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WHEN: Tuesday, September 12, 2006
9:00 a.m.–Noon

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Washington, DC 20002

RESERVATIONS: (202) 741–6008

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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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–24631; Directorate Identifier 2005–SW–01–AD; Amendment 39–14739; AD 2006–18–01]

RIN 2120–AA64

Airworthiness Directives; MD Helicopters, Inc. Model MD900 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) for MD Helicopters, Inc. (MDHI) Model MD900 helicopters, that currently requires reducing the life limit of certain Notar fan system tension-torsion (TT) straps. That existing AD also requires, at a specified time interval, removing each affected TT strap from the helicopter, doing a visual and X-ray inspection, and replacing any unairworthy part before further flight. This amendment requires the same actions as the existing AD, but also requires revising the life limit on the component history card or equivalent record and doing repetitive visual and X-ray inspections, and removes reporting requirements. This amendment is prompted by two in-flight TT strap failures. The actions specified by this AD are intended to prevent failure of a TT strap, loss of directional control, and subsequent loss of control of the helicopter.

DATES: Effective October 3, 2006.

The incorporation by reference of MD Helicopters Service Bulletin SB900–095, dated November 3, 2004, was approved previously by the Director of the Federal Register as of December 7, 2004 (69 FR 67806, November 22, 2004).

ADDRESSES: You may get the service information identified in this AD from MD Helicopters Inc., Attn: Customer Support Division, 4555 E. McDowell Rd., Mail Stop M615, Mesa, Arizona 85215–9734, telephone 1–800–388–3378, fax 480–346–6813, or on the web at *http://www.mdhelicopters.com.*

Examining the Docket

You may examine the docket that contains this AD, any comments, and other information on the Internet at *http://dms.dot.gov*, or at the Docket Management System (DMS), U.S. Department of Transportation, 400 Seventh Street, SW., Room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Roger Durbin, Aviation Safety Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5233, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend 14 CFR part 39 by superseding AD 2004–23–15, Amendment 39–13870 (69 FR 67805, November 22, 2004), for MDHI Model MD900 helicopters, was published in the **Federal Register** on May 10, 2006 (71 FR 27212). The action proposed to require the following for MDHI Model MD900 helicopters with a TT strap, part number (P/N) 900R3442009–103, 900R6442009–103, 900R3442009–101, or 500N5311–5, installed:

- Before further flight, unless accomplished previously, for TT strap, P/N 900R3442009–103 and 900R6442009–103, reducing the life limit from 3,034 to 2,500 hours TIS and revising the life limit on the component history card or equivalent record;
- Within 10 hours TIS, unless accomplished previously, and then at intervals not to exceed 300 hours TIS, for any TT strap that has accumulated 1,190 or more hours TIS, doing a visual and X-ray inspection of each TT strap and replacing any unairworthy TT strap before further flight; and
- Before the TT strap accumulates 1,200 hours TIS, and then at intervals not to exceed 300 hours TIS, for any TT strap with less than 1,190 hours TIS, doing a visual and X-ray inspection of each strap and replacing any unairworthy TT strap before further flight.

At the time that we issued AD 2004–23–15, the cause of the TT strap failures was not known, and that AD was considered interim action. The actions required by this AD are also are interim actions, because the cause of the failures is still unknown and the investigation is ongoing. We will consider further rulemaking once our investigation is complete.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed, with one change—contact information for the FAA has been added to paragraph (f) of the AD. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that this AD will affect 31 helicopters of U.S. registry, and the required actions will take approximately 7 work hours for each visual inspection and replacement at an average labor rate of $65 per work hour. Because you must remove the TT strap to inspect it, there is no additional labor cost for replacing the TT strap. It will also cost $100 for each X-ray inspection. Required parts will cost about $757 to replace each strap. Based on these figures, we estimate the total cost impact of this AD on U.S. operators to be $168,950 in the first year (assuming a total of 5 TT straps are replaced per helicopter and 3 visual inspections and 3 X-ray inspections are conducted the first year for each helicopter).

Regulatory Findings

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

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

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

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

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

We prepared an economic evaluation of the estimated costs to comply with this AD. See the DMS to examine the economic evaluation.

Authority for This Rulemaking

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing Amendment 39–13870 (69 FR 67805, November 22, 2004), and by adding a new airworthiness directive (AD), Amendment 39–14739, to read as follows:

2006–18–01 MD Helicopters, Inc.: Amendment 39–14739. Docket No. FAA–2006–24631; Directorate Identifier 2005–SW–01–AD. Supersedes AD 2004–23–15, Amendment 39–13870, Docket No. FAA–2004–19613, Directorate Identifier 2004–SW–38–AD.

Applicability: Model MD900 helicopters, with a Notar fan system that has a tension-torsion (TT) strap, part number (P/N) 900R3442009–103, 900R6442009–103, 900R3442009–101, or 500N5311–5, installed, certificated in any category.

Compliance: Required as indicated.

To prevent failure of a TT strap in the Notar fan system, loss of directional control, and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight, unless accomplished previously, for TT Straps, P/N 900R3442009–103 and 900R6442009–103, reduce the life limit from 3,034 to 2,500 hours time-in-service (TIS) and revise the life limit on the component history card or equivalent record to reflect this reduced retirement life.

(b) Within 10 hours TIS, unless accomplished previously, for any TT strap that has accumulated 1,190 or more hours TIS, and then at intervals not to exceed 300 hours TIS, remove the TT strap from the helicopter and do a visual and an X-ray inspection in accordance with the Inspection Instructions, paragraph 2.B.(1). through (5)., and Figures 1 and 2 of MD Helicopters Service Bulletin SB900–095, dated November 3, 2004 (SB). Replace any unairworthy TT strap before further flight.

(c) Before the TT strap accumulates 1,200 hours TIS, for any TT strap with less than 1,190 hours TIS, and then at intervals not to exceed 300 hours TIS, remove the TT strap from the helicopter and do a visual and an X-ray inspection in accordance with the Inspection Instructions, paragraph 2.B.(1). through (5)., and Figures 1 and 2 of the SB. Replace any unairworthy TT strap before further flight.

(d) The X-ray inspection of the TT strap must be performed by a Level II or higher X-ray technician who is qualified under the guidelines established by MIL–STD–410E, ATA Specification 105, AIA–NAS–410, or an FAA-accepted equivalent for qualification standards.

(e) This AD revises the Airworthiness Limitations section of the maintenance manual by reducing the life limit of the TT straps, P/N 900R3442009–103 and 900R6442009–103, from 3,034 hours TIS to 2,500 hours TIS. Additionally, this AD revises the Airworthiness Limitations section of the maintenance manual by adding repetitive inspection requirements at intervals not to exceed 300 hours TIS for TT straps, P/N 900R3442009–103, 900R6442009–103, 900R3442009–101, and 500N5311–5, that have 1,200 or more hours TIS until the TT strap reaches its retirement life.

(f) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Los Angeles Aircraft Certification, FAA, ATTN: Roger Durbin, Aviation Safety Engineer, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5233, fax (562) 627–5210, for information about previously approved alternative methods of compliance.

(g) The X-ray inspection shall be done in accordance with the specified portions of MD Helicopters Service Bulletin SB900–095, dated November 3, 2004. The incorporation by reference of that document was approved previously by the Director of the Federal Register, in accordance with 5 U. S.C. 552(a) and 1 CFR part 51, as of December 7, 2004 (69 FR 67806, November 22, 2004). Copies may be obtained from MD Helicopters Inc., Attn: Customer Support Division, 4555 E. McDowell Rd., Mail Stop M615, Mesa, Arizona 85215–9734, telephone 1–800–388–3378, fax 480–346–6813, or on the web at *http://www.mdhelicopters.com.* Copies may be inspected 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.*

(h) This amendment becomes effective on October 3, 2006.

Issued in Fort Worth, Texas, on August 22, 2006.

Mark R. Schilling,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. E6–14291 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2006–25647; Airspace Docket No. 06–AWP–14]

RIN 2120–AA66

Amendment to Class D Airspace; Provo, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace area at Provo, UT. A review of the legal description revealed that it does not reflect the current airport reference point (ARP) for Provo Municipal Airport.

EFFECTIVE DATE: 0901 UTC, November 23, 2006. The Director of the Federal Register approves this incorporation by reference action under 14 CFR 71.1, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Francie Hope, Western Terminal Operations Airspace Specialist, AWP–520.3, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, CA 90261, telephone (310) 725–6502.

SUPPLEMENTARY INFORMATION:

History

An examination of the Class D airspace area designation at Provo, UT, revealed that the legal description did

not reflect the current ARP for Provo Municipal Airport. This action will change the longitude in the ARP for the airport. Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9N dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the longitude in the legal description of Provo Municipal Airport's ARP. Accordingly, since this action only involves a change in the airport's legal description of the Provo, UT, Class D airspace area, and does not involve a change in the dimensions or operating requirements of that airspace, notice and public procedure under 5 U.S.C. 553(b) are unnecessary. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM UT D Provo, UT [Amended]

Provo Municipal, Airport, UT
(Lat. 40°13′09″ N, long. 111°43′24″ W)

* * * * *

Issued in Los Angeles, California, on August 16, 2006.

Anthony J. DiBernardo,

Acting Area Director, Western Terminal Operations.

[FR Doc. 06–7205 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2006–24234; Airspace Docket No. 06–AWP–5]

RIN 2120–AA66

Amendment to Class E Airspace; Provo, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule; correction.

SUMMARY: This action corrects an error in the airport reference point (ARP) for Provo Municipal Airport, Provo, UT, in the final rule that was published in the **Federal Register** on August 1, 2006, (71 FR 43355), Docket No. FAA–2006–24234; Airspace Docket No. 06–AWP–5. In addition, corrections are made to change FAA Order 7400.9O to FAA Order 7400.9N, amending its date in two references to September 1, 2005, effective September 15, 2005; and make two editorial changes, replacing the word attends with amends in the Summary, and Class D to Class E in the legal description.

DATES: *Effective Date:* 0901 UTC, September 28, 2006. The Director of the Federal Register approves this incorporation by reference action under 14 CFR 71.1, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Francie Hope, Western Terminal Operations Specialist, AWP–520.3, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6502.

SUPPLEMENTARY INFORMATION:

History

On August 1, 2006, a final rule was published in the **Federal Register** (71 FR 43355), Docket No. FAA–2006–24234; Airspace Docket No. 06–AWP–5. This rule amended the Class E airspace area at Provo, UT, revising the legal description ARP to match that of the Provo, UT, Class D airspace. Unfortunately, the Class D airport ARP was also incorrect in that it did not match the current ARP in the National Airspace System Resource Database. The correction to the Class E ARP is made in this docket. In addition, the two references to FAA Order 7400.9O, dated September 1, 2006, and effective September 15, 2006, are corrected to read FAA Order 7400.9N, dated September 1, 2005, and effective September 15, 2005, which is current as of this date. Two editorial changes are made; in the Summary, the word amends replaces attends, and in the legal description, the term Class E replaces Class D airspace.

Correction to Final Rule

■ Accordingly, pursuant to the authority delegated to me, the changes as described above are corrected, and the legal description for Provo, UT, as published in the **Federal Register** on August 1, 2006, (71 FR 43355), and incorporated by reference in 14 CFR 71.1, is corrected as follows:

PART 71—[AMENDED]

§ 71.1 [Amended]

* * * * *

ANM UT E2 Provo, UT [Amended]

Provo Municipal Airport, UT
(Lat. 40°13′09″ N, long. 111°43′24″ W)
Spanish Fork-Springville, UT
(Lat. 40°08′30″ N, long. 111°39′41″ W)

That airspace extending upward from the surface to and including 7,000 feet MSL within a 4.3-mile radius of Provo Municipal airport, excluding that airspace within a 2.4 mile radius of the Spanish Fork-Springville Airport. This Class E airspace is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Los Angeles, California, on August 16, 2006.

Anthony J. DiBernardo,

Acting Area Director, Western Terminal Operations.

[FR Doc. 06–7204 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 260

[Docket No. RM06–18–000; Order No. 682]

Revision of Regulations To Require Reporting of Damage to Natural Gas Pipeline Facilities

Issued August 23, 2006.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is amending its regulations to require that jurisdictional natural gas companies report damage to facilities as the result of a natural disaster or terrorist activity that results in a reduction in pipeline throughput or storage deliverability. The Commission is issuing this Final Rule based on its experience following Hurricanes Rita and Katrina under the existing reporting requirements which only require pipeline companies to report service interruptions and therefore did not require natural gas companies to report significant hurricane damage to facilities in instances where service interruptions were avoided by rerouting gas supplies or other means. The Commission has determined that the additional reporting requirements are necessary in order to effectively monitor the nation's natural gas infrastructure in crisis situations.

EFFECTIVE DATE: The rule will become effective August 29, 2006.

FOR FURTHER INFORMATION CONTACT:

Berne Mosley, Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. (202) 502–8625.

Howard Wheeler, Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. (202) 502–8688.

William Blome, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. (202) 502–8462.

SUPPLEMENTARY INFORMATION: Before Commissioners: Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellinghoff.

I. Introduction

1. On June 9, 2006, the Federal Energy Regulatory Commission (Commission) issued a Notice of Proposed Rulemaking (NOPR) in this proceeding.[1] In that NOPR, we proposed to revise § 260.9 of our regulations,[2] which requires the reporting of serious service interruptions on interstate natural gas pipeline facilities operated under authority granted by the Commission under the Natural Gas Act.[3] This Final Rule revises § 260.9 largely in the manner described in the NOPR, with certain modifications to clarify and limit the scope of the new reporting requirements in response to the comments that have been filed. The revisions to § 260.9 will ensure that the Commission has adequate and timely information concerning damage to jurisdictional pipeline and storage facilities as the result of natural disasters or terrorist activity.

II. Background

2. In the NOPR, the Commission explained that the severe hurricanes during the summer of 2005 did serious and widespread damage to the energy production and delivery systems of the United States, particularly in the Gulf Coast region. We noted that as of May 3, 2006, shut-in natural gas production in the Gulf of Mexico from Hurricanes Katrina and Rita was equivalent to 12.95 percent of current daily gas production.[4] The Commission also explained that it had participated in the Federal effort, led by the U.S. Department of Energy, to collect post-hurricane information on damage to the nation's energy infrastructure.[5] The Commission learned that, although it had been kept informed of serious service interruptions as the regulations required, it lacked vital information regarding the physical condition of facilities affecting operation of the pipeline grid.

3. The deficiency in reporting following the 2005 hurricanes resulted because the current reporting requirements of § 260.9 apply only in the event of service interruptions. In instances where service interruptions were avoided by adjusting nomination schedules, rerouting gas flows over alternate facilities, or drawing down storage supplies, § 260.9 did not require that companies report damage to gas facilities. Therefore, it was necessary for our staff to informally gather information regarding damage to facilities from pipeline companies and industry groups by telephone calls and other means. While we took steps based on available information to encourage rapid repair of facilities and restoration of service, including the granting of waivers of various regulations where necessary,[6] the informal information gathering process was not adequate to ensure timely and accurate monitoring of gas infrastructure.

4. As the result of our experience during and following the 2005 hurricane season, we concluded that additional reporting requirements are necessary to ensure that the Commission has enough information to assess the status of the nation's natural gas pipeline infrastructure at any given time and share this information with other agencies, such as the U.S. Department of Energy and the U.S. Department of Transportation. Therefore, the Commission's June 9 NOPR proposed modifications to § 260.9 of the regulations to add a requirement that pipelines report damage to certificated facilities that results in loss of or reduction in service through such facilities and also report when service through such facilities has been restored. The Commission proposed to expand the informational requirements of § 260.9 to require reports including specific information concerning the location and cause of damage to facilities and service interruptions, the time of occurrence, emergency actions taken to maintain service, and other matters. The revised § 260.9 would also require that a company send copies of damage reports to state commissions, as is already required for reports of serious service interruptions. We also proposed to allow filing by e-mail and to eliminate the reference to filing by telegraph.

