. Access to information stored on automated storage media at other VA locations is controlled by individually unique passwords/codes. Access by Office of Inspector General (OIG) staff conducting an audit, investigation, or inspection at the healthcare facility, or an OIG office location remote from the healthcare facility, is controlled in the same manner.

3. Information downloaded from VistA and maintained by the OIG headquarters and Field Offices on automated storage media is secured in storage areas for facilities to which only OIG staff have access. Paper documents are similarly secured. Access to paper documents and information on automated storage media is limited to OIG employees who have a need for the information in the performance of their official duties. Access to information stored on automated storage media is controlled by individually unique passwords/codes.

4. Access to the VA Austin Automation Center (AAC) is generally restricted to AAC employees, custodial personnel, Federal Protective Service and other security personnel. Access to computer rooms is restricted to authorized operational personnel through electronic locking devices. All other persons gaining access to computer rooms are escorted. Information stored in the AAC databases may be accessed.

5. Access to records maintained at the VA Allocation Resource Center (ARC) and the VISN Offices is restricted to VA employees who have a need for the information in the performance of their official duties. Access to information stored in electronic format is controlled by individually unique passwords/codes. Records are maintained in manned rooms during working hours. The facilities are protected from outside access during non-working hours by the Federal Protective Service or other security personnel.

RETENTION AND DISPOSAL:

Paper records and information stored on electronic storage media are maintained and disposed of in accordance with records disposition authority approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

The official responsible for policies and procedures is the Chief Business Officer, Chief Business Office (16), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. The local officials responsible for maintaining the system are the Director of the facility where the individual is or was associated.

NOTIFICATION PROCEDURE:

An individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the last VA healthcare facility where care was rendered. Addresses of VA healthcare facilities may be found in VA Appendix 1 of the biennial publication of VA Privacy Act Issuances. All inquiries must reasonably identify the place and approximate date that medical care was provided. Inquiries should include the patient's full name, social security number, insurance company information, policyholder and policy identification number as well as a return address.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records in this system may write, call or visit the VA facility location where they were treated.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

The patient, family members or guardian, and friends, employers or other third parties when otherwise unobtainable from the patient or family; health insurance carriers; private medical facilities and healthcare professionals; state and local agencies; other Federal agencies; VA regional offices; Veterans Benefits Administration automated record systems, including Veterans and Beneficiaries Identification and Records Location Subsystem-VA (38VA23) and the Compensation, Pension, Education and Rehabilitation Records-VA (58VA21/22); and various automated systems providing clinical and

managerial support at VA healthcare facilities to include Health Care Provider Credentialing and Privileging Records-VA (77VA10Q) and Veterans Health Information Systems and Technology Architecture (VistA) (79VA19).

[FR Doc. 05–18728 Filed 9–19–05; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 70, No. 181

Tuesday, September 2005

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[OAR–2003–0200; FRL–7966–2]

RIN 2060–AM98

Revisions to the California State Implementation Plan and Revision to the Definition of Volatile Organic Compounds (VOC)—Removal of VOC Exemptions for California's Aerosol Coating Products Reactivity-based Regulation

Correction

In rule document 05–18016 beginning on page 53930 in the issue of Tuesday, September 13, 2005, make the following correction:

On page 53931, in the first column, in footnote 1, in the first line, ''*http:www.arb.ca.gov/colsprod/reg/apt.pdf*' should read ''*http://www.arb.ca.gov/consprod/regs/apt.pdf*'.

[FR Doc. C5–18016 Filed 9–19–05; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
September 20, 2005

Part II

Department of the Treasury

31 CFR Part 103

Finding That Banco Delta Asia SARL Is a Financial Institution of Primary Money Laundering Concern; Notice

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations—Imposition of Special Measure Against Banco Delta Asia SARL; Proposed Rule

DEPARTMENT OF THE TREASURY

Finding That Banco Delta Asia SARL Is a Financial Institution of Primary Money Laundering Concern

AGENCY: The Financial Crimes Enforcement Network, Treasury.

ACTION: Notice of finding.

SUMMARY: Pursuant to the authority contained in 31 U.S.C. 5318A, the Secretary of the Treasury, through his delegate, the Director of the Financial Crimes Enforcement Network, finds that reasonable grounds exist for concluding that Banco Delta Asia SARL (Banco Delta Asia) is a financial institution of primary money laundering concern.

DATES: The finding made in this notice is effective as of September 20, 2005.

FOR FUTHER INFORMATION CONTACT: Regulatory Policy and Programs Division, the Financial Crimes Enforcement Network, (800) 949–2732.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the USA PATRIOT Act), Public Law 107–56. Title III of the USA PATRIOT Act amends the anti-money laundering provisions of the Bank Secrecy Act (BSA), codified at 12 U.S.C. 1829b, 12 U.S.C 1951–1959, and 31 U.S.C. 5311–5314, 5316–5332, to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism. Regulations implementing the BSA appear at 31 CFR part 103.

Section 311 of the USA PATRIOT Act (''section 311'') added section 5318A to the BSA, granting the Secretary of the Treasury (the ''Secretary'') the authority, upon finding that reasonable grounds exist for concluding that a foreign jurisdiction, institution, class of transactions, or type of account is of ''primary money laundering concern,'' to require domestic financial institutions and financial agencies to take certain ''special measures'' against the primary money laundering concern. Section 311 identifies factors for the Secretary to consider and Federal agencies to consult before the Secretary may conclude that a jurisdiction, institution, class of transaction, or type of account is of primary money laundering concern. The statute also provides similar procedures, *i.e.*, factors and consultation requirements, for selecting the specific special measures to be imposed against the primary money laundering concern. For purposes of the finding contained in this notice, the Secretary has delegated his authority under section 311 to the Director of the Financial Crimes Enforcement Network.[1]

Taken as a whole, section 311 provides the Secretary with a range of options that can be adapted to target specific money laundering and terrorist financing concerns most effectively. These options give the Secretary the authority to bring additional pressure on those jurisdictions and institutions that pose money laundering threats. Through the imposition of various special measures, the Secretary can gain more information about the jurisdictions, institutions, transactions, or accounts of concern; can more effectively monitor the respective jurisdictions, institutions, transactions, or accounts; or can protect U.S. financial institutions from involvement with jurisdictions, institutions, transactions, or accounts that pose a money laundering concern.

Before making a finding that reasonable grounds exist for concluding that a foreign financial institution is of primary money laundering concern, the Secretary is required to consult with the both the Secretary of State and the Attorney General. The Secretary is also required by section 311 to consider ''such information as the Secretary determines to be relevant, including the following potentially relevant factors'':

- The extent to which such financial institution is used to facilitate or promote money laundering in or through the jurisdiction;
- The extent to which such financial institution is used for legitimate business purposes in the jurisdiction; and
- The extent to which the finding that the institution is of primary money laundering concern is sufficient to ensure, with respect to transactions involving the institution operating in the jurisdiction, that the purposes of the BSA continue to be fulfilled, and to guard against international money laundering and other financial crimes.

If the Secretary determines that reasonable grounds exist for concluding that a foreign financial institution is of primary money laundering concern, the Secretary must determine the appropriate special measure(s) to address the specific money laundering risks. Section 311 provides a range of special measures that can be imposed individually, jointly, in any combination, and in any sequence.[2] The Secretary's imposition of special measures requires additional consultations to be made and factors to be considered. The statute requires the Secretary to consult with appropriate federal agencies and other interested parties[3] and to consider the following specific factors:

- Whether similar action has been or is being taken by other nations or multilateral groups;
- Whether the imposition of any particular special measures would create a significant competitive disadvantage, including any undue cost or burden associated with compliance, for financial institutions organized or licensed in the United States;
- The extent to which the action or the timing of the action would have a significant adverse systemic impact on the international payment, clearance, and settlement system, or on legitimate business activities involving the particular institution; and
- The effect of the action on the United States national security and foreign policy.[4]

B. Banco Delta Asia

Banco Delta Asia, located and licensed in the Macau Special Administrative Region, China, is the commercial banking arm of its parent company, Delta Asia Group (Holdings)

[1] Therefore, references to the authority and findings of the Secretary in this document apply equally to the Director of the Financial Crimes Enforcement Network.