5. The NOPR was published in the **Federal Register** on June 19, 2006,[7] with July 19, 2006 being the deadline for comments. We received nine sets of comments on the NOPR. Comments were filed by American Gas Association (AGA),[8] American Public Gas

[1] 71 FR 35226 (June 19, 2006); FERC Stats. & Regs. ¶ 32,604 (2006).

[2] 18 CFR 260.9 (2006).

[3] 15 U.S.C. 717–717z (2006).

[4] Hurricane Katrina/Hurricane Rita Evacuation and Production Shut-in Statistics Report as of Wednesday, May 3, 2006 [Final Report], U.S. Department of the Interior, Minerals Management Service (May 3, 2006).

[5] *See* Homeland Security Presidential Directive (HSPD)–5 (February 28, 2003), directing the Secretary of Homeland Security to develop a National Response Plan.

[6] *See* NOPR, at P. 4.

[7] 71 FR 35226.

[8] AGA represents 197 local energy utility companies delivering gas to more than 56 million homes, business and industries in the United States. AGA states that its members account for about 83 percent of all natural gas delivered by local distribution companies.

Association (APGA),[9] Boardwalk Pipeline Partners, LP (Boardwalk Pipelines), Duke Energy Gas Transmission, LLC (Duke Energy),[10] Interstate Natural Gas Association of America (INGAA), National Fuel Gas Distribution Corporation (National Fuel Gas),[11] NiSource, Inc. (NiSource),[12] Paiute Pipeline Company (Paiute), and Williston Basin Interstate Pipeline Company (Williston Basin). The comments are described and addressed below.

III. Comments

6. The commenters representing local distribution companies express strong support for the Commission's effort to ensure timely reporting of damage to the natural gas infrastructure. These commenters emphasize that information on the operating status of the pipelines' facilities is a critical component of price formation, particularly during periods of infrastructure distress such as that experienced as the result of Hurricanes Katrina and Rita. They believe the proposed reporting requirements are needed to help consumers assess the supply and transportation situation following such damaging events.

7. The other commenters represent the interstate pipeline industry and are potential respondents to the new reporting requirements. These commenters generally acknowledge the need for this expedited rulemaking proceeding to remedy the current gap in reporting requirements so that the Commission is able to quickly identify significant infrastructure problems in the event this season produces hurricanes as damaging as last year's.

8. However, the pipeline companies strongly urge the Commission to work toward the long-term goal of minimizing duplicative Federal reporting requirements by engaging in cooperative efforts with the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (DOT/Pipeline Safety)[13] and the National Response Center. Some commenters believe the Commission and these other agencies ultimately should be able to develop a single, comprehensive form that could be filed in one place and made available to any agency needing the information.[14]

9. In the interim, the pipeline companies request that the Commission clarify and narrow the definition of ''damage'' in § 260.9 so that pipeline companies will not be required to file reports unnecessary to fulfill the Commission's objective in this rulemaking of ensuring that it has adequate and timely information to identify significant problems with the nation's natural gas infrastructure. The pipeline companies emphasize that, as proposed, the new reporting requirements would cause the agency to be inundated with reports of trivial damage from routine or unimportant occurrences which could result in important matters being obscured.

10. These commenters also state that their employees' efforts to locate and repair more serious areas of damage could suffer if they are busy completing and filing forms on less serious matters in the middle of an emergency. Thus, they urge the Commission to limit the damage reporting requirement to situations where there is severe damage causing serious disruption of service, and to exclude minor damage resulting from occasional third-party activities and disruptions resulting from routine maintenance.

11. The pipeline companies emphasize that, absent clarification and revision of the proposed regulations, the required reporting of damage to facilities could capture many events irrelevant to the Commission's objective in this rulemaking proceeding which, they believe, is to ensure timely identification of damage resulting from serious events that have the potential for impacts which, in the aggregate, may significantly undermine the integrity of the nation's gas infrastructure.

12. As examples of incidents for which immediate reporting generally is not necessary to achieve this objective, the pipeline companies note accidental backhoe damage from construction, a farmer's plow hitting a farm tap valve, compressor engine faults resulting in short periods of service disruption or reduction of throughput capability, corrosion and other damage revealed by regular inspections and requiring a temporary reduction in pressure until repairs can be made, and maintenance to replace equipment at the end of its useful life or worn out from wear and tear. The pipeline companies also discuss how much customer load is seasonal, so that a compressor failure or even a line break, on a looped line, may have no effect on customer service at all, depending upon when it happens.

13. In sum, the pipeline companies stress that, while minor incidents and accidents and routine maintenance may temporarily reduce available service or capacity through particular facilities, such incidents generally have no serious effect on the affected pipeline system's ability to meet its service obligations or on the national pipeline grid. These commenters believe that for these types of routine occurrences, which number in thousands each year for the pipeline industry as a whole, existing reporting requirements are sufficient.[15] Thus, these commenters request that the Final Rule's expansion of current reporting requirements be limited to significant damage from terrorism or natural disasters or other serious events significantly affecting operation of the affected pipeline system or the interstate pipeline grid. These commenters believe the Commission should focus on damage resulting in a loss of or reduction in a significant amount of firm service capacity—*e.g.*, firm service capacity of one million Dekatherms per day—for an extended period of time which, depending on the commenter, should be between three and 15 days. If the pipeline company believes a damaged facility can be fully restored to service within such time period, the commenters do not believe the new reporting requirements should apply unless, in the judgment of the pipeline company, the loss of or reduction in capacity of the damaged facilities is

[9] APGA is an association of approximately 650 municipal and other publicly-owned local distribution systems in 36 states.

[10] Duke Energy owns Texas Eastern Transmission, LP; Egan Hub Storage, LLC; Algonquin Gas Transmission, LLC; Saltville Gas Storage, LLC; and East Tennessee Natural Gas, LLC. It is a part-owner of Maritimes & Northeast Pipeline, L.L.C., and Gulfstream Natural Gas System, L.L.C.

[11] National Fuel Gas is a local distribution company subject to the jurisdiction of the New York Public Service Commission and the Pennsylvania Public Utility Commission. It is a member of AGA and supports AGA's comments.

[12] NiSource owns and operates five interstate pipelines, ten local distribution companies and a joint venture storage company.

[13] DOT/Pipeline Safety's reporting requirements are part of its administration of the Natural Gas Pipeline Safety Act of 1968, 49 U.S.C. 60101 *et seq.*

[14] Additional discussion pertaining to reporting burden is included below in this Final Rule's Information Collection Statement.

[15] As discussed in the NOPR (at n. 9) and referenced by commenters, pipeline companies are required to submit reports of replacement facilities pursuant to 18 CFR 2.55(b) and annual reports of construction activities under the automatic provisions of the blanket certificate regulations in Part 157, Subpart F. Since these reports are annual reports due on or before May 1 of each year and hurricanes frequently occur in July, nine months can pass before a pipeline is required to report construction activities. Further, the information in these annual reports is not sufficient to determine whether a particular construction activity was undertaken due to damage to facilities resulting from a hurricane or other cause. In addition, while the emergency regulations in Part 284, Subpart I, require that the commencement of an emergency transaction be reported within 48 hours, the emergency regulations do not require the reporting of damage to facilities that may have made the emergency transaction necessary or reporting regarding facilities constructed to address the emergency.

significantly impairing its ability to meet its customers' needs for natural gas service.

14. Paiute Pipeline Company (Paiute), which operates a liquefied natural gas (LNG) peak shaving plant in Nevada, requests that all jurisdictional LNG storage facilities be exempted from the proposed new reporting requirements. Paiute believes LNG storage operators already are subject to adequate reporting requirements that were imposed as conditions of the original authorizations for their LNG storage facilities. Paiute also notes that a June 23, 2006 letter from the Director of the Commission's Office of Energy Projects (OEP Director) to LNG storage operators clarified the Commission's applicable reporting conditions, which are similar to the reporting requirements prescribed by the U. S. Department of Transportation pursuant to 49 CFR Part 191 for LNG storage facilities.

IV. Commission Response

15. On July 31, 2006, the U.S. Department of Energy (DOE) released a report titled ''Impact of the 2005 Hurricanes on the Natural Gas Industry in the Gulf of Mexico Region.'' The report summarizes findings from Federal monitoring of the impact of Hurricanes Katrina and Rita on the natural gas industry in the Gulf of Mexico region from late August 2005 through early March 2006. It details the coordination of Federal agencies, including the Commission, and various natural gas industry personnel to track storm recovery efforts on a daily basis and identify disrupted natural gas flows and possible bypasses.

16. The July 31 report establishes insights into the complex supply delivery operation associated with offshore natural gas production and highlights the importance of accurate, timely information during supply-related emergencies. The report finds that 3,050 of the Gulf's 4,000 platforms and 22,000 of the 33,000 miles of Gulf pipelines were in the direct path of either Katrina or Rita, which caused destruction and substantial damage to offshore production platforms and pipelines, onshore production wells and pipelines, and other infrastructure supporting the Gulf production and delivery system. When active Federal monitoring of storm recovery efforts ended on March 8, 2006, production had returned to about 9 Bcf per day, with an estimated 9.4 percent of daily gas production remaining shut in as of June 19, 2006.

17. DOE's report illustrates and confirms the need for additional reporting requirements to ensure the Commission's timely gathering of information to monitor the status of the nation's gas infrastructure in emergency situations. Therefore, the Commission will adopt its proposal to revise § 260.9 of the regulations to require that natural gas companies report damage to jurisdictional facilities as the result of hurricanes and other natural disasters, such as earthquakes and floods, or terrorist activity.

18. The Commission recognizes that in many instances reporting by pipeline companies pursuant to the existing and new reporting requirements of § 260.9 will duplicate aspects of the initial telephonic and subsequent written pipeline incident reports required by DOT/Pipeline Safety. However, in view of the timing and format in which such reports are submitted to DOT/Pipeline Safety, the Commission cannot at the present time rely on those reports to meet its goals in monitoring emerging problems with gas infrastructure during and immediately following natural disasters or terrorist events. Further, while the Commission has already initiated consultation with DOT/Pipeline Safety regarding the possible development of a unified reporting system to meet the needs of the Commission, DOT/Pipeline Safety, the National Resource Center and other Federal agencies, such an initiative does not offer an immediate solution to the problem of duplicative reporting requirements, as the commenters acknowledge.

19. However, the Commission is revising the proposed regulations to narrow the scope of the new reporting requirements, since it was not our intention in the June 9 NOPR to require that pipeline companies immediately report incidents involving equipment failure, accidents and other situations which neither result in serious service interruptions (which are already subject to reporting under § 260.9) nor threaten a pipeline company's ability to meet its service obligations or otherwise significantly affect the integrity of the nation's gas infrastructure. While the commenters are correct that information relating to many such incidents is reflected in the annual construction reports pipeline companies are required to file,[16] our reason here for not requiring that these incidents be reported under § 260.9 is because immediate reporting in such instances is not crucial to our objective in this rulemaking proceeding of ensuring that our reporting requirements are adequate for timely gathering of information to monitor gas infrastructure in crisis situations that present serious threats to such infrastructure. Therefore, we will revise the proposed regulations to make clear that § 260.9 does not require the reporting of such incidents.

20. We do not agree, however, that our objectives can be met if we limit reporting under § 260.9 to damage to facilities only used for firm service or only in instances where throughput or capacity is reduced by more than a certain amount or the pipeline expects the facilities to be compromised for more than a few days. Since the new reporting requirements will be triggered by natural disasters or terrorist activity, the Commission will need all relevant information regarding damage to facilities and all affected pipeline systems. While a particular pipeline system may be able to take measures so that damage to its facilities does not cause that pipeline system to experience any immediate service interruptions, the damage on that pipeline system contributes to cumulative impacts that may significantly strain the gas infrastructure. Further, following a natural disaster or terrorist event, the Commission needs information on the status of all affected facilities, including facilities experiencing minimal damage, to facilitate the identification of possible paths for rerouting gas around more seriously damaged facilities.

21. In view of these considerations, the Commission is adopting new reporting requirements but is revising its proposal in the NOPR so that the additional reporting will be limited to requiring that pipeline companies report any damage to pipeline or storage facilities from a natural disaster or terrorist activity if such damage reduces pipeline throughput or storage deliverability. These limited new reporting requirements will ensure that the Commission has adequate, timely information to assess the status of gas infrastructure immediately following a natural disaster or terrorist event. However, as some commenters recognize, there may be other situations in which damage to pipeline and storage facilities creates the potential for destabilization of the gas infrastructure. Therefore, as a means of obtaining information regarding such occurrences without imposing overly inclusive reporting requirements that would unduly burden respondents, revised § 260.9 also will include a provision, as recommended by some commenters, to encourage pipeline companies to report any other damage which the pipeline companies, in their judgment, think creates the potential for serious delivery problems on their own systems or the pipeline grid. We are providing for this

[16] *Id.*

additional reporting in pipeline companies' discretion in recognition of their systems' wide variations in size, configuration, and levels and types of service. Incorporating a further level of discretion into the reporting provisions of § 260.9 is appropriate, since pipeline companies know their own systems and the nuances of their operations, and therefore can judge what other instances involving damage to facilities present the potential for significant problems on their own systems or the pipeline grid.

22. We also agree with Paiute's position that existing reporting requirements applicable to LNG storage operators are adequate, and that it is therefore appropriate to exclude damage to such facilities from the new reporting requirements in § 260.9. As emphasized by Paiute, when the Commission authorizes new LNG storage facilities under either section 3 of the NGA for imported LNG supplies or under section 7 of the NGA for liquefied domestic natural gas facilities, the Commission makes such authorization subject to specific reporting conditions.[17] These conditions require that an LNG storage operator report to Commission staff within 48 hours any significant non-scheduled event.[18] In the event an abnormality is of significant magnitude to threaten public or employee safety, cause significant property damage, or interrupt service, notification is required to be made immediately, provided that making such notification shall not unduly interfere with any necessary or appropriate emergency repair, alarm, or other emergency procedure. Further, on June 23, 2006, as noted by Paiute in its comments, the OEP Director sent all LNG storage operators a letter providing guidance and instructions for reporting significant incidents and reiterating and reinforcing the reporting conditions applicable to LNG storage operators.

23. In view of the above-described reporting requirements already applicable to LNG facilities, the Commission agrees that it is not necessary to make the new reporting requirements of § 260.9 applicable to such facilities. Therefore, revised § 260.9 will specifically exclude the reporting of damage to LNG facilities.

24. However, Paiute's comments have caused the Commission to identify wording in existing and proposed § 260.9 which needs to be revised in order to avoid the potential for a significant gap in reporting. Specifically, the current and proposed wording of § 260.9 provide for the reporting of damage and service interruptions only with respect to natural gas facilities operated under ''certificate'' authorization from the Commission. Since import and export facilities authorized under section 3 of the NGA are not certificated facilities, § 260.9 does not explicitly address these facilities. In particular, the Commission is concerned that the reporting requirements of § 260.9 do not presently specifically apply to border crossing facilities authorized under NGA section 3. Such facilities, which are used to import or export gas between the United States and Canada or Mexico, are of national security interest, as evidenced by the requirement, pursuant to Executive Order Nos. 10485 and 12038, dated September 3, 1953, and February 3, 1978, respectively, and the Secretary of Energy's Delegation Order No. 00–004.00A, effective May 16, 2006, that applicants for such facilities must accept Presidential Permits granted by the Commission after consultation with the Secretary of State and the Secretary of Defense.[19] Under the conditions of a Presidential Permit, the President of the United States may determine that the safety of the United States demands that the United States take possession and control of any facilities operated under the Presidential Permit.[20] Section 260.9 is revised to ensure that NGA section 3 non-LNG facilities are subject to the reporting requirements.

V. Summary of Final Rule's Regulations

25. Section 260.9(a) currently requires that natural gas companies report serious service interruptions. The amended regulations add a new requirement to § 260.9 in revised subparagraph (a)(1) that natural gas companies report (i) damage to natural gas facilities from a hurricane or other natural disaster or terrorist activity that results in loss of or reduction in pipeline throughput or storage deliverability, and (ii) when the damaged facilities' pipeline throughput or storage deliverability has been fully restored. Section 260.9 also is amended, as reflected in revised subparagraph (a)(2), to provide that, in the event of damage to a natural gas company's jurisdictional natural gas facilities by reason other than hurricane, earthquake or other natural disaster or terrorist activity, the natural gas company should report such damage if, in the natural gas company's judgment, such damage creates the potential for serious delivery problems on its own system or the pipeline grid.

26. Section 260.9(b) is amended to remove the reference to ''telegraph'' and to require that natural gas companies make required reports of interruptions to service or damage to facilities by e-mail or, as currently provided for in § 260.9(b), facsimile transmission. All reports shall be due at the earliest feasible time after an interruption of service or damage to pipeline facilities for which a report is required pursuant to subparagraph (a)(1) or provided for in subparagraph (a)(2).

27. The information required by § 260.9(b) is revised to reflect the addition of the proposed new requirement that natural gas companies report damage to facilities and subsequently report when the damaged facilities have been repaired. Revised § 260.9(b) requires that a report of service interruption or damage to natural gas facilities state:

(1) The location of the service interruption or damage to natural gas pipeline or storage facilities;

(2) The nature of any damage to pipeline or storage facilities;

(3) Specific identification of the facilities damaged;

(4) The time the service interruption or damage to the facilities occurred;

(5) The customers affected by the service interruption or damage to the facilities;

(6) Emergency actions taken to maintain service; and

(7) Company contact and telephone number.

28. Section 260.9(b) also is revised to require that a company make a subsequent report stating when pipeline throughput or storage deliverability has been restored.

29. Section 260.9(d) is revised to change, from 20 days to 30 days following a service interruption or damage to facilities, the time within which a natural gas pipeline company must furnish to the Commission a copy of any incident report required to be made to the U.S. Department of

[17] *See, e.g.*, Sabine Pass LNG, L.P. and Cheniere Sabine Pass Pipeline Company, 109 FERC ¶ 61,324 (2004) at Appendix B, Environmental Condition 44.

[18] Examples of reportable LNG-related incidents set forth in the conditions include, but are not limited to, fires; explosions; free flow of LNG for five minutes or more that results in pooling; unintended movement or abnormal loading by environmental causes, such as an earthquake, landslide or flood, that impairs the serviceability, structural integrity, or reliability of an LNG facility; any crack or other material defect that impairs an LNG facility's structural integrity or reliability; any malfunction or operating error that causes a dangerous rise in the pressure of an LNG facility; any leak that constitutes an emergency; or any safety-related condition that could lead to an imminent hazard and cause a 20 percent reduction in operating pressure or shutdown of operation of an LNG facility.

[19] *See, e.g.*, Clark Fork & Blackfoot, L.L.C. and EnCana Border Pipelines Limited, 115 FERC ¶ 61,131 (2006).

[20] *Id.*, at Appendix, Presidential Permit, Article 10.

Transportation under the Natural Gas Pipeline Safety Act of 1968.

30. Section 260.9(e) currently requires that a company send copies of reports of service interruptions to state commissions. Section 260.9(e) is revised by adding a new requirement that a company also must send state commissions copies of reports of damage to facilities required by revised subparagraph (a)(1)(i) and (ii).

VI. Environmental Analysis

31. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[21] As stated in the NOPR, no environmental consideration is raised by promulgation of a rule that is procedural in nature or that does not substantially change the effect of legislation or regulations being amended.[22] The regulations adopted herein make changes to the type of information to be provided to the Commission by pipeline companies and the way it is provided, and slightly alter the timeframe (giving the companies more time) to file with the Commission a copy of the incident report required to be filed with the U.S. Department of Transportation. The modified procedures will not substantially change the regulatory requirements to which pipeline companies are currently subject. Accordingly, the preparation of an environmental document is not required.

VII. Regulatory Flexibility Act Certification

32. The Regulatory Flexibility Act of 1980 (RFA)[23] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect. Under the industry standards used for the RFA, a natural gas pipeline company qualifies as a ''small entity'' if it has annual receipts of $6.5 million or less.

33. Most companies regulated by the Commission do not fall within the RFA's definition of a small entity.[24] Approximately 114 natural gas companies are potential respondents subject to the additional reporting requirements adopted by this rule. For the year 2004 (the most recent year for which information is available), 32 companies had annual revenues of less than $6.5 million.

34. Section 260.9 of the regulations already requires natural gas companies to report serious service interruptions. Thus, the new reporting requirements will only increase the number of reports that a company must file to the extent that damage to facilities is the result of a natural disaster or terrorist action and does not result in a loss of or reduction in service. Further, the required information will already be known and identified by companies and can be submitted either by e-mail or facsimile. While the revised provisions of § 260.9 also encourage natural gas companies to report damage to jurisdictional facilities as the result of occurrences other than natural disasters and terrorist activity if, in the natural gas company's judgment, such damage may create the potential for serious delivery problems on its system on the pipeline grid, such reporting is in the respondent's discretion. In view of these considerations, the Commission hereby certifies that this Final Rule's amendments to the regulations will not have a significant impact on a substantial number of small entities.

VIII. Information Collection Statement

35. Office of Management and Budget (OMB) regulations require that OMB approve certain reporting, record keeping, and public disclosure (collections of information) requirements imposed by agency rules.[25] Pursuant to OMB regulations, the Commission is submitting these reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act of 1995 (PRA).[26] Upon approval of a collection of information OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

36. Interested persons may obtain information on the reporting requirements by contacting: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 [Attention: Michael Miller, Office of the Executive Director, Phone: (202) 502–8415, fax: (202) 273–0873, e-mail: *michael.miller@ferc.gov*].

37. As discussed above, § 260.9 of the Commission's regulations already requires natural gas companies to report serious service interruptions. The new requirements will only increase the number of reports that a pipeline company is required to file to the extent that damage to facilities is the result of a natural disaster or terrorist activity and does not cause an interruption of service. Since these reports are event-driven, it is possible that there will be no additional reports filed at all if the pipelines do not experience any hurricane, other act of nature, or act of terrorism in a year. While the revised provisions of § 260.9 also encourage natural gas companies to report damage to jurisdictional facilities as the result of occurrences other than natural disasters and terrorist activity if, in the natural gas company's judgment, such damage may create the potential for serious delivery problems on its system on the pipeline grid, such reporting is in the respondent's discretion.

38. Information regarding damage to facilities will be readily ascertainable by companies and may be submitted either by e-mail or facsimile. Such electronic submission of reports will reduce the number of data entry errors, permit Commission staff to analyze data in a timely manner, and provide for storage of data on digital storage media. The new rule eliminates the no longer feasible option of filing by telegraph. It is expected that electronic filing will save time and resources since electronic filings require fewer personnel than are needed for paper processing and mailing. The integrity of the data should be improved because the Commission and companies subject to its jurisdiction will be able to correct errors more promptly. The Commission has initiated consultation with DOT/Pipeline Safety to pursue the commenters' recommendation that the Commission and other Federal agencies cooperate to develop a unified reporting system that would minimize duplicative filing requirements.

39. FERC–576, ''Report of Service Interruptions,'' identifies the Commission's information collection relating to Part 260, ''Statements and Reports (Schedules),'' of the regulations which apply to natural gas pipeline companies having facilities subject to

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[21] Order No. 486, Regulations Implementing the National Environmental Policy Act, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986–1990 ¶ 30,783 (1987).

[22] 18 CFR 380.4(a)(2)(ii) (2006).

[23] 5 U.S.C. 601–612.

[24] 5 U.S.C. 601(3), citing section 3 of the Small Business Act, 15 U.S.C. 623. Section 3 of the SBA defines a ''small business concern'' as a business which is independently owned and operated and which is not dominant in its field of operation. The Small Business Size Standards component of the North American Industry Classification System (NAICS) defines a small natural gas pipeline company as one that transports natural gas and whose annual receipts (total income plus cost of goods sold) did not exceed $6.5 million for the previous year.

[25] 5 CFR 1320.11 (2005).

[26] 44 U.S.C. 3507(d) (2005).

the Commission's jurisdiction under the Natural Gas Act. This Final Rule establishes a new requirement that natural gas pipeline companies report damage to jurisdictional facilities as the result of natural disasters and terrorist activity and report when damaged facilities are fully restored to service. The regulations maintain the existing requirement that natural gas companies report serious interruptions of service and report restoration of service. The regulations also require natural gas pipeline companies to submit copies of required damage reports to relevant state agencies and maintain the requirement that copies of serious service interruptions be submitted to the relevant state agencies. The rule provides an additional 10 days for the pipeline company to file with the Commission a copy of any incident reporting form required to be filed within 30 days of the incident with the U.S. Department of Transportation pursuant to the Natural Gas Pipeline Safety Act of 1968.

40. *Public Reporting Burden:* Three commenters stated that the Commission's burden estimates in the NOPR were too low,[27] and five commenters felt that the requirements were overly broad and burdensome.[28] Further, six commenters stated their concerns about the duplication of the information that is provided to the Commission and to the Department of Transportation.[29] As discussed above, it was not the Commission's intention to require that natural gas companies report accidents, equipment failures or other occurrences having minimal effect on normal operations. Rather, the Commission's limited objective in adopting additional reporting requirements is to ensure that natural gas companies report damage as the result of hurricanes or other natural disasters or terrorist activities since these events present the potential for serious destabilization of the nations' gas infrastructure, as demonstrated following Hurricanes Katrina and Rita. Therefore, the Final Rule revises the proposed regulations to limit the scope of the new reporting requirements accordingly. Further, the Final Rule revises the proposed regulations to exclude LNG facilities from the scope of the reporting requirements under § 260.9, as recommended in the comments. Finally, while the Final Rule clarifies that the § 260.9 reporting requirements cover non-LNG facilities authorized under section 3 of the NGA, we have explained that there are few such facilities and they generally are limited to a few hundred feet of pipeline extending from the international borders. In view of these revisions and clarifications in this Final Rule, we find that the NOPR's estimates of reporting burden remain appropriate and believe that commenters' concerns should be assuaged. While the provisions of revised § 260.9 encourage natural gas companies to also report damage to jurisdictional facilities as the result of causes other than natural disasters and terrorist activity, if the natural gas company believes such damage presents the potential for causing serious delivery problems on its system or the pipeline grid, such additional reporting is not mandatory.

41. In light of the above discussion, the burden estimates for complying with the additional filing requirements of this rule pursuant to the procedures in the amended § 260.9 of the Commission's regulations are the same as estimated in the NOPR issued in this proceeding on June 9, 2006, as set forth below:

Data collection	Number of respondents	Number of responses	Hours per response	Total hours
FERC–576	15	35	2	70

Total Annual Hours for Collection: 70.

These are mandatory information collection requirements.

Information Collection Costs: The Commission sought comments about the time and corresponding costs needed to comply with this requirement. No comments were received. Because of the regional differences and the various staffing levels that will be involved in preparing the documentation (legal, technical and support) the Commission is using an hourly rate of $150 to estimate the costs for filing and other administrative processes (reviewing instructions, searching data sources, completing and transmitting the collection of information). The estimated annual cost is anticipated to be $10,500 (70 hours × $150).

Title: FERC 576 ''Report of Service Interruptions.''

Action: Information Collection.

OMB Control No.: 1902–0004.

Respondents: Natural gas companies/business or other for-profit.

Frequency of Responses: On occasion.

Necessity of Information: The amended regulation revises the reporting requirements for service interruptions and damage to facilities subject to the Federal Energy Regulatory Commission's jurisdiction. The information filed with the Commission apprises it of serious pipeline service interruptions and also of serious damage to the nation's natural gas pipeline infrastructure. The amendment enhances this information by requiring filers to describe specifically which facilities have been damaged and how the damage occurred.

42. Comments on the Final Rule may also be sent to the Office of Management and Budget. For information on the requirements, submitting comments on the collection of information and the associated burden estimates including suggestions for reducing this burden, please send your comments to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 (Attention: Michael Miller, Office of the Executive Director, (202) 502–8415; or send comments to the Office of Management and Budget (Attention: Desk Officer for the Federal Energy Regulatory Commission, fax: 202–395–7285, e-mail: *oria_submission@omb.eop.gov*, and reference this rulemaking Docket No. RM06–18–000 in your submission.

IX. Document Availability

43. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington DC 20426. From FERC's Home Page on the Internet, this information is available in the Commission's document management system, eLibrary. The full text of this document is available in eLibrary in PDF and Microsoft Word format for viewing, printing, and

[27] Boardwalk Pipeline, Williston Basin, and NiSource.

[28] Duke Energy, Boardwalk Pipeline, Williston Basin, INGAA, and NiSource.

[29] AGA, INGAA, Duke Energy, Boardwalk Pipeline, Williston Basin, and NiSource.

downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

44. User assistance is available for eLibrary and the FERC's Web site during normal business hours. For assistance, please contact Online Support at 1–866–208–3676 (toll free) or (202) 502–6652 (e-mail at *FERCOnlineSupport@FERC.gov*), or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659 (e-mail at *public.referenceroom@ferc.gov*).

X. Effective Date

45. These regulations are effective August 29, 2006. Section 553(d) of the APA [30] generally requires a rule to be effective not less than 30 days after publication in the **Federal Register** unless good cause is found to shorten the time period. The need for this rule to fill a gap in the Commission's reporting requirements was identified as the result of the Hurricanes Rita and Katrina. Another hurricane season is in progress. Therefore, it is crucial that this rule's reporting requirements be in effect immediately to ensure that the Commission has adequate information to monitor the nation's natural gas infrastructure and identify any gas supply delivery problems and possible paths to reroute gas supplies around facilities damaged by a hurricane. Accordingly, the Commission finds good cause to make this rule effective immediately upon publication in the **Federal Register**.

XI. Congressional Notification

46. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this rule is not a major rule within the meaning of section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.[31] The Commission will submit the Final Rule to both houses of Congress and the Government Accountability Office.[32]

List of Subjects in 18 CFR Part 260

Natural gas, Reporting and recordkeeping requirements.

By the Commission.

Magalie R. Salas,

Secretary.

■ In consideration of the foregoing, the Commission amends Part 260 of Chapter I, Title 18, Code of Federal Regulations, as follows.

[30] 5 U.S.C. 553(d) (2006).

[31] 5 U.S.C. 804(2) (2000).

[32] 5 U.S.C. 801(a)(1)(A) (2000).

PART 260—STATEMENTS AND REPORTS (SCHEDULES)

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

■ 2. Section 260.9 is amended by revising the section heading and paragraphs (a), (b), (d) and (e) to read as follows:

§ 260.9 Reports by natural gas pipeline companies on service interruptions and damage to facilities.

(a)(1) Every natural gas company must report to the Director, Division of Pipeline Certificates, at the earliest feasible time:

(i) Damage to any jurisdictional natural gas facilities other than liquefied natural gas facilities caused by a hurricane, earthquake or other natural disaster or terrorist activity that results in a loss of or reduction in pipeline throughput or storage deliverability; and

(ii) Serious interruptions of service to any shipper involving jurisdictional natural gas facilities other than liquefied natural gas facilities. Such serious interruptions of service shall include interruptions of service to communities, major government installations and large industrial plants outside of communities or any other interruptions which are significant in the judgment of the pipeline company. Interruptible service interrupted in accordance with the provisions of filed tariffs, interruptions of service resulting from planned maintenance or construction and interruptions of service of less than three hours duration need not be reported.