[2] Available special measures include requiring: (1) Recordkeeping and reporting of certain financial transactions; (2) collection of information relating to beneficial ownership; (3) collection of information relating to certain payable-through accounts; (4) collection of information relating to certain correspondent accounts; and (5) prohibition or conditions on the opening or maintaining of correspondent or payable-through accounts. 31 U.S.C. 5318A(b)(1)–(5). For a complete discussion of the range of possible countermeasures, *see* 68 FR 18917 (April 17, 2003) (proposing special measures against Nauru).

[3] Section 5318A(a)(4)(A) requires the Secretary to consult with the Chairman of the Board of Governors of the Federal Reserve System, any other appropriate Federal banking agency, the Secretary of State, the Securities and Exchange Commission (SEC), the Commodity Futures Trading Commission (CFTC), the National Credit Union Administration (NCUA), and, in the sole discretion of the Secretary, ''such other agencies and interested parties as the Secretary may find to be appropriate.'' The consultation process must also include the Attorney General, if the Secretary is considering prohibiting or imposing conditions on domestic financial institutions opening or maintaining correspondent account relationships with the designated entity.

[4] Classified information used in support of a section 311 finding and measure(s) may be submitted by Treasury to a reviewing court *ex parte* and *in camera*. *See* section 376 of the Intelligence Authorization Act for fiscal year 2004, Pub. L. 108–177 (amending 31 U.S.C. 5318A by adding new paragraph (f)).

Ltd. (Delta Asia Group).[5] In addition to commercial banking, Delta Asia Group engages in investment banking and insurance activities. Banco Delta Asia was originally established in 1935 as Banco Hang Sang,[6] and its name changed to Banco Delta Asia in December 1993. With approximately 340 employees and a total equity of approximately $35 million at the close of 2003, Banco Delta Asia is the fourth smallest commercial bank in Macau. Banco Delta Asia operates eight branches in Macau (including a branch at a casino) and is served by a representative office in Japan. In addition, Banco Delta Asia maintains correspondent accounts in Europe, Asia, Australia, Canada, and the United States, and has two wholly owned subsidiaries: Delta Asia Credit Ltd., and Delta Asia Insurance Limited.[7]

C. Macau

Money laundering has been identified as a significant problem in the Macau Special Administrative Region, China.[8] According to the International Narcotics Strategy Control Report (INSCR) published in March 2005 by the U.S. Department of State, Macau's lack of adequate controls and regulatory oversight of the banking and gaming industries (many of which are associated with organized criminal activity) has led to an environment that can be exploited by money launderers. Moreover, the March 2005 INCSR designates Macau as a ''jurisdiction of primary concern.'' [9] The International Monetary Fund (IMF) conducted a study in 2002 concluding that, despite its anti-money laundering legal framework, Macau was ''materially non-compliant'' in terms of monitoring and reporting of suspicious financial transactions.[10] Of special concern is Macau's lack of cross-border currency reporting requirements. In 2003, Macau prepared money laundering legislation that sought to incorporate the Financial Action Task Force's revised Forty Recommendations on Money Laundering, and to establish a Financial Intelligence Unit. Such legislation has not been adopted and the Financial Intelligence Unit has not been established. As noted in a 2004 IMF study, significant vulnerabilities remain in Macau, although it has made progress in its anti-money laundering regime in the past several years, including the establishment of a Fraud Investigation Section to examine suspicious transactions reports filed by financial institutions.

Government agencies and front companies of the Democratic People's Republic of Korea (DPRK or North Korea) that are engaged in illicit activities use Macau as a base of operations for money laundering and other illegal activities. For example, banks in Macau have allowed these organizations to launder counterfeit currency and the proceeds from government-sponsored illegal drug transactions.

D. North Korea

The involvement of North Korean government agencies and front companies in a wide variety of illegal activities, including drug trafficking and counterfeiting of goods and currency, has been widely reported.[11] Earnings from criminal activity, by their clandestine nature, are difficult to quantify, but studies estimate that proceeds from these activities amount to roughly $500 million annually.[12]

Customs and police officials of many countries have regularly apprehended North Korean diplomats or quasi-official representatives of state trading companies trying to smuggle narcotics. For example, in December 2004, Turkish officials arrested two North Korean diplomats in Turkey in possession of illegal drugs valued at $7 million. Earlier that year, Egyptian authorities expelled two other North Korean diplomats who attempted to deliver a shipment of controlled substances valued at $150,000 in Egypt.[13] In fact, since 1990, North Korea has been positively linked to nearly 50 drug seizures in 20 different countries, a significant number of which involved the arrest or detention of North Korean diplomats or officials.[14] Proceeds from narcotics trafficking may amount to between $100 million and $200 million annually.[15]

During the past three decades, there also have been many incidents and arrests involving North Korean officials for distributing supernotes. Since first detected, the United States has taken possession of more than $45 million of these highly deceptive counterfeit notes.

Substantial evidence exists that North Korean governmental entities and officials launder the proceeds of narcotics trafficking, counterfeit activities, and other illegal activities through a network of front companies that use financial institutions in Macau for their operations.

II. Analysis of Factors

Based upon a review and analysis of relevant information, consultations with relevant Federal agencies and departments, and after consideration of the factors enumerated in section 311, the Secretary has determined that reasonable grounds exist for concluding that Banco Delta Asia is a financial institution of primary money laundering concern. A discussion of the section 311 factors relevant to this finding follows:

1. The Extent to Which Banco Delta Asia Has Been Used To Facilitate or Promote Money Laundering in or Through the Jurisdiction

The Secretary has determined, based upon a variety of sources, that Banco Delta Asia is used to facilitate or promote money laundering and other financial crimes. Banco Delta Asia has provided financial services for over 20 years to multiple North Korean government agencies and front companies that are engaged in illicit activities, and continues to develop these relationships. In fact, such account holders comprise a significant amount of Banco Delta Asia's business. Banco Delta Asia has tailored its services to the DPRK's demands. For example, sources show that the DPRK pays a fee to Banco Delta Asia for financial access to the banking system with little oversight or control. The bank also handles the bulk of the DPRK's precious metal sales, and helps North Korean agents conduct surreptitious, multi-million dollar cash deposits and

[5] The Bankers Almanac (2004). This finding of primary money laundering concern shall apply exclusively to Banco Delta Asia and its branches, offices, and subsidiaries, and not to Delta Asia Group (Holdings) Ltd., or any of its other subsidiaries.

[6] Banco Delta Asia's historical name, Banco Hang Sang, is not to be confused with Hang Seng Bank, a Hong Kong bank, nor the Hang Seng Index, an index of certain shares traded on the Hong Kong Stock Exchange.

[7] The Banker's Almanac (2004).

[8] References in this rule to the money laundering risks in Macau are limited to that jurisdiction, and not applicable to the entire jurisdiction of China.

[9] ''Jurisdictions of primary concern'' are jurisdictions that are identified as ''major money laundering countries,'' that is, countries ''whose financial institutions engage in currency transactions involving significant amounts of proceeds from international narcotics-trafficking.'' See, *http://www.state.gov/g/inl/rls/nrcrpt/2005/vol2/html/42388.htm.*

[10] *See* International Monetary Fund, Monetary and Exchange Affairs Department, *Macau SAR 2002 http://www.amcm.gov.mo/Press_Release/IMF/IMF_Macao_Review.pdf.*

[11] Emergency Response and Research Institute: ''North Korea Government Deeply Involved With Organized Crime?'' June 30, 1998; BBC News: ''What is a Superdollar?'', June 20, 2004; Washington Post: ''North Korea's Conduit for Crime'', April 25, 1999; Pacific Forum CSIS: ''End North Korea's Drug Trade'', June 16, 2003.

[12] Congressional Research Service Report for Congress: ''Drug Trafficking and North Korea: Issues for U.S. Policy'', Updated March 4, 2005.

[13] *See* INCSR 2005 [pg. 335].

[14] Congressional Research Service Report for Congress: ''Drug Trafficking and North Korea: Issues for U.S. Policy,'' Updated March 4, 2005.

[15] Id.

withdrawals. Banco Delta Asia's questionable relationship with the DPRK is further demonstrated by its maintenance of an uninterrupted banking relationship with one North Korean front company despite the fact that the head of the company was charged with attempting to deposit large sums of counterfeit currency into Banco Delta Asia and was expelled from Macau. Although this same person later returned to his previous leadership position at the front company, services provided by Banco Delta Asia were not discontinued.

Banco Delta Asia's special relationship with the DPRK has specifically facilitated the criminal activities of North Korean government agencies and front companies. For example, sources show that senior officials in Banco Delta Asia are working with DPRK officials to accept large deposits of cash, including counterfeit U.S. currency, and agreeing to place that currency into circulation. Additionally, it has been widely reported that one well-known North Korean front company that has been a client of Banco Delta Asia for over a decade has conducted numerous illegal activities, including distributing counterfeit currency and smuggling counterfeit tobacco products. In addition, the front company has also long been suspected of being involved in international drug trafficking.

Moreover, Banco Delta Asia facilitated several multi-million dollar wire transfers connected with alleged criminal activity on behalf of another North Korean front company.

In addition to facilitating illicit activities of the DPRK, investigations have revealed that Banco Delta Asia serviced a multi-million dollar account on behalf of a known international drug trafficker.

2. The Extent to Which Banco Delta Asia Is Used for Legitimate Business Purposes in the Jurisdiction

It is difficult to determine the extent to which Banco Delta Asia is used for legitimate purposes. Most banking transactions within Macau are conducted by the jurisdiction's largest banks, while Banco Delta Asia ranks as one of the smallest in Macau. Although Banco Delta Asia likely engages in some legitimate activity, the Secretary believes that any legitimate use of Banco Delta Asia is significantly outweighed by its use to promote or facilitate money laundering and other financial crimes.

3. The Extent to Which Such Action Is Sufficient To Ensure, With Respect to Transactions Involving Banco Delta Asia, That the Purposes of the BSA Continue To Be Fulfilled, and To Guard Against International Money Laundering and Other Financial Crimes

As detailed above, the Secretary has reasonable grounds to conclude that Banco Delta Asia is being used to promote or facilitate international money laundering, and is therefore an institution of primary money laundering concern. Currently, there are no protective measures that specifically target Banco Delta Asia. Thus, finding Banco Delta Asia to be a financial institution of primary money laundering concern, which would allow consideration by the Secretary of special measures to be imposed on the institution under section 311, is a necessary first step to prevent Banco Delta Asia from facilitating money laundering or other financial crime through the U.S. financial system. The finding of primary money laundering concern will bring criminal conduct occurring at or through Banco Delta Asia to the attention of the international financial community and, it is hoped, further limit the bank's ability to be used for money laundering or for other criminal purposes.

III. Finding

Based on the foregoing factors, the Secretary, acting through the Director of the Financial Crimes Enforcement Network, hereby finds that Banco Delta Asia is a financial institution of primary money laundering concern.

Dated: September 12, 2005.

William F. Baity,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 05–18660 Filed 9–19–05; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–A83

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations—Imposition of Special Measure Against Banco Delta Asia SARL

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: In a notice of finding published elsewhere in this issue of the **Federal Register,** the Secretary of the Treasury, through his delegate, the Director of the Financial Crimes Enforcement Network, found that reasonable grounds exist for concluding that Banco Delta Asia SARL (Banco Delta Asia) is a jurisdiction of primary money laundering concern pursuant to 31 U.S.C. 5318A. The Financial Crimes Enforcement Network is issuing this notice of proposed rulemaking to impose a special measure against Banco Delta Asia.

DATES: Written comments on the notice of proposed rulemaking must be submitted on or before October 20, 2005.

ADDRESSES: You may submit comments, identified by RIN 1506–A83 by any of the following methods:

- Federal e-rulemaking portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *regcomments@fincen.gov.* Include RIN 1506–A83 in the subject line of the message.
- Mail: The Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Include RIN 1506–A83 in the body of the text.

Instructions. It is preferable for comments to be submitted by electronic mail because paper mail in the Washington, DC area may be delayed. Please submit comments by one method only. All submissions received must include the agency name and the Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fincen.gov,* including any personal information provided. Comments may be inspected at the Financial Crimes Enforcement Network between 10 a.m. and 4 p.m., in the Financial Crimes Enforcement Network reading room in Washington, DC. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 354–6400 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Regulatory Policy and Programs Division, the Financial Crimes Enforcement Network, (800) 949–2732.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Provisions

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the USA PATRIOT Act), Public Law 107–56. Title III of the USA PATRIOT Act amends the anti-money laundering provisions of the Bank Secrecy Act (BSA), codified at 12 U.S.C. 1829b, 12 U.S.C 1951–1959, and 31 U.S.C. 5311–5314, 5316–5332, to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism. Regulations implementing the BSA appear at 31 CFR part 103. The authority of the Secretary of the Treasury (''the Secretary'') to administer the BSA and its implementing regulations has been delegated to the Director of the Financial Crimes Enforcement Network.[1]

Section 311 of the USA PATRIOT Act (''section 311'') added section 5318A to the BSA, granting the Secretary the authority, upon finding that reasonable grounds exist for concluding that a foreign jurisdiction, institution, class of transaction, or type of account is of ''primary money laundering concern,'' to require domestic financial institutions and financial agencies to take certain ''special measures'' against the primary money laundering concern. Section 311 identifies factors for the Secretary to consider and Federal agencies to consult before the Secretary may conclude that a jurisdiction, institution, class of transaction, or type of account is of primary money laundering concern. The statute also provides similar procedures, i.e., factors and consultation requirements, for selecting the specific special measures to be imposed against the primary money laundering concern.

Taken as a whole, section 311 provides the Secretary with a range of options that can be adapted to target specific money laundering and terrorist financing concerns most effectively. These options give the Secretary the authority to bring additional pressure on those jurisdictions and institutions that pose money laundering threats. Through the imposition of various special measures, the Secretary can gain more information about the jurisdictions, institutions, transactions, or accounts of concern; can more effectively monitor the respective jurisdictions, institutions, transactions, or accounts; or can protect U.S. financial institutions from involvement with jurisdictions, institutions, transactions, or accounts that pose a money laundering concern.

Before making a finding that reasonable grounds exist for concluding that a foreign financial institution is of primary money laundering concern, the Secretary is required to consult with the both the Secretary of State and the Attorney General. The Secretary is also required by section 311 to consider ''such information as the Secretary determines to be relevant, including the following potentially relevant factors:

- The extent to which such financial institution is used to facilitate or promote money laundering in or through the jurisdiction;
- The extent to which such financial institution is used for legitimate business purposes in the jurisdiction; and
- The extent to which the finding that the institution is of primary money laundering concern is sufficient to ensure, with respect to transactions involving the institution operating in the jurisdiction, that the purposes of the BSA continue to be fulfilled, and to guard against international money laundering and other financial crimes.

If the Secretary determines that a foreign financial institution is of primary money laundering concern, the Secretary must determine the appropriate special measure(s) to address the specific money laundering risks. Section 311 provides a range of special measures that can be imposed individually, jointly, in any combination, and in any sequence.[2] The Secretary's imposition of special measures requires additional consultations to be made and factors to be considered. The statute requires the Secretary to consult with appropriate federal agencies and other interested

[1] Therefore, references to the authority of the Secretary of the Treasury under section 311 of the USA PATRIOT Act apply equally to the Director of the Financial Crimes Enforcement Network.