(2) In the event of damage to a natural gas company's jurisdictional natural gas facilities other than liquefied natural gas facilities by reason other than hurricane, earthquake or other natural disaster or terrorist activity, the natural gas company should report such damage if, in the natural gas company's judgment, such damage creates the potential for serious delivery problems on its own system or the pipeline grid.

(b) Any report of damage to facilities required by paragraph (a)(1)(i) of this section, any report of service interruption required by paragraph (a)(1)(ii) of this section and any report made pursuant to paragraph (a)(2) of this section in a natural gas company's discretion must be submitted by the natural gas company by e-mail to *pipelineoutage@ferc.gov* or by facsimile transmission to the Director, Division of Pipeline Certificates, Office of Energy Projects at FAX number (202) 208–2853.

(1) Reports required by paragraph (a)(1)(i) or (ii) or made in a natural gas company's discretion pursuant to paragraph (a)(2) shall be made at the earliest feasible time and must state:

(i) The location and cause of the service interruption or damage to natural gas pipeline or storage facilities;

(ii) The nature of any damage to pipeline or storage facilities;

(iii) Specific identification of any facilities damaged;

(iv) The time the service interruption or damage to facilities occurred;

(v) The customers affected by the interruption of service or damage to facilities;

(vi) Emergency actions taken to maintain service; and

(vii) Company contact and telephone number.

(2) Following a report required by paragraph (a)(1)(i) of this section of damage to natural gas facilities resulting in loss of pipeline throughput or storage deliverability or a report pursuant to paragraph (a)(2) of this section in a natural gas company's discretion, the natural gas company shall report to the Director, Division of Pipeline Certificates, at the earliest feasible time when pipeline throughput or storage deliverability has been restored.

* * * * *

(d) In any instance in which an incident or damage report involving jurisdictional natural gas facilities is required by Department of Transportation reporting requirements under the Natural Gas Pipeline Safety Act of 1968, a copy of such report shall be submitted to the Director, Division of Pipeline Certificates, within 30 days of the reportable incident.

(e) When a report of damage to facilities is required by paragraph (a)(1)(i) of this section or a report of service interruption is required by paragraph (a)(1)(ii) of this section, a copy of the e-mail or facsimile report required pursuant to paragraph (b) of this section must be sent to each State commissions for the States in which the reported service interruptions or damage has occurred.

[FR Doc. E6–14281 Filed 8–28–06; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1309

[Docket No. DEA–266F]

RIN 1117–AA96

Controlled Substances and List I Chemical Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final Rule.

SUMMARY: This final rule establishes the fee schedule for DEA registration and reregistration fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals to appropriately reflect all costs associated with its Diversion Control Program for the conduct of activities as mandated by 21 U.S.C. 822 and 958. Specifically, this final rule revises the fee schedule for controlled substances and List I chemical handlers so that all manufacturers, distributors, importers, exporters, and dispensers of controlled substances and of List I chemicals pay an annual fee, by registrant category, irrespective of whether they handle controlled substances or List I chemicals. In doing so, this rule implements clarifications to the Diversion Control Program and the Diversion Control Fee Account made by Congress in the Consolidated Appropriations Act of 2005 (Pub. L. 108–447) that amended 21 U.S.C. 886a.

EFFECTIVE DATE: This rule is effective November 1, 2006. The new fee schedule will be in effect for all new applications postmarked on or after November 1, 2006 and for all renewal applications postmarked on or after November 1, 2006.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Drug Enforcement Administration published a Notice of Proposed Rulemaking in the **Federal Register** on November 16, 2005 (70 FR 69474) to adjust the registration and reregistration fees for controlled substances and List I chemical handlers.

The Controlled Substances Act (CSA) requires that all manufacturers, distributors, dispensers, importers and exporters of controlled substances and List I chemicals obtain an annual registration with DEA (21 U.S.C. 822 and 958(f)). In addition, the CSA, as codified in 21 U.S.C. 821, authorizes the Attorney General, who in turn redelegates this authority to the Administrator of DEA, to ''promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals'' (21 U.S.C. 821 as amended by Pub. L. 108–447).

In October 1992, Congress passed the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 1993 which changed the source of funding for DEA's Diversion Control Program (DCP) from being part of DEA's Congressional appropriation to full funding by registration and reregistration fees through the establishment of the Diversion Control Fee Account (DCFA). The Appropriations Act of 1993 required that ''[f]ees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' The legislation did not, however, provide clarification on what constituted the ''Diversion Control Program,'' thus leaving open the issue as to what fee-setting criteria should be used to determine which costs could be reimbursed from the DCFA.

In response to the Appropriations Act of 1993, DEA published a Notice of Proposed Rulemaking (NPRM) in December 1992 to adjust the registration and reregistration fees for controlled substance registrants (57 FR 60148, December 18, 1992). In the absence of guidelines from Congress regarding the specific criteria to be followed in identifying costs and setting the fees, DEA relied on the plain language of the Appropriations Act of 1993 and proposed fees necessary to cover the costs of the activities that were identified within the budget decision unit known as the ''Diversion Control Program.''

At the time that the Appropriations Act of 1993 was passed, 21 U.S.C. 821 did not extend to chemical control activities; accordingly, there were no registration or fee requirements for handlers of listed chemicals. DEA therefore excluded chemical control costs from its Final Rule implementing the requirements of the Appropriations Act of 1993 (58 FR 15272, March 22, 1993). Congress amended 21 U.S.C. 821 on December 17, 1993 to require reasonable fees relating to ''the registration and control of regulated persons and of regulated transactions'' (Domestic Chemical Diversion Control Act of 1993, 3(a), Pub. L. 103–200, 107 Stat. 2333); however, despite this amendment, DEA continued to endeavor to maintain separate funding for its controlled substances diversion control and its chemical diversion control activities. That is, DEA has paid for its controlled substance diversion control activities through the Diversion Control Fee Account and registration fees and its chemical diversion control activities through appropriated funds.

Following publication of DEA's Final Rule, the American Medical Association (AMA) and others filed a lawsuit objecting to the increase in registration and reregistration fees on the grounds that DEA had failed to provide adequate information as to what activities were covered by the fees and how they were justified. Upon appeal, the United States Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the DCP. In doing so, the court confirmed the boundaries of the DCP that DEA can fund by registration fees, finding that the current statutory scheme (21 U.S.C. 821 and 958) required DEA to set reasonable registration fees to recover the full costs of the DCP. (*AMA* v. *Reno,* 57 F.3d 1129, 1135 (DC Cir. 1995)).

Thus, in the absence of a simple, objective measure by which DCP costs could be identified and the appropriate fees calculated, both DEA and the courts have looked to 21 U.S.C. 821 and 958 to define the guidelines for determining what costs should be included in the calculation of the fees and from whom the fees might be collected.

On November 20, 2004, Congress passed the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 2005 which provided clarification as to the activities constituting the DCP. This Act was included in the Consolidated Appropriations Act of 2005, which was signed into law by the President on December 8, 2004 (Pub. L. 108–447). The Act amended 21 U.S.C. 886a to define the Diversion Control Program as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration,'' which are further defined as the ''activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed

chemicals.'' It also amended the section to provide that reimbursements from the DCFA ''* * * shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities.'' Finally, the Act amended 21 U.S.C. 821 and 958(f) to make the language of those sections consistent with the definition of the DCP (Pub. L. 108–447). The net effect of the amendments is to allow DEA to deposit all registration and reregistration fees (controlled substance and chemical) into the Fee Account and fund all controlled substance and chemical diversion control activities from the account without distinguishing as to the type of activity (controlled substance or chemical) being funded.

While the comingling of controlled substances diversion control and chemical diversion control fees and activities might seem initially to be incongruous, there is, in fact, a significant amount of overlap, both in terms of activities and registrant populations. While it is easy to distinguish between handlers of controlled substances and the handlers of commodity chemicals such as red phosphorous, hydriotic acid, acetic anhydride and nitroethane, the line between handlers of controlled substances and handlers of drug products that contain listed chemicals is blurred considerably. Not only are the drug products that contain List I chemicals often manufactured by controlled substances manufacturers, they are commonly distributed by controlled substances distributors and routinely sold or dispensed by pharmacies, hospitals, and individual practitioners. In calendar year 2004, there were over 30 million prescriptions filled for drug products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, which is still routinely used in veterinary products. There are undoubtedly many instances in which practitioners also provided their patients with free samples of allergy and cough and cold preparations that contain those chemicals. Within this general environment, the use of a single, unified account to fund the controlled substances and chemical diversion control activities of DEA is consistent with the mandates of the law.

DEA is bound by all of the above-referenced statutory requirements in setting fees that recover the ''full cost'' of the Diversion Control Program and its activities, as defined in the most recent lawmaking action. Therefore, DEA has developed this rulemaking according to these legislative mandates.

II. Comments Received

Following publication of the Notice of Proposed Rulemaking on November 16, 2005, DEA received 12 comments to the notice. Three comments were received from practitioners (one physician, one physician assistant, and one dentist); three comments were received from manufacturers or distributors; five comments were received from organizations representing different registrant groups; and one comment was submitted anonymously.

Most commenters raised concern about the increase in fees, particularly for chemical registrants. Two commenters in particular wrote that the increase in fees will have a significant impact on chemical registrants compared to current fee rates and proposed an alternative fee increase. One commenter wrote that programs within DEA should be downsized or eliminated to maintain a ''neutral budget'' and keep costs lower. Three commenters expressed concern that the fee increase is coming at a time when Congress and other entities are re-evaluating medical reimbursements; one physician commented that he would pay the new fee as soon as his reimbursements increased by the same percentage. Another expressed concern that the cost of the increased fees would discourage physicians from registering with DEA and using controlled substances, thus affecting patient care.

Five commenters objected to the removal of the waiver of the chemical registration requirement for controlled substances registrants that handle drug products that are regulated as List I chemicals. The commenters wrote that they believed removal of this waiver would damage the ability of affected registrants to service their customer base and posed an unreasonable hardship. Two commenters also noted that removal of the waiver could create expensive administrative burdens for both registrants and for DEA.

Two registrants objected to the existing fee exemption for certain entities such as some Federal agencies, certain charitable organizations, law enforcement entities, and military personnel. Commenters noted that exempting these organizations results in larger fees for fee-paying registrants and requested reevaluation of this policy by DEA.

Two commenters raised the issue of performance standards tied to the increase in fees and requested clarification on DEA's expected outcomes as a result of the increased fees and the performance measures and metrics DEA has established to assess these outcomes.

One commenter wrote that the required $15 million annual transfer to the U.S. Treasury out of collected fee funds was a significant percentage of the total fees collected, and the commenter urged DEA to request that Congress resume its annual $15 million appropriation to offset this transfer. The commenter wrote that it, too, would work to see this appropriation restored.

One anonymous commenter wrote that medical marijuana is ''most popular in California especially with grayhaired men and women.'' Marijuana is not a licit controlled substance or listed chemical covered by this rulemaking and is not affected by this final rule; accordingly, this comment is not further addressed in this section. Another commenter, a practitioner, submitted a request for reregistration materials through the comment response vehicle. These materials were provided to the commenter, and this matter is not addressed further in this rulemaking.

Three commenters requested that DEA extend implementation of the final rule, noting that the rule comes in the middle of budget cycles for many registrants who had not planned for increased fees as part of their budgets and that it also comes at a time of statutory and other change for the industry. Each of these comments is addressed below.

III. Objection to Fee Increase

Nine of the twelve comments received by DEA expressed opposition to the increase in fees. As described above, 21 U.S.C. 821 (as amended by Pub. L. 108–447) authorizes DEA to collect reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals. In addition, the 1993 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act that established the Diversion Control Fee Account (DCFA) specifically mandated that fees ''shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program'' (21 U.S.C. 886a(3)). Congress, in using the mandatory term ''shall'' as opposed to the discretionary ''may,'' unambiguously required DEA to increase its then-existing registration fees resulting in registrants fully funding DCP expenses. DEA, therefore, lacks discretion in this matter and must fund the DCP totally from registration fees (that is, not from fines, Congressional appropriations or other potential sources).

Accordingly, while DEA recognizes the economic pressures facing practitioners, such as declining Medicaid reimbursements and increasing operating, equipment, and insurance costs, the current statutory scheme requires DEA to set registration fees to recover the full costs of the DCP, while limiting DEA to charge ''reasonable'' fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals. DEA does not have the discretion to partially fund the DCP or to find alternative sources of funding for the program. Rather DEA is mandated by law to fund the DCP fully through registration fees. The registration fees outlined below are set at a level to support the full costs of the DCP as mandated by law.

With clarification of the activities constituting the DCP in the Appropriations Act of 2005, DEA is now required to evaluate the ''full costs'' of the DCP to include all controlled substances and all listed chemical diversion control activities; whereas, previously the only DCP costs supported through registrant fees were controlled substances diversion control costs, and listed chemical diversion control activities were supported through appropriated funds. (See the Notice of Proposed Rulemaking published on November 17, 2005, 70 FR 69474) for additional discussion on this separation of activities.) In fact, operating the DCP as a cohesive whole, that is without distinction in activities between controlled substances and chemical diversion control activities, offers scale efficiencies and ultimately cost savings and improved services for registrants.

The fees set forth in this final rule reflect calculation of the full costs of both the controlled substances and chemical diversion control activities of the DCP. The revised fee structure contained in this final rule includes annual fees (or fee equivalent) ranging from $184 to $2,293. DEA recognizes that the increase in fees may represent a budgeting challenge for registrants, particularly registrants with multiple sites requiring separate registrations (*e.g.,* chain drug stores), however, because the fees do not represent a significant financial burden on registrants, DEA has determined that the fees contained in this final rule are reasonable. DEA expects that among all registrants, mid-level practitioners and chemical distributors may feel the greatest impact of the new fees (see discussion in Section XII). However, for most registrants qualifying as small businesses the revised fee will have a minimal impact, representing from 0.28 percent to as little as 0.01 percent of average annual sales (or income). For registrants that are large businesses with higher annual sales, the impact of the fee is far less.

A. Differences in Fee Increase Among Registrant Categories

Two commenters expressed concern that the fees for chemical registrants under this final rule reflect a higher percentage increase than the change in fees for controlled substances registrants. Commenters noted that fees for chemical manufacturers will increase by approximately 300 percent and that fees for chemical distributors will increase by about 100 percent compared to the current fee structure for these chemical registrants. Commenters proposed an alternative fee increase for these categories based on the same percentage increase as controlled substances manufacturers and distributors.

Currently, chemical handlers pay a user fee that supports only the costs of registration/reregistration and some administrative oversight—not the operating costs of the DEA's chemical diversion control program. With the transfer of DEA's chemical control program costs to the DCFA, chemical registrants must, together with controlled substances registrants, pay a fee to cover the full costs of the DCP. The same circumstance occurred in 1993 with the establishment of the DCFA; controlled substances registrants were faced with a substantial increase in their fees as they transferred from a similar user fee that supported registration costs only to a fee schedule to cover the full costs of DEA's controlled substances diversion control activities. With the transfer of the chemical control program costs to the DCFA and the amendments to the law that reimbursements shall be made without distinguishing between chemical and controlled substances activities, chemical registrants must now be included in the DCFA population and pay the fees necessary to sustain that account.

DEA does not have the discretion to adjust fees according to percentages, such as was proposed by the commenters, as it is required to fully fund the DCP through fees paid by the registrants while also maintaining reasonable fees.