[2] Available special measures include requiring: (1) Recordkeeping and reporting of certain financial transactions; (2) collection of information relating to beneficial ownership; (3) collection of information relating to certain payable-through accounts; (4) collection of information relating to certain correspondent accounts; and (5) prohibition or conditions on the opening or maintaining of correspondent or payable-through accounts. 31 U.S.C. 5318A(b)(1)–(5). For a complete discussion of the range of possible countermeasures, *see* 68 FR 18917 (April 17, 2003) (proposing special measures against Nauru).

parties [3] and to consider the following specific factors:

- Whether similar action has been or is being taken by other nations or multilateral groups;
- Whether the imposition of any particular special measures would create a significant competitive disadvantage, including any undue cost or burden associated with compliance, for financial institutions organized or licensed in the United States;
- The extent to which the action or the timing of the action would have a significant adverse systemic impact on the international payment, clearance, and settlement system, or on legitimate business activities involving the particular institution; and
- The effect of the action on the United States national security and foreign policy.[4]

B. Banco Delta Asia

In this rulemaking, the Financial Crimes Enforcement Network proposes to impose the fifth special measure (31 U.S.C. 5318A(b)(5)) against Banco Delta Asia. The fifth special measure prohibits or conditions the opening or maintaining of correspondent or payable-through accounts for the designated institution by U.S. financial institutions. This special measure may be imposed only through the issuance of a regulation.

Banco Delta Asia, located and licensed in the Macau Special Administrative Region, China, is the commercial banking arm of its parent company, Delta Asia Group (Holdings) Ltd. (Delta Asia Group).[5] In addition to commercial banking, Delta Asia Group engages in investment banking and insurance activities. Banco Delta Asia was originally established in 1935 as Banco Hang Sang,[6] and its name changed to Banco Delta Asia in December 1993. With approximately 340 employees and a total equity of approximately $35 million at the close of 2003, Banco Delta Asia is the fourth smallest commercial bank in Macau. Banco Delta Asia operates eight branches in Macau (including a branch at a casino) and is served by a representative office in Japan. In addition, Banco Delta Asia maintains correspondent accounts in Europe, Asia, Australia, Canada, and the United States, and has two wholly owned subsidiaries: Delta Asia Credit Ltd., and Delta Asia Insurance Limited.[7]

II. Imposition of Special Measure Against Banco Delta Asia as a Financial Institution of Primary Money Laundering Concern

As a result of the finding on September 20, 2005 by the Secretary, through his delegate, the Director of the Financial Crimes Enforcement Network, that reasonable grounds exist for concluding that Banco Delta Asia is a financial institution of primary money laundering concern (see the notice of this finding published elsewhere today in the **Federal Register**), and based upon the additional consultations and the consideration of all relevant factors discussed in the finding and in this notice of proposed rulemaking, the Secretary, through the Financial Crimes Enforcement Network, has determined that reasonable grounds exist for the imposition of the special measure authorized by section 5318A(b)(5).[8] That special measure authorizes the prohibition against the opening or maintaining of correspondent accounts [9] by any domestic financial institution or agency for or on behalf of a targeted financial institution. A discussion of the section 311 factors relevant to imposing this particular special measure follows.

1. Whether Similar Actions Have Been or Will Be Taken by Other Nations or Multilateral Groups Against Banco Delta Asia

Other countries or multilateral groups have not yet taken action similar to the one proposed in this rulemaking that would prohibit domestic financial institutions and agencies from opening or maintaining a correspondent account for or on behalf of Banco Delta Asia, and to require those domestic financial institutions and agencies to screen their correspondents for nested correspondent accounts held by Banco Delta Asia. The Financial Crimes Enforcement Network encourages other countries to take similar action based on the findings contained in this rulemaking.

2. Whether the Imposition of the Fifth Special Measure Would Create a Significant Competitive Disadvantage, Including Any Undue Cost or Burden Associated With Compliance, for Financial Institutions Organized or Licensed in the United States

The fifth special measure sought to be imposed by this rulemaking would prohibit covered financial institutions from opening and maintaining correspondent accounts for, or on behalf of, Banco Delta Asia. As a corollary to this measure, covered financial institutions also would be required to take reasonable steps to apply special due diligence, as set forth below, to all of their correspondent accounts to help ensure that no such account is being used indirectly to provide services to Banco Delta Asia. The Financial Crimes Enforcement Network does not expect the burden associated with these requirements to be significant, given its understanding that few U.S. financial institutions currently maintain a correspondent account for Banco Delta Asia. There is a minimal burden involved in transmitting a one-time notice to all correspondent account holders concerning the prohibition on indirectly providing services to Banco Delta Asia. In addition, U.S. financial institutions generally apply some degree of due diligence in screening their transactions and accounts, often through the use of commercially available software such as that used for compliance with the economic sanctions programs administered by the Office of Foreign Assets Control (OFAC) of the Department of the Treasury. As explained in more detail in the section-by-section analysis below, financial institutions should, if necessary, be able to easily adapt their current screening procedures to comply with this special

[3] Section 5318A(a)(4)(A) requires the Secretary to consult with the Chairman of the Board of Governors of the Federal Reserve System, any other appropriate Federal banking agency, the Secretary of State, the Securities and Exchange Commission (SEC), the Commodity Futures Trading Commission (CFTC), the National Credit Union Administration (NCUA), and, in the sole discretion of the Secretary, ''such other agencies and interested parties as the Secretary may find to be appropriate.'' The consultation process must also include the Attorney General, if the Secretary is considering prohibiting or imposing conditions on domestic financial institutions opening or maintaining correspondent account relationships with the designated entity.

[4] Classified information used in support of a section 311 finding and measure(s) may be submitted by Treasury to a reviewing court *ex parte* and *in camera. See* section 376 of the Intelligence Authorization Act for fiscal year 2004, Pub. L. 108–177 (amending 31 U.S.C. 5318A by adding new paragraph (f)).

[5] The Bankers Almanac (2004). For purposes of this rulemaking, The Financial Crimes Enforcement Network's designation of primary money laundering concern and imposition of special measures shall apply exclusively to Banco Delta Asia and its branches, offices, and subsidiaries, and not to Delta Asia Group (Holdings) Ltd., or any of its other subsidiaries.

[6] Banco Delta Asia's historical name, Banco Hang Sang, is not to be confused with Hang Seng Bank, a Hong Kong bank, nor the Hang Seng Index, an index of certain shares traded on the Hong Kong Stock Exchange.

[7] The Banker's Almanac (2004).

[8] In connection with this action, the Financial Crimes Enforcement Network consulted with staff of the Federal functional regulators, the Department of Justice, and the Department of State.

[9] For purposes of the proposed rule, a correspondent account is defined as an account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

measure. Thus, the special due diligence that would be required by this rulemaking is not expected to impose a significant additional burden upon U.S. financial institutions.

3. The Extent to Which the Proposed Action or Timing of the Action Will Have a Significant Adverse Systemic Impact on the International Payment, Clearance, and Settlement System, or on Legitimate Business Activities of Banco Delta Asia

This proposed rulemaking targets Banco Delta Asia specifically; it does not target a class of financial transactions (such as wire transfers) or a particular jurisdiction. Banco Delta Asia is not a major participant in the international payment system and is not relied upon by the international banking community for clearance or settlement services. Thus, the imposition of the fifth special measure against Banco Delta Asia will not have a significant adverse systemic impact on the international payment, clearance, and settlement system. In light of the reasons for imposing this special measure, the Financial Crimes Enforcement Network does not believe that it will impose an undue burden on legitimate business activities, and notes that the presence of approximately ten larger banks in Macau will alleviate the burden on legitimate business activities within that jurisdiction.