B. Program Costs

One commenter suggested that DEA downsize or eliminate programs to maintain a neutral budget and keep fees low. DEA works diligently to achieve administrative efficiencies in all of its programs, including the Diversion Control Program. Through a scheduled, periodic review process, virtually all aspects of the DCP are inspected to detect any waste, fraud or abuse. All expenditures charged to the DCFA also are reviewed and approved by an independent unit within DEA that reviews, approves, and audits fee-funded expenditures.

Moreover, each of DEA's annual budget requests to Congress, which contain all components of each DEA program, including the DCP, is available for public review. Each budget request is examined and approved by both the Department of Justice and the Office of Management and Budget.

DEA has undertaken several initiatives to streamline aspects of the DCP both for DEA and for registrants. For example, DEA is developing a system to permit the electronic transmission of controlled substances prescriptions through electronic creation, signature and record retention, which will significantly increase the efficiency by which prescriptions are transmitted from prescriber to pharmacy; however, it will not reduce the review requirements of DEA employees that monitor the prescription process for controlled substances. DEA has developed a system that permits the electronic transmission of controlled substances orders which provides increased efficiencies for industry. Moreover, in 2005, DEA underwent an internal reorganization to increase operational efficiencies and keep costs as low as possible. This reorganization shifted the focus from business decision units to activities that support the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals. However, DEA is also subject to costs related to inflation and additional costs of ''doing business'' that face all organizations despite its best efforts to keep these expenses reasonable.

C. Effect of Fee Increase on Practitioner Registration

One practitioner commenter noted concern that increases to annual registrant fees could reduce the number of physicians registering with DEA and using controlled substances as part of patient care. The Controlled Substances Act requires that every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual

registration (21 U.S.C. 822(a)(1) and 822(a)(2)).

DEA notes that the impact of the annual registration fee on practitioners ($184 annual equivalent) is not significant, ranging from a high of 0.28% to a low of 0.13% based on annual income for this registrant category (see discussion below on small business impacts). The majority of registered practitioners (71 percent) are physicians whose annual income averages more than $140,000 and for whom the $184 annual fee equivalent represents approximately 0.13 percent of annual income. Other large practitioner groups in this category include dentists (16 percent of practitioners) for whom the annual fee equivalent represents about 0.14 percent of their average annual income of $133,000 and veterinarians (5 percent of practitioners) for whom the annual fee equivalent equates to 0.25 percent of their average annual income of $76,000. The revised fee will have greater impacts on other types of practitioners (less than 5 percent of all registered practitioners) with lower annual incomes, including nurse practitioners, physician assistants, optometrists, and others for whom the annual fee equivalent has an average impact of approximately 0.16–0.28 percent.

IV. Removal of Waiver for Chemical Registrants Holding an Existing Controlled Substances Registration

Four commenters objected to the removal of the waiver of the registration requirement for persons who distribute, import or export a drug product containing a List I chemical if that person is already registered with DEA to manufacture, distribute or dispense, import or export a controlled substance. Commenters noted that removal of this waiver could dramatically increase the annual registration fees for affected registrants and would damage their ability to service their customers, would pose an ''unreasonable hardship,'' and could adversely affect the List I chemical supply chain since many affected registrants also hold a controlled substances registration. One commenter also noted that removal of this waiver could require significant changes to internal operations for affected registrants who would have to maintain two DEA registrations, imposing significant paperwork, technological and operational burdens. The commenter also suggested removal of the waiver could result in increased operational burdens for DEA.

After careful review of these comments and consideration of the benefits compared to the drawbacks associated with removal of this waiver, DEA has decided to retain the current registration waiver for persons who distribute, import, or export a product containing a List I chemical who already hold a valid DEA registration to manufacture, distribute or dispense, import, or export a controlled substance.

Accordingly, the proposed changes to the waiver provision are removed.

DEA will address registration issues created by passage of the Combat Methamphetamine Epidemic Act of 2005, included in the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177) as part of the Act's implementing regulations.

V. Registration Fee Waivers for Certain Organizations and Persons

Two commenters objected to DEA's fee exemption for certain entities and persons. Currently, government institutions, law enforcement agencies, and military personnel are exempt from fees. In addition, DEA waives fees for some charitable organizations. The commenters objected to these fee waivers suggesting that the process is inequitable and that the net result is higher fees for fee-paying registrants than if these organizations were also required to pay annual registration and reregistration fees. The commenters also asserted that fee-paying registrants are paying a ''hidden contribution'' or ''forced donation'' to charitable organizations, without tax relief, by partially subsidizing their fee requirements.

DEA appreciates these comments. DEA recognizes that exempting certain entities from paying annual fees provides a benefit to some at the expense of others and is evaluating its current practice of exempting certain organizations and persons from annual registration fees. Any changes to this practice will require a separate regulatory process, including notice and comment.

VI. Performance Standards

Two commenters objected to the omission of anticipated outcomes or results expected by DEA as a result of the increased fees. The commenters requested detail on how DEA will track such results and correlate them to the higher fees while recommending the development of a system of metrics, accountability and reporting for the DCP.

The Government Performance and Results Act (GPRA) and the President's Management Agenda (PMA), requires DEA, like all other agencies and components, to provide a budget summary that incorporates performance information on a quarterly basis. In response to these requirements, DEA already integrates budget and performance in order to evaluate the effectiveness of programs relative to long-term, measurable outcome goals.

More specifically, in response to GPRA and the PMA, the DCP's budgetary reporting on outlays from the DCFA includes performance measures that are consistent with DEA's Strategic Plan and that reflect the effectiveness of programmatic activities funded by registrant fees. Among the objectives included in DEA Strategic Plan is continued support to the registrant population through improved technology, including E-commerce and customer support, while maintaining cooperation, support, and assistance from the regulated industry. These efforts, funded through registration fees, are intended to provide benefits to the registrant population such as streamlined processing and improved access to information. They are also intended to reduce the paperwork burden on small businesses; reduce forged or stolen prescriptions; improve authentication and verification of the prescribing or ordering party and reduce processing time; increase overall security; and improve DEA's data quality, agency efficiency and responsiveness in carrying out its mission.

All budget submissions for the Diversion Control Program, like submissions for all programs across DEA, are subject to multiple levels of scrutiny and review within DEA, the Department of Justice, and the Office of Management and Budget before being included in the President's annual Budget Request to Congress.

VII. $15 Million Treasury Transfer

One commenter urged DEA to request that Congress resume the annual $15 million appropriation to offset the requirement that the first $15 million in fee collections be transferred to the Treasury, so that all fee funds may be used for DCP activities. The commenter noted that the annual $15 million transfer represents a ''significant component'' of the amounts to be collected each year.

The Appropriations Act of 1993 requires that DEA transfer the first $15 million of fee revenue to the General Fund of the Treasury each year (21 U.S.C. 886a(1)). For each fiscal year from Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional $15 million to offset this requirement (a total infusion to the DCFA of $90 million). However, beginning in Fiscal Year 1999, Congress

discontinued this additional appropriation. Accordingly, since Fiscal Year 1999, DEA has to include the annual $15 million transfer for fee calculations; that is, DEA must pay for all operational costs of the DCP plus the $15 million transfer out of fee funds collected from registrants.

VIII. Extension of Implementation of the Final Rule

Three commenters requested delay of implementation of the final rule to Fiscal Year 2007 or later. Two commenters requested the delay because of the potential effects of removal of the registration waiver for chemical handlers holding a current controlled substance registration. Following careful review of comments, DEA has decided to keep this waiver intact (see discussion above).

Three commenters requested the delay because of ongoing changes in the industry, including pending state and Federal legislation affecting over-the-counter products containing listed chemicals (such as products containing pseudoephedrine and ephedrine). One commenter noted that such pending legislation could affect distributors carrying these products and therefore DEA registrations and revenue projections. The commenters also noted that the fee modifications are coming at a time when Congress, Federal agencies, and private party payers are exploring methods for reducing reimbursement for prescription drugs. Two commenters wrote that implementation of the final rule would come in the middle of budget cycles for affected registrants and would, therefore, impose financial challenges because of the unanticipated additional expenses in the annual fees, particularly for chain drug stores with many separately registered sites. DEA notes that very few chain registrants have registrations expiring during the current calendar year, thus limiting the potential impact of the fee increase in the current budget cycle. With respect to pending legislation and its possible effect on DEA registrations, DEA takes into account the potential ebb and flow of the registrant population through the retirement of old registrations and new applications for registration when calculating the fees. DEA cannot delay implementation of the new fee schedule as the agency is required, by statute, to recover the full costs of the diversion control program through registration fees.

IX. Overview of Diversion Control Program Responsibilities

The mission of DEA's Diversion Control Program (DCP) is to enforce the provisions of the Controlled Substances Act as they pertain to ensuring the availability of controlled substances and listed chemicals for legitimate uses in the United States while exercising controls to prevent the diversion of these substances and chemicals for illegal uses.

DCP activities include: Program priorities and field management oversight; coordination of major investigations; drafting and promulgating of regulations relating to the enforcement of the CSA and other legislation; establishment of national policy on diversion; fulfillment of U.S. obligations under drug control treaties; advice and leadership on state legislation/regulation; legal control of drugs and chemicals not previously under Federal control; control of imports and exports of licit controlled substances and chemicals; and program resource planning and allocation, among other activities.

As was outlined in the Notice of Proposed Rulemaking, DCP activities funded to date out of the DCFA have been limited to controlled substances diversion control activities, including controlled substances scheduling, registration, investigation, inspection, data collection and analysis, training, establishing production quotas, cooperative efforts with state, local and other Federal agencies, cooperative efforts with the regulated industry, international activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances, and attendant management, personnel, administrative and clerical oversight for the DCP. Fee-fundable activities also have included travel, rent, utilities, supplies, equipment, and services associated with the above-listed activities and activities related to the control of licit controlled substances in the U.S. in which the initial source is foreign. One commenter wrote that administrative expenses should not be paid for out of the DCFA and fee funds; however, the courts have found that all activities and expenses that are directly related to diversion control may be funded with registration and reregistration fees (*AMA* v. *Reno,* 57 F.3d 1129, 1135 (DC Cir. 1995)). Administrative and other operational costs are directly related to the ongoing diversion control efforts of the DCP.

With the inclusion of the chemical diversion control activities in the DCFA and registrant fees by the Appropriations Act, activities related to the overall control of listed chemicals, registration, investigation, inspection, data collection and analysis, cooperative efforts with the regulated industry, related management and administrative positions devoted to diversion control activities, other personnel, and administrative and clerical oversight have been included in the budget calculations that are used to determined the registration fees.

For detail on the specific DCP components to be funded through the DCFA and their associated costs for the Fiscal Year 2006–2008 period covered by this rulemaking, please see DEA's Notice of Proposed Rulemaking, published in the **Federal Register** on November 16, 2005 (70 FR 69474).

X. Budget Changes

In calculating the registration and reregistration fees contained in this Final Rule, DEA has included all DCP activities associated with the ''registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals'' (Pub. L. 108–447).

As discussed in detail in the Notice of Proposed Rulemaking (70 FR 69474), beginning in Fiscal Year 2006, both controlled substance and chemical diversion control costs must be included in the calculation of DCFA registration and reregistration fees. Among the chemical diversion control costs to be included among the ''full costs'' of operating the DCP are a portion of the Office of Training (TR) that specifically supports the activities of the DCP by providing training, guidance and instruction for Diversion Investigators, Diversion Task Force Officers, regulatory agencies, state and local law enforcement, and DCP personnel on controlled substances and chemical diversion control, advanced skills and technical knowledge, and systems applications. Also included are 188 chemical diversion control positions; 12 overseas diversion investigators dedicated to the DCP; and costs associated with the chemical transaction system (CTRANS).

The chemical diversion control costs that will be supported through the DCFA total $24,499,000 for Fiscal Year 2006, $24,880,000 for Fiscal Year 2007, and $25,235,000 for Fiscal Year 2008, accounting for salary growth and inflation.

In addition to the chemical control costs, DEA is including among fee-fundable activities certain other internal resources that support the DEA's diversion control activities, but that, as was discussed more fully in previous rulemakings regarding the DCFA, had previously been supported through appropriated funds despite their direct

relationship to and support of the DCP. These activities include portions of the Office of Chief Counsel, the Office of Forensic Sciences Special Testing Laboratory, and the Special Operations Division; and additional special agent and intelligence analyst costs not previously supported through the DCFA. These components and associated costs are described below. A portion of DEA's internal computer system, Firebird, which already is supported through the DCFA, is included in the fee-fundable cost. The total cost of these non-chemical additions for Fiscal Year 2006 is $26,996,000; for Fiscal Year 2007 is $31,198,000; and for Fiscal Year 2008 is $34,736,000.

In calculating the revised fee schedule, DEA used the Fiscal Year 2006 enacted Appropriation, the President's Budget Request for Fiscal Year 2007, the expected Budget Request for Fiscal Year 2008, and the annual $15 million transfer to the U.S. Treasury as mandated by the CSA (21 U.S.C. 886a). In addition to fee funding all program elements and activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals, DEA must transfer the first $15 million of fee revenue to the General Fund of the Treasury each year as described above (21 U.S.C. 886a(1)).

The Fiscal Year 2006 cost of the DCP is $201,673,000, including a base of $150,178,000 for controlled substances diversion control activities, $24,499,000 in chemical diversion control activities, and $26,996,000 for the additional non-chemical DCP support activities outlined above and described in detail in the November 16, 2005 Notice of Proposed Rulemaking (70 FR 69474), including 52 additional special agent positions; a portion of the Forensic Sciences Special Testing Laboratory; a portion of the Office of Chief Counsel that directly supports diversion control activities; 34 of the 67 field intelligence analysts to be phased in between Fiscal Year 2006–2007 and 6 Headquarters intelligence analysts to support domestic and international diversion control investigations (the remaining 33 field intelligence analysts will be phased in during Fiscal Year 2007); a portion of the Special Operations Division directly related to diversion control efforts; and Firebird operations costs to support communication and infrastructure of the diversion control program.

With the addition of the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2006 is $216,673,000.

The DCP cost for Fiscal Year 2007, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is $212,078,000, as reflected in the President's Budget Request to Congress. Including the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2007 is $227,078,000. The anticipated costs of the DCP for Fiscal Year 2008, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is $218,669,000. Including the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2008 is $233,669,000.

The total amount that must be collected through fee funds for the Fiscal Year 2006–2008 period to fully fund the DCP as mandated by statute is $677,420,000. Without an increase in fees, DEA would fall short by $185,475,536 in funds to support the operations of the DCP. The new fee structure contained in this final rule, therefore, provides the necessary additional funds to ensure that the operational costs of the DCP are fully funded through registrant fees as mandated by statute. As explained above, DEA is required by statute to collect the ''full costs'' associated with operating the DCP.

XI. Calculation of Fees

Based on the total amount necessary to collect for Fiscal Years 2006–2008, DEA developed the specific fee levels for each registrant category according to its current fee structure and the fee-paying ratios that have been in existence since the inception of registrant fees. New fees are shown in the table below. For discussion on DEA's analysis of alternative fee schedules and approaches to calculating registrant fees, please see DEA's 2002 Final Rule (67 FR 51988, August 9, 2002) and its 1996 Final Rule (61 FR 68624, December 30, 1996).

In developing the fee schedule, DEA opted to set the fee level for a three-year period (FY 2006–2008) for two reasons. First, the vast majority of registrants are practitioners who pay a three-year registration fee. These registrants are divided into roughly three separate groups who pay their three-year registration fees on alternate year cycles. Accordingly, the fees below reflect the *total amount* necessary to be collected for the full three-year period (FY 2006–2008), divided by projected registrants and accounting for projected registrant growth by category for each fiscal year. Because different categories of registrants pay different amounts, DEA weighted the number of registrants in each category to ensure the appropriate reflection in the fee schedule. In calculating the final fee schedule reflected below, DEA relied on the latest and current registrant population figures, which have fluctuated since the proposed fees contained in the Notice of Proposed Rulemaking. Because the fees reflect the total amount necessary for collection over a three-year period (Fiscal Years 2006–2008) and because the type and number of registrants varies from year to year, the total amount of fees collected may not equal the requested budget level for any given year. Surplus fees collected in one year are used to offset fee collection shortfalls in another year. In no case are fees spent in excess of the levels enacted by Congress.

In evaluating options to structure the fee schedule, DEA opted to remain with the current fee structure to reduce reporting burdens on registrants and operational costs associated with the DCP which would then be passed on to registrants through annual fees.

To recover the full costs of the DCP as required by statute and as outlined in the preceding sections, DEA is adjusting the fees in accordance with its existing fee structure as shown in the following table. Under this fee schedule, controlled substances registrants and chemical registrants in the same registrant category (*e.g.*, manufacturers) pay the same fee regardless of the substance or chemical being handled. The table also includes the current fees paid by each category.

Registrant class	New annual fee	Current annual fee
Manufacturers (controlled substances)	$2,293	$1,625

Registrant class	New annual fee	Current annual fee
Manufacturers (chemical)	2,293	595 (registration)
Distributors, Importers/Exporters (controlled substances), including reverse distributors	1,147	813
Distributors, Importers/Exporters (chemical)	1,147	595 (registration)
Chemical Retail Distributors	1,147	255 (registration)
Dispensers/Practitioners *	184	130
Researchers, Narcotic Treatment Programs	184	130

* Practitioners, mid-level practitioners, pharmacies, hospitals/clinics, and teaching institutions will pay a fee of $551 for a three-year registration period.

The fee structure above supplants the current fee structure for controlled substances and for chemical registrants. These fees go into effect November 1, 2006.

XI. Related Issues and Waivers

Also by this Notice, DEA is removing differentiation between retail and non-retail distributors of List I chemicals. As of the effective date of this final rule, both retail and non-retail distributors must pay the same fee as described above.

DEA also is withdrawing, by this notice, its Notice of Proposed Rulemaking issued on December 1, 1999, which proposed changes in registration and reregistration fees for manufacturers, distributors, importers, exporters and retail distributors of List I chemicals (64 FR 67216, December 1, 1999).

DEA also is rescinding the 1997 Notice of Fee Waiver published on October 17, 1997 (62 FR 53958) which had waived a portion of the registration fee for non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products.

XII. Effects on Small Businesses

The new registrant fees range from $184 to $2,293 annually per location and per registered business activity. To assess whether the fees could impose a significant economic impact on a small entity, DEA considered whether the fees represent more than one percent of annual revenues for the registrant groups that qualify as small entities under the Small Business Administration (SBA) standards. As discussed below, DEA does not anticipate that the increase in fees will have a significant impact on a substantial number of small entities.

Most DEA registrants qualify as small entities under the SBA standards. Almost all practitioners, who compose 85 percent of all registrants affected by this rulemaking, would be considered small. For practitioners and dispensers, the annual revenues would have to be below $18,400 to have the annual registration fee or equivalent represent more than one percent of revenues. Medical practitioners who are granted authority to handle controlled substances have annual incomes well above that level. Eighty-six percent of all practitioners have annual incomes in excess of $133,000 (Bureau of Labor Statistics salary information). For these practitioners, the new annual fee equivalent of $184 represents less than 0.14 percent of annual income. Physician assistants, the mid-level practitioner with the lowest average salary, have annual salaries of about $65,000 (*ibid.*). For this practitioner group, which represents about 2 percent of registered practitioners, the annual fee equivalent equates to 0.28 percent of annual income.

The higher fees also will not impose a significant burden on dispensers. The average independent pharmacy has sales of almost $2 million according to the National Association of Chain Drug Stores. The smallest clinics have revenue streams higher than $18,400. Among dispensers, the greatest impact of this regulatory fee change will be on chain pharmacies which must hold a registration for each of their locations. The largest chain holds retail pharmacy registrations for more than 5,000 locations as well as almost 40 registrations for its distribution centers. However, these businesses do not qualify as small entities; moreover, for the annual fee to have a significant economic impact, annual revenues would have to be less than $18,400.

DEA acknowledges the concerns of one commenter that fee increases going into effect in the middle of a budget cycle represent a non-controllable and, perhaps, unanticipated, expense for large chain drug stores and chain pharmacy distribution centers; however, as discussed above, only a small fraction of registered chain drug stores must renew their DEA registration in the second half of Calendar Year 2006 and are thus affected by the budgetary implications of the fee increase.

For manufacturers, the 2002 Census data indicate that the value of shipments for the smallest chemical manufacturers (including drugs) ranged from $477,000 to $1.1 million per location (establishment). For this registrant group, therefore, the fee of $2,293 does not represent more than one percent of revenues and will not impose a significant burden.

The one registrant group for which the fees could exceed one percent of revenues and have a significant economic impact is chemical distributors. According to 2004 Duns data, between one percent and 11 percent of the wholesale sectors handling listed chemicals have revenues below $100,000. DEA does not collect financial data on its registrants, but it is possible that some chemical distributor registrants have revenues below $100,000. The increase in the annual reregistration fee for chemical distributors (from $477 to $1,147) may impose a significant burden on these registrants. The increase in the initial registration fee (from a subsidized $116 for certain entities to $1,147 annually) also could be a barrier to entrance for these very small firms. Based on its experience, however, DEA considers it unlikely that any firm that lacked the resources to pay the initial registration fee would be granted a registration because it would be unlikely to have the resources necessary to prevent diversion of the products. Moreover, the new registration fees for all wholesale level activities are far less than the estimated annual fee of $6,400 that chemical registrants would be charged if they were required to independently fund the chemical portion of the diversion control program, as previously discussed in the Notice of Proposed Rulemaking (70 FR 69474, November 16, 2005).

In short, combining all diversion control activities into a single Diversion Control Program, as mandated by the Consolidated Appropriations Act of

2005, results in scale efficiencies and overall reduced costs to all registrants.

XIII. Regulatory Analysis

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has provided above detailed regulatory analysis on the effects of this rulemaking on small entities. The rule will not have a significant economic impact on a substantial number of small entities as discussed in Section XII. While DEA recognizes that this regulation will have a financial effect on registrants, the change in fees is necessary to fully comply with 21 U.S.C. 886a and related statutes, which mandate that DEA establish the fees at a level necessary to recover the full costs of the Diversion Control Program.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). DEA has determined that, because the increased fees will result in a total increase of less than $70 million annually to be collected through fees (that is the difference between the amount collected annually under the previous fee structure and the amount to be collected under the new fee structure), this is not a significant regulatory action; however, it was reviewed by the Office of Management and Budget. The fees to be collected represent an increase of less than $70 million each year for the Fiscal Year 2006–2008 period (based on estimated fee collection figures and compared to the previous fee schedule) and are required to fully support the President's budget for the DCP, as approved by Congress through the appropriations process. Therefore, DEA has no discretion in the establishment of the new fees and is required by law to collect registration and reregistration fees of sufficient amount to fully support the DCP.

Executive Order 12988

This regulation meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate of $118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. The increase in fees for private sector entities and individuals will result in a total increase of less than $70 million annually to be collected through fees (that is the difference between the amount collected annually under the prior fee structure and the amount to be collected under the new fee structure). Moreover, the effect on individual entities and practitioners is minimal. The majority of the affected entities will pay a fee of $551 for a three year registration period (the equivalent of $184 per year) which equates to about 0.13 percent of annual income for most practitioners (the vast majority of all registrants). This rule is promulgated in compliance with 21 U.S.C. 886a that the full cost of operating the DCP be collected through registrant fees.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. While this rule will result in an annual effect on the economy of $100,000,000 or more, in that it will result in the collection of approximately $216–$234 million annually, the increase in fees (that is, the difference between the amount collected annually under the previous fee structure compared to the new fee structure) will result in a total increase of less than $70 million annually. Moreover, it will not result in a major increase in costs or prices or cause significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. This rule is not a discretionary action but rather responds to statutory clarification as to the activities constituting the DCP which, by law, must be fully funded through registrant fees (21 U.S.C. 821 and 958 and 21 U.S.C. 886a, respectively). Moreover, the individual effect on small business registrants is minimal. The majority of registrants considered to be small businesses are practitioners who will pay a three-year registration fee of $551 or the equivalent of $184 per year. For the majority of these practitioners, who compose the vast majority of registrants and registrants qualifying as small businesses, this annual fee equivalent represents about 0.13 percent of their annual mean salary. The impact on other small business entities is described in greater detail in the preceding regulatory analysis.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

■ For the reasons set out above, 21 CFR parts 1301 and 1309 are amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957.

■ 2. Section1301.13 is amended by revising paragraph (e)(1) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1)

Business activity	Controlled substances	DEA application forms	Application fee (dollars)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I–V	New—225 Renewal—225a	2,293 2,293	1	Schedules I–V: May distribute that substance or class for which registration was issued; may not distribute or dispose any substance or class for which not registered. Schedules II–V: except a person registered to dispose of any controlled substance may conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfg. was issued.
(ii) Distributing	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	
(iii) Reverse distributing	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central fill pharmacy, Teaching Institution).	Schedules II–V	New—224 Renewal—224a	551 551	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.
(v) Research	Schedule I	New—225 Renewal—225a	184 184	1	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(vi) Research	Schedules II–V	New—225 Renewal—225a	184 184	1	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances.
(vii) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II–V.	New—363 Renewal—363a	184 184	1	
(viii) Importing	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(ix) Exporting	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	
(x) Chemical Analysis	Schedules I–V	New—225 Renewal—225a	184 184	1	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

* * * * *

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS

■ 3. The authority citation for part 1309 is amended to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 958.

■ 4. Section 1309.11 is revised to read as follows:

§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture for distribution the applicant shall pay an annual fee of $2,293.

(b) For each application for registration or reregistration to distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay an annual fee of $1,147.

■ 5. Section 1309.12 is revised to read as follows:

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture for distribution, distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to ''Drug Enforcement Administration.'' Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14286 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–269F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Embutramide Into Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance embutramide, including its salts, into Schedule III of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of embutramide and products containing embutramide.

DATES: *Effective Date:* September 28, 2006.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Embutramide has the chemical name of N-[2-(m-methoxyphenyl)-2-ethyl-butyl]-*gamma*-hydroxybutyramide (CAS number 15687–14–6). On May 20, 2005, the Food and Drug Administration (FDA) approved a New Animal Drug Application (NADA) for embutramide for marketing under the trade name Tributame™ Euthanasia Solution (70 FR 36336). This product is a combination of embutramide, chloroquine phosphate, and lidocaine for prescription use by intravenous injection for euthanasia of dogs.

On January 26, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that embutramide be placed into Schedule III of the CSA. Enclosed with the January 26, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation to Control Embutramide in Schedule III of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b))

Similar to barbiturates, embutramide has a central nervous system (CNS) depressant effect. It produces a reversible stupor-like state (narcosis) in experimental animals. The effects of embutramide on locomotor activity, rearing, forelimb grip strength, hind-limb splay, and the performance of inverted screen tests on rodents were similar to those of pentobarbital, a classical barbiturate. Embutramide mimics discriminative stimulus effects of pentrobarbital in mice. Methohexital-trained rhesus monkeys self-administer embutramide, suggesting that embutramide produces positive reinforcing effects.

The pharmacological data suggest that the abuse potential of embutramide may be similar to that of CNS depressants such as barbiturates and their products (Schedule III through IV) that are controlled under the CSA. Embutramide as one of the ingredients in the veterinary euthanasia drug product T–61, was previously marketed in the United States. T–16 was withdrawn from the market in 1991. Embutramide is not currently marketed in the United States. During the period of marketing of T–61, a limited number of case reports of suicides, attempted suicides, and accidental exposures involving this and similar embutramide containing products were published in the scientific literature. DEA searched, but has not found, any evidence of abuse or trafficking of either T–61 or embutramide.

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a July 29, 2005, **Federal Register** Notice of Proposed Rulemaking (70 FR 43809), proposed placement of embutramide into Schedule III of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before August 29, 2005.

On August 2, 2005, DEA received a request for an extension of the period in which to comment and request a hearing. The requestor indicated that the additional time was necessary to review the scientific articles and other information cited by DEA in support of its scheduling proposal. DEA granted a 30 day extension of the time to comment and request a hearing, until September 28, 2005 (70 FR 50996).

Comments Received

DEA received two comments in response to the notice of proposed rulemaking. One commenter supported the current proposal to control embutramide as a Schedule III drug. Another commenter supported the proposal to schedule embutramide, the substance, but not its finished pharmaceutical product, Tributame™. This commenter stated that the abuse potential of Tributame™ is non-existent because the negative characteristics such as the presence of a cardiotoxin and the high cost of this formulation outweigh its desirable effects.

DEA does not agree. Careful consideration of all the available data suggests that the amounts of cardiotoxin present in the Tributame™ formulation are insufficient to eliminate the abuse potential of this product. DEA field experience suggests that the cost of a given product is not a consistent predictor of its actual abuse.

DEA also received a request for a hearing on the scheduling of embutramide and a request for an exemption of the product, Tributame™, from scheduling; however, the requestor subsequently withdrew these requests and asked that the scheduling of embutramide be expedited.

Scheduling of Embutramide

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with Section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the notice of proposed rulemaking, the Deputy Administrator of DEA, pursuant to Sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, embutramide has a potential for abuse less than the drugs or other substances in Schedules I and II;

(2) Embutramide has a currently accepted medical use in treatment in the United States; and

(3) Abuse of embutramide may lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Deputy Administrator of DEA concludes that embutramide, including its salts, warrants control in Schedule III of the CSA. The applicable regulations are as follows:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with embutramide, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with embutramide, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before September 28, 2006 and may continue their activities until DEA has approved or denied that application.

Security. Embutramide is subject to Schedule III–V security requirements and must be manufactured, distributed and stored in accordance with Sections 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations on and after September 28, 2006.

Labeling and Packaging. All labels and labeling for commercial containers of embutramide shall comply with requirements of Sections 1302.03–1302.07 of Title 21 of the Code of Federal Regulations and on and after September 28, 2006.

Inventory. Every registrant required to keep records and who possesses any quantity of embutramide must keep an inventory of all stocks of embutramide on hand pursuant to Sections 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on and after September 28, 2006. Every registrant who desires registration in Schedule III for embutramide is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to Sections 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on and after September 28, 2006.

Prescriptions. All prescriptions for embutramide or prescriptions for products containing embutramide are to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for embutramide or products containing embutramide issued on and after September 28, 2006, if authorized for refiling, shall, as of that date, be limited to five refills and shall not be refilled after six months of the date is issuance.

Importation and Exportation. All importation and exportation of embutramide must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on and after September 28, 2006.

Criminal Liability. Any activity with embutramide not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on and after September 28, 2006.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 56 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Embutramide products will be prescription drugs used for the euthanasia of animals. Handlers of embutramide also handle other controlled substances used to euthanize animals which are already subject to the regulatory requirements of the CSA.

Embutramide is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule III of the CSA. This finalrule will allow these entities to have access to a new pharmaceutical product.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.13 is amended by redesignating paragraphs (c)(5) through (c)(13) as paragraphs (c)(6) through (c)(14), and adding a new paragraph (c)(5) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(c) * * *

(5) Embutramide 2020

* * * * *

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14287 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–06–042]

RIN 1625–AA08

Special Local Regulations for Marine Events; Susquehanna River, Port Deposit, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the ''Ragin' on the River'' powerboat race to be held Labor Day weekend, September 2 and 3, 2006, on the waters of the Susquehanna River, adjacent to Port Deposit, Maryland. This action is necessary to provide for the safety of life on navigable waters during the event. The effect will be to restrict general navigation in the regulated area for the safety of participants and vessels transiting the event area.