4. The Effect of the Proposed Action on United States National Security and Foreign Policy

The exclusion from the U.S. financial system of banks that serve as conduits for significant money laundering activity and other financial crimes enhances national security, making it more difficult for terrorists and money launderers to access the substantial resources of the U.S. financial system. To the extent that this prevents North Korean front companies engaged in illicit activities from accessing the U.S. financial system, the proposed action supports and upholds U.S. national security and foreign policy goals. More generally, the imposition of the fifth special measure would complement the U.S. Government's worldwide efforts to expose and disrupt international money laundering.

Therefore, pursuant to the finding of the Secretary of the Treasury that Banco Delta Asia is an institution of primary money laundering concern, and after conducting the required consultations and weighing the relevant factors, the Financial Crimes Enforcement Network has determined that reasonable grounds exist for imposing the special measure authorized by 31 U.S.C. 5318A(b)(5) against Banco Delta Asia.

III. Section-by-Section Analysis

The proposed rule would prohibit covered financial institutions from establishing, maintaining, or managing in the United States any correspondent account for, or on behalf of, Banco Delta Asia. As a corollary to this prohibition, covered financial institutions would be required to apply special due diligence to their correspondent accounts to guard against their indirect use by Banco Delta Asia. At a minimum, that special due diligence must include two elements. First, a covered financial institution must notify its correspondent account holders that they may not provide Banco Delta Asia with access to the correspondent account maintained at the covered financial institution. Second, a covered financial institution must take reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia, to the extent that such indirect use can be determined from transactional records maintained by the covered financial institution in the normal course of business. A covered financial institution should take a risk-based approach when deciding what, if any, additional due diligence measures it should adopt to guard against the indirect use of its correspondent accounts by Banco Delta Asia, based on risk factors such as the type of services it offers and geographic locations of its correspondents.

A. Section 103.193(a)—Definitions

1. Banco Delta Asia

Section 103.193(a)(1) of the proposed rule defines Banco Delta Asia to include all branches, offices, and subsidiaries of Banco Delta Asia operating in Macau or in any jurisdiction. These branches, offices, and subsidiaries include, but are not necessarily limited to, the Amaral, Antonio, Barca, Campo, Ioa Hon, Lisboa, Outubro, and Tap Sac branches in Macau, the Airport Service Centre, Financial Services Centre, Macao Administrative Centre, The Bank Centre, Delta Asia Credit Ltd., Delta Asia Insurance Limited, and the Tokyo Representative Office. The Financial Crimes Enforcement Network will provide updated information, as it is available; however, covered financial institutions should take commercially reasonable measures to determine whether a customer is a branch, office, or subsidiary of Banco Delta Asia.

2. Correspondent Account

Section 103.193(a)(2) defines the term ''correspondent account'' by reference to the definition contained in 31 CFR 103.175(d)(1)(ii). Section 103.175(d)(1)(ii) defines a correspondent account to mean an account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

In the case of a U.S. depository institution, this broad definition would include most types of banking relationships between a U.S. depository institution and a foreign bank, including payable-through accounts.

In the case of securities broker-dealers, futures commission merchants, introducing brokers, and investment companies that are open-end companies (mutual funds), a correspondent account would include any account that permits the foreign bank to engage in (1) trading in securities, commodity futures, or options, (2) funds transfers, or (3) other types of financial transactions.

For purposes of the proposed rule, the Financial Crimes Enforcement Network is using the same definition of correspondent account as that established in the final rule implementing sections 313 and 319(b) of the USA PATRIOT Act [10] except that the term is being expanded to cover such accounts maintained by futures commission merchants, introducing brokers, and mutual funds.

3. Covered Financial Institution

Section 103.193(a)(3) of the proposed rule defines ''covered financial institution'' to mean all of the following: Any insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)); a commercial bank or trust company; a private banker; an agency or branch of a foreign bank in the United States; a credit union; a thrift institution; a corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*); a broker or dealer registered, or required to register, with the SEC under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*); a futures commission merchant or an introducing broker registered, or required to register, with the CFTC under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*); and an investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3)) that is an open-end company (as defined in section 5 of the Investment Company Act of 1940 (15 U.S.C. 80a–5)) that is registered, or required to register, with the SEC under Section 8 of the

[10] *See* 67 FR 60562 (September 26, 2002) codified at 31 CFR 103.175 (d)(1).

Investment Company Act of 1940 (15 U.S.C. 80a–8).

B. Section 103.193(b) Requirements for Covered Financial Institutions

For purposes of complying with the proposed rule s prohibition on the opening or maintaining of correspondent accounts for, or on behalf of, Banco Delta Asia, the Financial Crimes Enforcement Network expects that a covered financial institution will take such steps that a reasonable and prudent financial institution would take to protect itself from loan fraud or other fraud or loss based on misidentification of a person's status.

1. Prohibition on Direct Use of Correspondent Accounts

Section 103.193(b)(1) of the proposed rule prohibits all covered financial institutions from establishing, maintaining, administering, or managing a correspondent or payable-through account in the United States for, or on behalf of, Banco Delta Asia. The prohibition would require all covered financial institutions to review their account records to ensure that they maintain no accounts directly for, or on behalf of, Banco Delta Asia.

2. Special Due Diligence of Correspondent Accounts To Prohibit Indirect Use

As a corollary to the prohibition on maintaining correspondent accounts directly for Banco Delta Asia, section 103.193(b)(2) requires a covered financial institution to apply special due diligence to its correspondent accounts [11] that is reasonably designed to guard against their indirect use by Banco Delta Asia. At a minimum, that special due diligence must include notifying correspondent account holders that they may not provide Banco Delta Asia with access to the correspondent account maintained at the covered financial institution. For example, a covered financial institution may satisfy this requirement by transmitting the following notice to all of its correspondent account holders:

Notice: Pursuant to U.S regulations issued under section 311 of the USA PATRIOT Act, 31 CFR 103.193, we are prohibited from establishing, maintaining, administering or managing a correspondent account for, or on behalf of, Banco Delta Asia or any of its subsidiaries (including, but not limited to, Delta Asia Credit Ltd., and Delta Asia Insurance Limited). The regulations also require us to notify you that you may not provide Banco Delta Asia or any of its subsidiaries with access to the correspondent account you hold at our financial institution. If we become aware that Banco Delta Asia or any of its subsidiaries is indirectly using the correspondent account you hold at our financial institution, we will be required to take appropriate steps to prevent such access, including terminating your account.

The purpose of the notice requirement is to help ensure cooperation from correspondent account holders in denying Banco Delta Asia access to the U.S. financial system, as well as to increase awareness within the international financial community of the risks and deficiencies of Banco Delta Asia. However, the Financial Crimes Enforcement Network does not require or expect a covered financial institution to obtain a certification from its correspondent account holders that indirect access will not be provided in order to comply with this notice requirement. Instead, methods of compliance with the notice requirement could include, for example, transmitting a one-time notice by mail, fax, or e-mail to a covered financial institution's correspondent account customers, informing them that they may not provide Banco Delta Asia with access to the covered financial institution's correspondent account, or including such information in the next regularly occurring transmittal from the covered financial institution to its correspondent account holders. The Financial Crimes Enforcement Network specifically solicits comments on the appropriate form and scope of the notice that would be required under the rule.

A covered financial institution also would be required under this rulemaking to take reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia, to the extent that such indirect use can be determined from transactional records maintained by the covered financial institution in the normal course of business. For example, a covered financial institution would be expected to apply an appropriate screening mechanism to be able to identify a funds transfer order that on its face listed Banco Delta Asia as the originator's or beneficiary's financial institution, or otherwise referenced Banco Delta Asia in a manner detectable under the financial institution's normal screening processes. An appropriate screening mechanism could be the mechanism used by a covered financial institution to comply with various legal requirements, such as the commercially available software programs used to comply with the economic sanctions programs administered by OFAC. The Financial Crimes Enforcement Network specifically solicits comments on the requirement under the proposed rule that covered financial institutions take reasonable steps to screen its correspondent accounts in order to identify any indirect use of such accounts by Banco Delta Asia.