DATES: *Effective Dates:* 33 CFR 100.535 will be enforced from 10:30 a.m. to 6:30 p.m. on September 2 and 3, 2006. If the event is postponed due to weather, this section will be enforced during the same time period on Monday, September 4, 2006.

FOR FURTHER INFORMATION CONTACT: Ronald Houck, Coast Guard Sector Baltimore, Prevention Department, at (410) 576–2674.

SUPPLEMENTARY INFORMATION: Annually, during Labor Day weekend, the Port Deposit, Maryland Chamber of Commerce sponsors the ''Ragin' on the River'' powerboat race, on the waters of the Susquehanna River. The event consists of approximately 60 inboard hydroplanes and runabouts racing in heats counterclockwise around an oval racecourse. A fleet of spectator vessels is anticipated to gather nearby to view the competition. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels. In order to ensure the safety of the event participants and transiting vessels, 33 CFR 100.535 will be enforced for the duration of the event. Under provisions of 33 CFR 100.535, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander.

In addition to this notice, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers, so mariners can adjust their plans accordingly.

Dated: August 14, 2006.

L.L. Hereth,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. E6–14268 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2006–0484; FRL–8213–9]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the state of Iowa for the purpose of establishing exemptions for indoor sources of air pollution that are not directly vented to the outside but have emissions that leave the building through doors, vents or other means. This revision also clarifies that the permitting exemptions do not relieve the owner or operator of any source from any obligation to comply with any other applicable requirements. The state has demonstrated that air pollution emissions from this equipment are negligible and these exemptions are likely to result in no significant impact on human health or the environment. We have reviewed the state's justification for the revisions and agree with its conclusions.

DATES: This direct final rule will be effective October 30, 2006, without further notice, unless EPA receives adverse comment by September 28, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2006–0484, by one of the following methods:

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

2. E-mail: *Hamilton.heather@epa.gov.*

3. Mail: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. Hand Delivery or Courier: Deliver your comments to Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2006–0484. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://*

www.regulations.gov or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. The Regional Office's official hours of business are Monday through Friday, 8 to 4:30 excluding Federal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Heather Hamilton at (913) 551–7039, or by e-mail at *Hamilton.heather@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This section provides additional information by addressing the following questions:

What is a SIP?
What is the Federal approval process for a SIP?
What does Federal approval of a state regulation mean to me?
What is being addressed in this document?
Have the requirements for approval of a SIP revision been met?
What action is EPA taking?

What is a SIP?

Section 110 of the Clean Air Act (CAA) requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the national ambient air quality standards established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants. These pollutants are: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each Federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

What is the Federal approval process for a SIP?

In order for state regulations to be incorporated into the Federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. This process generally includes a public notice, public hearing, public comment period, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state submits it to us for inclusion into the SIP. We must provide public notice and seek additional public comment regarding the proposed Federal action on the state submission. If adverse comments are received, they must be addressed prior to any final Federal action by us.

All state regulations and supporting information approved by EPA under section 110 of the CAA are incorporated into the Federally-approved SIP. Records of such SIP actions are maintained in the Code of Federal Regulations (CFR) at title 40, part 52, entitled ''Approval and Promulgation of Implementation Plans.'' The actual state regulations which are approved are not reproduced in their entirety in the CFR outright but are ''incorporated by reference,'' which means that we have approved a given state regulation with a specific effective date.

What does Federal approval of a State regulation mean to me?

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, we are authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the CAA.

What is being addressed in this document?

EPA is approving a revision to the SIP for the State of Iowa which establishes exemptions from construction permitting for certain categories of air pollution sources. This revision became state effective on April 19, 2006.

The exemptions include equipment, processes and activities identified in the rule and summarized below. The reader should refer to the Iowa Administrative Code, Chapter 22.1 and the technical support document, which are part of the docket for this rulemaking for more detail concerning the exemptions.

1. An amendment to paragraph 22.1(2) ''m'', which exempts certain storage tanks, raises the maximum capacity and throughput of tanks which may qualify for the exemption.

2. An amendment to paragraph 22.1(2) ''x'' adds an exemption for certain applications of hot melt adhesives from specified closed-pot systems.

3. An amendment to subrule 22.1(2) adds several new exemptions as follows:

a. Product labeling using laser and ink-jet printers meeting specified performance criteria;

b. Equipment related to research and development activities at a stationary source meeting specified emissions and recordkeeping criteria, and meeting the definition of ''research and development activities'' specified in the rule;

c. Regional collection centers, as defined in Iowa's hazardous waste rules, involved in the processing of permitted hazardous materials from households and certain small quantity generators meeting specified quantity restrictions for materials containing volatile organic compounds (VOCs);

d. Cold solvent cleaning machines that are not in-line cleaning machines, which meet specified performance and operational criteria.

We note that the Iowa exemption rule provides that none of the exemptions are available to emissions units, processes, or activities that would trigger the requirements for major new source review (e.g., the prevention of significant deterioration program).

The Iowa Department of Natural Resources (IDNR) has provided a justification document which analyzes the projected emissions increases and air quality impact which may be attributable to the exemptions. For example, Iowa determined that the product labeling exemption would apply to equipment which emits no more than 3.75 tons per year of VOCs, which is the threshold included in the Iowa permit rules previously approved by EPA as de minimis for permitting of minor sources. Similar justifications for the other exemptions are included in the docket for this rulemaking.

Based on review of IDNR's technical evaluation documented in the exemption justification document submitted with the rule and included in the docket, EPA agrees that the emission units and activities exempted by the rule generate emissions that have little or no environmental or human health consequences and can be exempted from the requirement to obtain a construction permit.

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

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

CAA, including section 110 and implementing regulations.

What action is EPA taking?

EPA is approving a revision which adds permitting exemptions to the Iowa Administrative Code. This revision also clarifies that the permitting exemptions do not relieve the owner or operator of any source from any obligation to comply with any other applicable requirements.

We are processing this action as a direct final action because the revisions make minor changes to the existing rules that are noncontroversial. Therefore, we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 30, 2006. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: August 15, 2006.

William W. Rice,

Acting Regional Administrator, Region 7.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart Q—Iowa

■ 2. In § 52.820 the table in paragraph (c) is amended by revising the entry for 567–22.1 to read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED IOWA REGULATIONS

Iowa citation	Title	State effective date	EPA approval date	Explanation
Iowa Department of Natural Resources Environmental Protection Commission [567]				

EPA-APPROVED IOWA REGULATIONS—Continued

Iowa citation	Title	State effective date	EPA approval date	Explanation
*	* * * *	*	*	*
	Chapter 22—Controlling Pollution			
567–22.1	Permits Required for New or Existing Stationary Sources	04/19/06	08/29/06 [*insert FR page number where the document begins*]	
*	* * * *	*	*	*

* * * * *

[FR Doc. E6–14313 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2006–0225; FRL–8207–9]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the South Coast Air Quality Management District's (SCAQMD) portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on May 16, 2006 and concern oxides of nitrogen (NO_X) and oxides of sulfur (SO_X) emissions from facilities emitting 4 tons or more per year of NO_X or SO_X in the year 1990 or subsequent year under the SCAQMD's Regional Clean Air Incentives Market (RECLAIM) program. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: *Effective Date:* This rule is effective on September 28, 2006.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2006–0225 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Lily Wong, EPA Region IX, (415) 947–4114, *wong.lily@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

I. Proposed Action

On May 16, 2006 (71 FR 28290), EPA proposed to approve the following rules into the California SIP. Table 1 lists the rules addressed by this action with the dates that they were adopted by the SCAQMD and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
SCAQMD	2000	General	05/06/05	10/20/05
SCAQMD	2001	Applicability	05/06/05	10/20/05
SCAQMD	2002	Allocations for Oxides of Nitrogen (NO_X) and Oxides of Sulfur (SO_X).	01/07/05	12/21/05
SCAQMD	2005	New Source Review for Trading Requirements	05/06/05	10/20/05
SCAQMD	2007	Trading Requirements	05/06/05	10/20/05
SCAQMD	2010	Administrative Remedies and Sanctions	01/07/05	07/15/05
SCAQMD	2011	Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions.	01/07/05	07/15/05
SCAQMD	[1] 2011	Appendix A: Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions, Chapter 1.	05/06/05	10/20/05
SCAQMD	[1] 2011	Appendix A: Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions, Chapters 2–6 and Attachments A–F.	01/07/05	07/15/05
SCAQMD	2012	Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	01/07/05	07/15/05
SCAQMD	[1] 2012	Appendix A—Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions, Chapter 1.	05/06/05	10/20/05
SCAQMD	2012	Appendix A (Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions, Chapters 2–8 and Attachments A–G.	01/07/05	07/15/05

[1] Protocol Appedix A.

In EPA's proposed approval, we did not clarify that only Chapter 1 of Rule 2011 Protocol Appendix A and Chapter 1 of Rule 2012 Protocol Appendix A were adopted on May 6, 2005 and submitted on October 20, 2005. The remaining portions of those rules were adopted on January 7, 2005 and submitted on July 15, 2005.

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving these rules into the California SIP.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 30, 2006. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: July 26, 2006.

Wayne Nastri,

Regional Administrator, Region IX.

■ Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(337)(i)(C), (342)(i)(C)(2), and (343) to read as follows:

52.220 Identification of plan.

* * * * *

(c) * * *

(337) * * *

(i) * * *

(C) South Coast Air Quality Management District.

(*1*) Rules 2010, 2011, 2011 Protocol Appendix A Chapters 2–6 and Attachments A-F, 2012, and 2012 Protocol Appendix A Chapters 2–8 and Attachments A–G adopted on January 7, 2005.

* * * * *

(342) * * *

(i) * * *

(C) * * *

(*2*) Rules 2000, 2001, 2005, 2007, 2011 Protocol Appendix A Chapter 1, and 2012 Protocol Appendix A Chapter 1 adopted on May 6, 2005.

(343) An amended regulation for the following AQMD was submitted on December 21, 2005, by the Governor's designee.

(i) Incorporation by reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 2002 adopted on January 7, 2005.

[FR Doc. E6–14317 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 173 and 180

[Docket No. PHMSA–03–14405 (HM–220F)]

RIN 2137–AD78

Hazardous Materials: Aluminum Cylinders Manufactured of Aluminum Alloy 6351–T6 Used in SCUBA, SCBA, and Oxygen Services—Revised Requalification and Use Criteria

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Final rule.

SUMMARY: This final rule revises the Hazardous Materials Regulations to address a known safety problem with cylinders manufactured of aluminum alloy 6351–T6. The revisions include an inspection and testing program for early detection of sustained load cracking on cylinders manufactured of aluminum alloy 6351–T6 and used in self-contained underwater breathing apparatus (SCUBA), self-contained breathing apparatus (SCBA), and oxygen services.

DATES: *Effective date:* January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Mark Toughiry, Office of Hazardous Materials Technology, (202) 366–4545, or Kurt C. Eichenlaub, Office of Hazardous Materials Standards, (202) 366–8553; PHMSA, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

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I. Background

Cylinders made of aluminum alloy 6351–T6 are known to be susceptible to sustained load cracking (SLC) in the neck and shoulder area of the cylinder. While the exact cause and mechanism of SLC are not yet fully understood, it appears the cracks primarily originate from the bottom of the neck of the cylinder, at or below the lowest thread position in the interior of the cylinder. The cracking was first brought to PHMSA's attention by persons retesting cylinders under the periodic retest procedures of § 180.209 of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). The majority of SLC-related ruptures have occurred in self-contained underwater breathing apparatus (SCUBA), self-contained breathing apparatus (SCBA), and oxygen services. Since 1994, the Pipeline and Hazardous Materials Safety Administration (PHMSA, we) has been notified of thirteen suspected SLC ruptures of cylinders manufactured of aluminum alloy 6351–T6. Five of the thirteen ruptures resulted in serious injuries. Data from manufacturers show there are thousands of cylinders with small, non-leaking cracks, which are regularly detected during a diligent, detailed requalification process. Manufacturers of cylinders made from the 6351–T6 aluminum alloy have conducted research, testing, and analysis to determine whether there is any correlation between SLC and the probability of a cylinder rupture. The data indicate the cylinders may leak but not rupture when operated at marked service pressure. The data also indicate the probability of cracking increases with an increase in stress levels.

We performed additional metallurgical analysis on several ruptured cylinders to verify the cause of failure and failure mode. (See the metallurgical analysis reports at *http://hazmat.dot.gov/pubs/reports/cylinder/3al_cyls_info.htm*). Those metallurgical analyses revealed SLC caused the cylinder ruptures, but the results were inconclusive as to why the cylinders abruptly ruptured instead of developing leaks. North American manufacturers discontinued using aluminum alloy 6351–T6 prior to 1990, replacing it with aluminum alloy 6061–T6, which is not susceptible to SLC. Cylinders manufactured of aluminum alloy 6351–T6 prior to 1990 include seamless aluminum cylinders marked ''DOT 3AL;'' and those marked with one of the following exemption or special permit numbers: 6498, 7042, 8107, 8364, and 8422. We estimate approximately 3.7 million U.S. cylinders manufactured from aluminum alloy 6351–T6 are currently in use in SCUBA, SCBA, and oxygen services.

On August 8, 2002, we published a final rule (67 FR 51626) amending the requirements of the HMR applicable to the maintenance, requalification, repair, and use of DOT specification cylinders. On May 8, 2003, we issued a subsequent final rule (68 FR 24653) making further revisions in response to appeals. In these final rules, we added the following amendments pertaining to DOT specification cylinders made with aluminum alloy 6351–T6:

- Removed the authorization for the manufacture of DOT specification cylinders made with aluminum alloy 6351–T6 because cylinders manufactured with this aluminum alloy have a greater risk of failure than other aluminum cylinders.
- Prohibited the use of cylinders made with aluminum alloy 6351–T6 for the transportation of materials poisonous by inhalation in Hazard Zone A effective on October 1, 2002. After that date, cylinders made of aluminum alloy 6351–T6 may not be filled and offered for transportation in toxic inhalation hazard service.
- Prohibited the use of cylinders manufactured of aluminum alloy 6351–T6 for gases having pyrophoric properties.
- Required a visual inspection of DOT specification or exemption cylinders made of aluminum alloy 6351–T6 for evidence of SLC in the neck and shoulder area.

On September 10, 2003, the Research and Special Programs Administration, the predecessor agency to PHMSA, published an NPRM (68 FR 53314) proposing to amend HMR requirements applicable to aluminum cylinders manufactured using aluminum alloy 6351–T6. In the NPRM, for cylinders manufactured of aluminum alloy 6351–T6 used in SCUBA, SCBA, and oxygen service, we proposed the following amendments:

- A combined visual and eddy current examination at the time of requalification.
- A new Appendix C to Part 180, to specify the procedure to conduct the eddy current examination.
- Suitable safeguards to protect personnel and facilities should a cylinder fail during the filling process.

Although we believe the thirteen reported SLC ruptures under represent the extent of the SLC issue, we did not have sufficient data to determine whether the SLC-related ruptures extend beyond those services discussed above. Therefore, in the NPRM we requested additional information from manufacturers and users who were aware of a cylinder rupture, whether domestic or foreign, involving a DOT 3AL cylinder or any other cylinder manufactured from aluminum alloy 6351–T6. More broadly, we invited commenters to address the issue of

whether the new inspection requirements proposed in the NPRM should apply to cylinders manufactured of aluminum alloy 6351–T6 and used in services other than SCUBA, SCBA, or oxygen.