Notifying its correspondent accounts holders and taking reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia in the manner discussed above are the minimum due diligence requirements under the proposed rule. Beyond these minimum steps, a covered financial institution should adopt a risk-based approach for determining what, if any, additional due diligence measures it should implement to guard against the indirect use of its correspondent accounts by Banco Delta Asia, based on risk factors such as the type of services it offers and the geographic locations of its correspondent account holders.

A covered financial institution that obtains knowledge that a correspondent account is being used by a foreign bank to provide indirect access to Banco Delta Asia must take all appropriate steps to prevent such indirect access, including, where necessary, terminating the correspondent account. A covered financial institution may afford the foreign bank a reasonable opportunity to take corrective action prior to terminating the correspondent account. Should the foreign bank refuse to comply, or if the covered financial institution cannot obtain adequate assurances that the account will no longer be available to Banco Delta Asia, the covered financial institution must terminate the account within a commercially reasonable time. This means that the covered financial institution should not permit the foreign bank to establish any new positions or execute any transactions through the account, other than those necessary to close the account. A covered financial institution may reestablish an account closed under the proposed rule if it determines that the account will not be used to provide banking services indirectly to Banco Delta Asia. The Financial Crimes Enforcement Network specifically solicits comments on the requirement under the proposed rule that covered financial institutions prevent indirect access to Banco Delta Asia, once such indirect access is identified.

3. Reporting Not Required

Section 103.193(b)(3) of the proposed rule clarifies that the rule does not

[11] Again, for purposes of the proposed rule, a correspondent account is defined as an account established to receive deposits from, or make payments or other disbursements on behalf of, a foreign bank, or handle other financial transactions related to the foreign bank.

impose any reporting requirement upon any covered financial institution that is not otherwise required by applicable law or regulation. A covered financial institution must, however, document its compliance with the requirement that it notify its correspondent account holders that they must not provide Banco Delta Asia with access to the correspondent account maintained at the covered financial institution.

IV. Request for Comments

The Financial Crimes Enforcement Network invites comments on all aspects of the proposal to prohibit the opening or maintaining of correspondent accounts for or on behalf of Banco Delta Asia, and specifically invites comments on the following matters:

1. The appropriate form and scope of the notice to correspondent account holders that would be required under the rule;

2. The appropriate scope of the proposed requirement for a covered financial institution to take reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia;

3. The appropriate steps a covered financial institution should take once it identifies an indirect use of one of its correspondent accounts by Banco Delta Asia; and

4. The impact of the proposed special measure upon legitimate transactions with Banco Delta Asia involving, in particular, U.S. persons and entities; foreign persons, entities, and governments; and multilateral organizations doing legitimate business with persons, entities, or the government of Macau, or operating in Macau.

V. Regulatory Flexibility Act

It is hereby certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. The Financial Crimes Enforcement Network understands that Banco Delta Asia maintains few correspondent accounts in the United States. Thus, the prohibition on maintaining such accounts will not have a significant impact on a substantial number of small entities. In addition, all U.S. persons, including U.S. financial institutions, currently must exercise some degree of due diligence in order to comply with various legal requirements. The tools used for such purposes, including commercially available software used to comply with the economic sanctions programs administered by OFAC, can easily be modified to monitor for the use of correspondent accounts by Banco Delta Asia. Thus, the special due diligence that would be required by this rulemaking—*i.e.*, the one-time transmittal of notice to correspondent account holders and the screening of transactions to identify any indirect use of correspondent accounts, is not expected to impose a significant additional economic burden upon small U.S. financial institutions. The Financial Crimes Enforcement Network invites comments from members of the public who believe there will be a significant economic impact on small entities.

VI. Paperwork Reduction Act

The collection of information contained in this proposed rule is being submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent (preferably by fax (202–395–6974)) to the Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Office of Management and Budget, Paperwork Reduction Project (1506), Washington, DC 20503 (or by e-mail to *Alexander_T._Hunt@omb.eop.gov*) with a copy to the Financial Crimes Enforcement Network by mail or e-mail at the addresses previously specified. Comments on the collection of information should be received by October 20, 2005. In accordance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506c)(2)(A), and its implementing regulations, 5 CFR part 1320, the following information concerning the collection of information as required by 31 CFR 103.193 is presented to assist those persons wishing to comment on the information collection.

The collection of information in this proposed rule is in 31 CFR 103.193(b)(2)(i) and 31 CFR 103.193(b)(3)(i). The disclosure requirement in 31 CFR 103.193(b)(2)(i) is intended to ensure cooperation from correspondent account holders in denying Banco Delta Asia access to the U.S. financial system, as well as to increase awareness within the international financial community of the risks and deficiencies of Banco Delta Asia. The information required to be maintained by 31 CFR 103.193(b)(3)(i) will be used by federal agencies and certain self-regulatory organizations to verify compliance by covered financial institutions with the provisions of 31 CFR 103.193. The class of financial institutions affected by the disclosure requirement is identical to the class of financial institutions affected by the recordkeeping requirement. The collection of information is mandatory.

Description of Affected Financial Institutions: Banks, broker-dealers in securities, futures commission merchants and introducing brokers, and mutual funds maintaining correspondent accounts.

Estimated Number of Affected Financial Institutions: 5,000.

Estimated Average Annual Burden Hours Per Affected Financial Institutions: The estimated average burden associated with the collection of information in this proposed rule is one hour per affected financial institution.

Estimated Total Annual Burden: 5,000 hours.

The Financial Crimes Enforcement Network specifically invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the mission of the Financial Crimes Enforcement Network, including whether the information shall have practical utility; (b) the accuracy of the Financial Crimes Enforcement Network's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information required to be maintained; (d) ways to minimize the burden of the required 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 maintain the information.

VII. Executive Order 12866

The proposed rule is not a significant regulatory action for purposes of Executive Order 12866, ''Regulatory Planning and Review.''

List of Subjects in 31 CFR Part 103

Administrative practice and procedure, Banks and banking, Brokers, Counter-money laundering, Counter-terrorism, Foreign banking.

Authority and Issuance

For the reasons set forth in the preamble, part 103 of title 31 of the Code of Federal Regulations is proposed to be amended as follows:

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FINANCIAL TRANSACTIONS

1. The authority citation for part 103 is revised to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314, 5316–5332; Title III,

secs. 311, 312, 313, 314, 319, 326, 352, Pub. L. 107–56, 115 Stat. 307.

2. Subpart I of part 103 is proposed to be amended by adding new § 103.193 to read as follows:

§ 103.193 Special measures against Banco Delta Asia.

(a) *Definitions.* For purposes of this section:

(1) *Banco Delta Asia* means all branches, offices, and subsidiaries of Banco Delta Asia operating in any jurisdiction.

(2) *Correspondent account* has the same meaning as provided in § 103.175(d)(1)(ii).

(3) *Covered financial institution* has the same meaning as provided in § 103.175(f)(2) and also includes:

(i) A futures commission merchant or an introducing broker registered, or required to register, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*); and

(ii) An investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3)) that is an open-end company (as defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) and that is registered, or required to register, with the Securities and Exchange Commission under section 8 of the Investment Company Act (15 U.S.C. 80a–8).

(4) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

(b) *Requirements for covered financial institutions—(1) Prohibition on direct use of correspondent accounts.* A covered financial institution shall terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, Banco Delta Asia.

(2) *Special due diligence of correspondent accounts to prohibit indirect use.* (i) A covered financial institution shall apply special due diligence to its correspondent accounts that is reasonably designed to guard against their indirect use by Banco Delta Asia. At a minimum, that special due diligence must include:

(A) Notifying correspondent account holders that they may not provide Banco Delta Asia with access to the correspondent account maintained at the covered financial institution; and

(B) Taking reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia, to the extent that such indirect use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, other due diligence measures it should adopt to guard against the indirect use of its correspondent accounts by Banco Delta Asia.

(iii) A covered financial institution that obtains knowledge that a correspondent account is being used by the foreign bank to provide indirect access to Banco Delta Asia, shall take all appropriate steps to prevent such indirect access, including, where necessary, terminating the correspondent account.

(3) *Recordkeeping and reporting.* (i) A covered financial institution is required to document its compliance with the notice requirement set forth in paragraph (b)(2)(i)(A) of this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

Dated: September 12, 2005.

William F. Baity,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 05–18657 Filed 9–19–05; 8:45 am]

BILLING CODE 4810–02–P

Federal Register

Tuesday,
September 20, 2005

Part III

Department of the Treasury

Fiscal Service

Guidance on Cashing and Accepting for Deposit Federal Emergency Management Agency (FEMA) Disaster Assistance Checks and Government Benefit Checks Issued by the U.S. Treasury; Hurricane Katrina; Notice

DEPARTMENT OF THE TREASURY

Fiscal Service

Guidance on Cashing and Accepting for Deposit Federal Emergency Management Agency (FEMA) Disaster Assistance Checks and Government Benefit Checks Issued by the U.S. Treasury; Hurricane Katrina

AGENCY: Financial Management Service, Fiscal Service, Treasury.

SUMMARY: The Financial Management Service (FMS) is publishing additional guidance related to the cashing and accepting for deposit of U.S. Treasury checks for FEMA Disaster Assistance payments and Federal benefit payments (Treasury assistance and benefit checks), such as Social Security payments, to recipients who resided in areas affected by Hurricane Katrina. Depository institutions and retailers have experienced difficulty in confirming the identify of Hurricane Katrina evacuees seeking to cash Treasury checks. To encourage depository institutions and retailers to cash Treasury assistance and benefit checks for these individuals, FMS has established an interim policy to relieve depository institutions from liability in a reclamation action based on a forged or unauthorized indorsement. Under the interim policy, Treasury will relieve depository institutions from liability for cashing or subsequently accepting for deposit a Treasury assistance or benefit check bearing a forged or unauthorized indorsement, provided that the procedures set forth in the interim policy are followed.

DATES: The interim policy is effective for any Treasury assistance or benefit check cashed on or after September 3, 2005 and through November 14, 2005.

ADDRESSES: You can download this notice at the following World Wide Web address: *http://fms.treas.gov/katrina_fedregister_fema.html.*

FOR FURTHER INFORMATION CONTACT: Ronald Cymbor, Director, Financial Processing Division, at 202 874–7913 or *ronald.cymbor@fms.treas.gov;* or Natalie H. Diana, Senior Counsel, at 202 874–6680 or *natalie.diana@fms.treas.gov.*

SUPPLEMENTARY INFORMATION: Depository institutions and other entities that cash or subsequently accept for deposit [1] U.S. Treasury checks are generally liable to Treasury for the amount of a check cashed over a forged or unauthorized indorsement. 31 CFR part 240. In order to ensure that Treasury checks have been properly indorsed by the payee, depository institutions and retailers typically request certain standard forms of identification from non-customers seeking to cash Treasury checks. However, in the extraordinary circumstances resulting from Hurricane Katrina, many individuals displaced from their homes and communities do not have standard forms of identification. Depository institutions and retailers have experienced difficulty in confirming the identity of Hurricane Katrina evacuees who are seeking to cash Treasury assistance and benefit checks.

Treasury recognizes that it is critical that Hurricane Katrina evacuees be able to cash their Treasury assistance and benefit checks expeditiously and wishes to encourage depository institutions to assist evacuees in obtaining funds for their basic needs. Accordingly, Treasury has established an interim policy to relieve depository institutions from liability for cashing or subsequently accepting for deposit a Treasury assistance or benefit check containing a forged or unauthorized indorsement if (1) the identify of the individual cashing the check was verified by calling a telephone number provided by the issuing agency for this purpose or (2) other prudent to identify the individual were made. Depository institutions and other entities should consider documenting their efforts to verify the identify of individuals.

[1] In this context, subsequently accepting a check for deposit pertains to the sequence of events by which a check is accepted for deposit by any number of depository institutions (after it is cashed by an individual) in order to present it to Treasury for payment. It does not refer to the depositing of a check by an individual.

Interim Policy for U.S. Treasury Checks for FEMA Disaster Assistance Payments and Federal Benefit Payments to Recipients Who Resided in Areas Affected by Hurricane Katrina

Under Treasury's interim policy, a depository institution will be relieved from liability in a check reclamation action based on a forged or unauthorized indorsement of a Treasury assistance or benefit check if the identity of the individual is verified at the time the check is cashed either by calling a telephone number provided by the issuing agency for this purpose or by other prudent efforts. Prudent efforts depend upon the circumstances of each situation, but might include one or more of the following: seeking identification documents such as a driver's license, military identification or passport; inspecting other documents such as utility bills, leases, or revolving charge bills; or comparing information provided by the individual to information obtained through electronic searches of consumer reporting agencies, public databases or other sources.

This interim policy is effective for any Treasury assistance or benefit check cashed on or after September 3, 2005 and through November 14, 2005.

Dated: September 19, 2005.

Richard L. Gregg,

Commissioner.

[FR Doc. 05–18968 Filed 9–19–05; 1:28 pm]

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT SEPTEMBER 20, 2005

ENERGY DEPARTMENT

Climate change:
- Voluntary Greenhouse Gas reporting Program—General guidelines; published 3-24-05

COMMENTS DUE NEXT WEEK

AGENCY FOR INTERNATIONAL DEVELOPMENT

Assistance awards to U.S. non-Governmental organizations; marking requirements; Open for comments until further notice; published 8-26-05 [FR 05-16698]

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Cotton classing, testing and standards:
- Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]

Fresh fruit and vegetable terminal market inspection services; fees increase; comments due by 9-26-05; published 8-25-05 [FR 05-16863]

Grapes grown in—
- California; comments due by 9-25-05; published 7-25-05 [FR 05-14673]

Milk marketing orders:
- Mideast; comments due by 9-26-05; published 7-27-05 [FR 05-14769]

AGRICULTURE DEPARTMENT

Food and Nutrition Service

Child nutrition programs:
- Child and Adult Care Food Program—
  - For-profit center participation; comments due by 9-26-05; published 7-27-05 [FR 05-14811]

AGRICULTURE DEPARTMENT

Farm Service Agency

Agency appeal procedures; comments due by 9-26-05; published 7-27-05 [FR 05-14767]

AGRICULTURE DEPARTMENT

Natural Resources Conservation Service

Reports and guidance documents; availability, etc.:
- National Handbook of Conservation Practices; Open for comments until further notice; published 5-9-05 [FR 05-09150]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:
- Caribbean, Gulf, and South Atlantic fisheries—
  - Reef fish, spiny lobster, queen conch and coral; comments due by 9-28-05; published 9-13-05 [FR 05-17945]
- West Coast States and Western Pacific fisheries—
  - Pacific whiting; comments due by 9-26-05; published 8-31-05 [FR 05-17342]

COMMODITY FUTURES TRADING COMMISSION

Commodity Futures Modernization of 2000; implementation:
- Trading facilities; exempt markets, derivatives transaction execution facilities and designated contract markets, etc.; technical and clarifying amendments; comments due by 9-26-05; published 9-14-05 [FR 05-18174]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

DEFENSE DEPARTMENT

Acquisition regulations:
- Business restructuring costs-delegation of authority to make determinations relating to payment; comments due by 9-26-05; published 7-26-05 [FR 05-14625]
- Critical safety items; notification requirements; comments due by 9-30-05; published 8-1-05 [FR 05-15156]
- Pilot Mentor-Protege Program; Open for comments until further notice; published 12-15-04 [FR 04-27351]
- Sole source 8 (a) awards to small business concerns owned by Native Hawaiian organizations; comments due by 9-26-05; published 7-26-05 [FR 05-14624]
- Transportation; comments due by 9-26-05; published 7-26-05 [FR 05-14626]

Federal Acquisition Regulation (FAR):
- HUBZone certification; confirmation; comments due by 9-26-05; published 7-27-05 [FR 05-14669]
- Information technology; definition; comments due by 9-26-05; published 7-27-05 [FR 05-14666]
- Performance of Commercial Activities (Circular A-76); comments due by 9-26-05; published 7-26-05 [FR 05-14569]

DELAWARE RIVER BASIN COMMISSION

Water Quality Regulations, Water Code, and Comprehensive Plan:
- Lower Delaware River; special protection waters classification; comments due by 9-26-05; published 8-22-05 [FR 05-16526]

EDUCATION DEPARTMENT

Elementary and secondary education:
- State Charter School Facilities Incentive Program; comments due by 9-26-05; published 8-26-05 [FR 05-17049]

Grants and cooperative agreements; availability, etc.:
- Vocational and adult education—
  - Smaller Learning Communities Program; Open for comments until further notice; published 2-25-05 [FR E5-00767]

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- Environmental Management Site-Specific Advisory Board—
  - Oak Ridge Reservation, TN; Open for comments until further notice; published 11-19-04 [FR 04-25693]

ENERGY DEPARTMENT

Energy Efficiency and Renewable Energy Office

Commercial and industrial equipment; energy efficiency program:
- Test procedures and efficiency standards—
  - Commercial packaged boilers; Open for comments until further notice; published 10-21-04 [FR 04-17730]

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Electric rate and corporate regulation filings:
- Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]

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Air pollutants, hazardous; national emission standards:
- Reinforced plastic composites production; comments due by 9-26-05; published 8-25-05 [FR 05-16700]

Air programs:
- Stratospheric ozone protection—
  - Methyl bromide; critical use exemption process; supplemental request; comments due by 9-29-05; published 8-30-05 [FR 05-17190]
  - Methyl bromide; critical use exemption process; supplemental request; comments due by 9-29-05; published 8-30-05 [FR 05-17191]

Air quality implementation plans; approval and promulgation; various States:
- California; comments due by 9-29-05; published 8-30-05 [FR 05-17196]

Environmental statements; availability, etc.:
- Coastal nonpoint pollution control program—
  - Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
- 2,4-D; comments due by 9-26-05; published 7-27-05 [FR 05-14886]
- Lignosulonates; comments due by 9-26-05; published 7-27-05 [FR 05-14887]
- Pinoxaden; comments due by 9-26-05; published 7-27-05 [FR 05-14896]
- Propiconazole; comments due by 9-26-05; published 7-27-05 [FR 05-14599]

Pymetrozine; comments due by 9-26-05; published 7-27-05 [FR 05-14598]

Water pollution control:

National Pollutant Discharge Elimination System—

Concentrated animal feeding operations in New Mexico and Oklahoma; general permit for discharges; Open for comments until further notice; published 12-7-04 [FR 04-26817]

Texas; general permit for territorial seas; Open for comments until further notice; published 9-6-05 [FR 05-17614]

Water pollution; effluent guidelines for point source categories:

Meat and poultry products processing facilities; Open for comments until further notice; published 9-8-04 [FR 04-12017]

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Technological Advisory Council; Open for comments until further notice; published 3-18-05 [FR 05-05403]

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Hearing aid-compatible telephones; comments due by 9-26-05; published 7-27-05 [FR 05-14614]

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Incumbent local exchange carriers unbounding obligations; local competition provisions; wireline services offering advanced telecommunications capability; Open for comments until further notice; published 12-29-04 [FR 04-28531]

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Certain salaries and wages; State, district, and local party committee payment; comments due by 9-29-05; published 8-30-05 [FR 05-17156]

Federal election activity; definition; comments due by 9-29-05; published 8-30-05 [FR 05-17155]

Federal Election Campaign Act:

Electioneering communications; definitions; comment request; comments due by 9-30-05; published 8-24-05 [FR 05-16785]

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Jewelry, precious metals, and pewter industries; comments due by 9-28-05; published 7-6-05 [FR 05-13285]

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Information technology; definition; comments due by 9-26-05; published 7-27-05 [FR 05-14666]

Performance of Commercial Activities (Circular A-76); comments due by 9-26-05; published 7-26-05 [FR 05-14569]

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Evaluating safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern; Open for comments until further notice; published 10-27-03 [FR 03-27113]

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Dental noble metal alloys and base metal alloys; Class II special controls; Open for comments until further notice; published 8-23-04 [FR 04-19179]

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Tri-Cities area including Tri-Cities Regional Airport, VA and TN; port of entry establishment and user-fee status termination; comments due by 9-27-05; published 7-29-05 [FR 05-15045]

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Tennessee; comments due by 9-26-05; published 8-25-05 [FR 05-16859]

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Paiute cutthroat trout; Open for comments until further notice; published 9-10-04 [FR 04-20517]

Endangered and threatened species:

Critical habitat designations—

Gila chub; comments due by 9-30-05; published 8-31-05 [FR 05-17450]

San Jacinto Valley crownscale; comments due by 9-30-05; published 8-31-05 [FR 05-17451]

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Surface Mining Reclamation and Enforcement Office

Permanent program and abandoned mine land reclamation plan submissions:

Missouri; comments due by 9-29-05; published 8-22-05 [FR 05-16573]

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West Virginia; comments due by 9-26-05; published 8-26-05 [FR 05-17002]

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Schedules of controlled substances:

Embutramide; placement into Schedule III; comments due by 9-28-05; published 8-29-05 [FR 05-17163]

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Justice Programs Office

Public safety officers' death and disability benefits:

Benefits program; comments due by 9-26-05; published 7-26-05 [FR 05-14659]

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Federal Acquisition Regulation (FAR):

HUBZone certification; confirmation; comments due by 9-26-05; published 7-27-05 [FR 05-14669]

Information technology; definition; comments due by 9-26-05; published 7-27-05 [FR 05-14666]

Performance of Commercial Activities (Circular A-76); comments due by 9-26-05; published 7-26-05 [FR 05-14569]

NATIONAL CREDIT UNION ADMINISTRATION

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Insurance requirements; comments due by 9-27-05; published 7-29-05 [FR 05-14807]

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NCUA examiners; post-employment restrictions; comments due by 9-27-05; published 7-29-05 [FR 05-14808]

NUCLEAR REGULATORY COMMISSION

Environmental statements; availability, etc.:

Fort Wayne State Developmental Center; Open for comments until further notice; published 5-10-04 [FR 04-10516]

SMALL BUSINESS ADMINISTRATION

Disaster loan areas:

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OFFICE OF UNITED STATES TRADE REPRESENTATIVE

Trade Representative, Office of United States

Generalized System of Preferences:

2003 Annual Product Review, 2002 Annual Country Practices Review, and previously deferred product decisions; petitions disposition; Open for comments until further notice; published 7-6-04 [FR 04-15361]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Air carrier certification and operations:

Child restraint systems; comments due by 9-26-05; published 8-26-05 [FR 05-16782]

Airworthiness directives:

Boeing; Open for comments until further notice; published 8-16-04 [FR 04-18641]

CENTRAIR; comments due by 9-26-05; published 8-22-05 [FR 05-16529]

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McDonnell Douglas; comments due by 9-26-05; published 8-11-05 [FR 05-15881]

New Piper Aircraft, Inc.; comments due by 9-26-05; published 7-26-05 [FR 05-14389]

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TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

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Internal Revenue Service

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Credit for increasing research activities; comments due by 9-28-05; published 5-24-05 [FR 05-10236]

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Labeling and advertising; wines, distilled spirits, and malt beverages; comments due by 9-26-05; published 6-23-05 [FR 05-12396]

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*

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 3650/P.L. 109–63

Federal Judiciary Emergency Special Sessions Act of 2005 (Sept. 9, 2005; 119 Stat. 1993)

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