On October 26, 2005, based on comments received in response to the NPRM, we published an SNPRM (70 FR 61762) to revise the amendments originally proposed in the NPRM, expand the scope of the rulemaking, and propose additional requirements for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6. In the SNPRM, we proposed to:

- Require a combined visual and eddy current examination at the time of requalification of DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in carbon dioxide service, in addition to those used in SCUBA, SCBA, and oxygen services.
- Impose a 40-year service life for cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, oxygen and carbon dioxide services.
- Add additional training requirements for persons performing the eddy current examination combined with a visual inspection.
- Modify procedures and recordkeeping requirements for eddy current examinations.
- Add a requirement to perform the initial eddy current examination combined with visual inspection for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 within three years of publication of a final rule in the **Federal Register**.

II. Analysis of Comments

We received 10 comments from individuals and organizations, including cylinder manufacturers, representatives of the SCUBA and compressed gas industries, and eddy current test equipment manufacturers. The following companies, organizations, and individuals submitted comments: George Perez (Perez; RSPA–2003–14405–17); Matheson Tri Gas (Matheson; RSPA–2003–14405–18); Air Liquide Canada, Inc. (Air Liquide; RSPA–2003–14405–19); Engineered Inspection Systems (Engineered Inspection; RSPA–2003–14405–20); Western Sales & Testing of Deer Park, Inc. (Western Sales; RSPA–2003–14405–21, RSPA–2003–14405–22, RSPA–2003–14405–23, RSPA–2003–14405–24); Barlen and Associates, Inc. (Barlen; RSPA–2003–14405–25); Luxfer Gas Cylinders (Luxfer; RSPA–2003–14405–26); Brian H. Schumann (Schumann; RSPA–2003–14405–27); Compressed Gas Association (CGA; RSPA–2003–14405–28); and, Amy Morgan Bruecks (Bruecks; RSPA–2003–14405–29). These comments are available in their entirety at the U.S. DOT Docket Management System Web site: *http://dms.dot.gov*, under Docket No. PHMSA–03–14405.

In this final rule, we summarize comments submitted to the docket, address concerns raised by commenters, and discuss our decisions on specific issues.

A. Carbon Dioxide Service

The SNPRM proposed enhanced requalification requirements and a 40-year service life for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, oxygen, and carbon dioxide services. DOT 3AL cylinders used for carbon dioxide service were not included in the original NPRM, but were added to the SNPRM as a result of our own initiative and in response to comments submitted to the NPRM. Comments to the SNPRM are divided on the proposed scope of the rule. Several commenters [Bruecks; Engineered Inspection; Western Sales] recommend expanding the scope of the final rule to include ''all cylinders manufactured of aluminum alloy 6351–T6'' while others [CGA; Barlen] are opposed to expanding the scope beyond cylinders used in SCUBA, SCBA, and oxygen services.

Three commenters [Bruecks; Engineered Inspection; Western Sales] assert cylinders manufactured with aluminum alloy 6351–T6 are dangerous regardless of end use. One commenter [Western Sales] states, ''[T]o simplify, and because I believe that this cylinder is just as dangerous when being used in services not addressed, I believe that any reference to just the 4 specific services be dropped. While I appreciate that there are no catastrophic failures from other user groups, that have been reported, I believe including all cylinders made of 6351–T6 is in the best interest of the cylinder industry and the general public.'' Each of the three commenters recommends amending proposed requirements to include ''all'' cylinders manufactured of aluminum alloy 6351–T6 in the scope of this rule.

We disagree. As previously stated, the majority of cylinder ruptures due to SLC have occurred in SCUBA, SCBA, and oxygen services. We believe these ruptures are directly related to the increased frequencies with which these cylinders are filled and their higher operating pressures. As discussed in the NPRM (68 FR 53314), the probability of SLC increases the more frequently the cylinder is filled. Additionally, cylinders used in SCUBA and SCBA services may be used by a diver or firefighter, substantially increasing the risk of injury or fatality in the event of a cylinder rupture. To date, there have been no reported ruptures involving DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in carbon dioxide, fire extinguisher, or other industrial gas service. Therefore, we are not expanding the scope of the rule to include all DOT 3AL cylinders manufactured of aluminum alloy 6351–T6.

Two commenters [CGA; Barlen] to the SNPRM oppose expanding the scope of the rule to include cylinders used in carbon dioxide service. One commenter [CGA] states, ''SLC is most likely to occur at high pressures. Because cylinders used in [carbon dioxide] service are operated at a lower pressure than those used in SCBA and SCUBA service, the rate of cracking for cylinders in [carbon dioxide] service will be substantially less than for those used in SCBA and SCUBA service. Failure by SLC is not expected to occur in cylinders used in [carbon dioxide] service.''

A comment submitted by City Carbonic Sales Service [City Carbonic; RSPA–2003–14405–13] to the 2003 NPRM (68 FR 53314) asserts a significant number of cylinders used in carbon dioxide service were condemned due to SLC during a three-year in-house survey. However, a commenter [CGA] to the SNPRM disagrees with that assertion, suggesting it was unsubstantiated. The commenter [CGA] states the specific type of cracks observed in the condemned cylinders were not confirmed to be related to SLC, but were most likely due to the over-torquing of these cylinder's taper threaded valves causing cracks to occur in the neck of the cylinder. Two commenters [CGA; Barlen] suggest we are proposing to expand the scope of the rule without providing appropriate technical data to justify such an amendment. These commenters also assert SLC is not likely to develop in DOT 3AL cylinders used in carbon dioxide service and recommend we remove the proposed amendment to include these cylinders in the scope of this rule.

We agree. Therefore, in this final rule, we are removing the proposal expanding the scope of the rulemaking to include cylinders manufactured of aluminum alloy 6351–T6 and used in carbon dioxide service. We agree with the commenter's [CGA] statement that cylinders used in carbon dioxide service generally operate at lower pressures and, thus, have a reduced likelihood of developing SLC. Commenters are correct there have been no reported

cylinder ruptures involving DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in carbon dioxide, fire extinguisher, or other industrial gas services. However, we will continue to monitor these cylinders for evidence of SLC and, if the situation warrants, we may revisit this issue in a future rulemaking.

B. 40-Year Service Life

Currently, cylinders manufactured of aluminum alloy 6351–T6 may be used indefinitely so long as they conform to the requalification test and inspection criteria established in the HMR. The SNPRM proposed a 40-year service life from the date of manufacture for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, oxygen, and carbon dioxide services. Several commenters [CGA; Air Liquide; Barlen] to the SNPRM oppose the 40-year service life proposed for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6. These commenters suggest there is no evidence these cylinders are more likely to be susceptible to SLC as they age and state the proposed amendment lacks the appropriate test data, analysis, or statistical data to support the implication that older cylinders are more likely to develop SLC. These commenters further suggest requalification is the most appropriate method to identify and condemn DOT specification cylinders regardless of their age.

After consideration of these comments, we agree our proposed 40-year service life for cylinders manufactured of aluminum alloy 6451–T6 and used in SCUBA, SCBA, carbon dioxide, and oxygen services is not warranted at this time. We also agree with the commenters' [CGA; Air Liquide; Barlen] statements that the requalification process is an effective method of condemning deteriorated or damaged DOT specification cylinders. Further, there is evidence these cylinders are being voluntarily removed from service as defects are identified through inspections and testing. Therefore, we are not adopting the 40-year service life in this final rule. We will continue to monitor cylinders manufactured of aluminum alloy 6351–T6 for evidence of SLC. If the situation warrants, we may revisit this issue in a future rulemaking.

C. Requalification Schedule for Eddy Current Examinations

Currently, the HMR specify periodic requalification requirements for DOT 3AL cylinders. Periodic requalification includes a volumetric expansion test and visual examination at least once every five years. In the SNPRM, we proposed to require an initial eddy current examination to be performed within three years of the effective date of this final rule, and every 5 years thereafter. Commenters generally support the proposed eddy current examination for cylinders used in SCUBA, SCBA, oxygen and carbon dioxide services. However, several commenters [CGA; Barlen; Matheson; Engineered Inspection; Western Sales; Bruecks] assert the requirement to perform the initial eddy current examination within three years of the effective date of this final rule is unnecessary and may be difficult to comply with. These commenters point out requiring the eddy current examination within three years of the effective date may result in a large number of cylinders pulled from service for requalification twice within a five year period; once for the eddy current examination and once for the scheduled periodic requalification. Several commenters [Engineered Inspection; Western Sales; Bruecks] also assert the eddy current marking could cause confusion because it is required to be marked in association with the test date of the last volumetric expansion test, which could be different from the date of the eddy current examination. Additionally, one commenter [Matheson] is concerned the few companies currently equipped to conduct eddy current examinations may become overloaded with additional test work, resulting in backlogs and test delays. To alleviate confusion and reduce the overall burden, these commenters suggest revising the amendment to require eddy current examinations at the time of a cylinder's next scheduled periodic requalification, which is required every five years.

We agree. In this final rule, we are removing the proposal to perform an eddy current examination within three years of the effective date of this rule, and we are requiring an eddy current examination to be conducted at the cylinder's next required periodic requalification after January 1, 2007, the effective date of this final rule. As a result, the date stamp on each cylinder will accurately reflect the date of the last periodic requalification, including the eddy current and visual examination.

D. Appendix C to Part 180

In the SNPRM, we proposed to add a new Appendix C to part 180 to specify procedures, training, and recordkeeping requirements for performing the eddy current examination and visual inspection of cylinders manufactured of aluminum alloy 6351–T6 and used in SCBA, SCUBA, oxygen and carbon dioxide services. Two commenters [CGA; Engineered Inspection] oppose the requirement to include the location and type of defect on the test report. These commenters assert this information is not necessary and increases the time required to document each examination. One commenter [Engineered Inspection] states, ''details of this nature take much more time to note, and this will increase the amount of time required to perform a test. The end result will be an increased cost to the customer.'' Both commenters recommend removing this requirement since the pass/fail entry on the report is sufficient to indicate whether a defect was detected during the examination.

We agree. Since the eddy current with visual examination is conducted to locate SLC in the neck and shoulder of a cylinder, a pass/fail indication on the test report is sufficient for indicating whether a defect was found during the examination. Therefore, we are removing the proposal to notate the location and type of defect found on the test report.

One commenter [Western Sales] opposes the use of the term ''rejected'' in Appendix C to part 180 to describe cylinders failing the eddy current with visual examination. The commenter asserts the term ''rejected'' implies the cylinder can be repaired and returned to service. The commenter recommends removing the term ''rejection'' and replacing it with ''condemned'' to ensure the cylinder is not returned to service.

We agree. The terms ''rejection criteria,'' and ''rejected'' in Appendix C to part 180 were intended to indicate cylinders failing the eddy current combined with visual examination must be permanently removed from service. We did not intend to allow those cylinders to be reconditioned or reused under any circumstances. The commenter is correct the term is inconsistent with § 180.205(i), which uses the terms ''cylinder condemnation,'' and ''condemned'' to describe cylinders to be permanently removed from service. In this final rule, we are revising the terminology used in Appendix C to part 180 to be consistent with established requalification requirements.

A commenter [Western Sales] also points out the owners name and symbol may not be present (*i.e.* stamped on the cylinder). For this reason, the commenter recommends revising the language requiring a notation of the

cylinder owner's name or symbol to include the words ''if present.''

We agree. It is not necessary to record the owner's name or symbol if it is not present or available at the time of requalification. Therefore, in this final rule, we are revising the language to require requalification records to include the cylinder owner's name or symbol, if present. This revision is consistent with established cylinder requalification recordkeeping requirements.

One commenter [Western Sales] states the serial number must be included in the test report to readily identify the examined cylinder. We agree. We inadvertently omitted the cylinder serial number as a required notation on the test report. We are adding the serial number as information required to be included on the test report to identify cylinders that have been examined and tested.

In addition, we are revising the training requirements for persons who perform eddy current examinations to require an employer to certify they have been trained and tested in accordance with their company's specific eddy current and visual examination procedures. We are removing references to specific training criteria. It is the employer's responsibility to ensure each employee is properly trained in the functions he or she performs. The training requirements are consistent with those specified in § 172.704. Therefore, it is not necessary to list specific training criteria for persons who perform eddy current examinations.

Further, we are removing language from Appendix C to part 180, which required the visual examination to be conducted before and after the eddy current examination. After further review, we believe it is only necessary to conduct one visual inspection either before or after the eddy current examination. Cylinder requalifiers performing the visual examination prior to the eddy current examination may conduct a second visual examination afterwards to confirm the results of the eddy current examination, however, a second visual examination is not required.

E. Operational Controls

In the SNPRM, we proposed to add to the HMR operational controls as recommended safety practices for filling DOT 3AL cylinders manufactured of aluminum alloy 6351–T6. Two commenters [Barlen; Western Sales] oppose the proposed operational controls in the SNPRM. One commenter [Barlen] suggests it is inappropriate to require operational controls to be in place during the filling process unless we intend to provide specific instructions on ''how to fill'' an aluminum alloy cylinder. Another commenter [Western Sales] suggests liability issues could arise from the proposed requirement for only one person to be around a cylinder during the filling operation.

We disagree. The operational controls proposed in the SNPRM are recommendations intended to emphasize persons filling DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 should take additional safety precautions because of the risk of rupture during the filling process. The majority of cylinder ruptures due to SLC have occurred during the filling process. We do not believe the operational controls create potential liability issues because they are recommendations rather than mandatory requirements.

III. Section-by-Section Review

Part 173

Section 173.301

This section establishes general requirements for the shipment of compressed gases in cylinders. Paragraph (d) of this section addresses the transportation of gases capable of combining chemically and prohibits the use of DOT 3AL cylinders for the transportation of pyrophoric gases. In this final rule, we are revising paragraph (d) to remove reference to DOT 3AL cylinders manufactured of aluminum alloy 6351–T6. The prohibition is relocated to a new paragraph (o) titled ''DOT 3AL cylinders made of aluminum alloy 6351–T6.''

Section 173.302

This section addresses requirements for filling cylinders with non-liquefied compressed gases. In this final rule, we are adding a new paragraph (e) to recommend operational controls during the filling process for cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services. The operational controls will reduce the risk of personal injury and property damage during the filling process.

Part 180

Section 180.205

This section establishes general requirements for the requalification of cylinders used to transport hazardous materials. Paragraph (f) sets forth requirements for periodic visual inspections of cylinders. Paragraph (f)(4) specifically requires cylinders manufactured of aluminum alloy 6351–T6 to be inspected for evidence of SLC in the neck and shoulder areas. In this final rule, we are revising paragraph (f)(4) to reference part 180, Appendix C for requalification requirements for DOT 3AL cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services.

Section 180.209

This section establishes requirements for the requalification of DOT specification cylinders. Paragraph (a) of this section includes a table with the requalification criteria for DOT specification cylinders. In this final rule, we are amending the entry for the DOT 3AL cylinder in the ''Requalification of Cylinders'' table to add a reference to new paragraph (m). New paragraph (m) requires cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services to undergo an eddy current and visual examination for early detection of SLC in the neck and shoulder area of the cylinder. We are adding a footnote (3) to specify the eddy current and visual examinations do not apply to cylinders used for carbon dioxide, fire extinguisher or other industrial gas services.

Section 180.213

This section establishes marking requirements for cylinders passing periodic requalification testing. We are revising paragraph (d), which sets forth the specific markings required, and adding a new paragraph (f)(9) to specify the requalification marking requirements for aluminum cylinders successfully passing the combined eddy current examination and visual inspection.

Appendix C to Part 180

In this final rule, we are adding a new Appendix C to part 180 to specify procedures, training, and recordkeeping requirements for performing the eddy current examination and visual inspection of cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services. The new appendix includes:

(1) Eddy current and visual examination and inspection procedures to identify SLC;

(2) Eddy current equipment specifications and record retention requirements;

(3) Cylinder condemnation criteria;

(4) Record retention requirements for examinations and inspections; and,

(5) Training requirements for personnel who perform eddy current and visual examinations and inspections.

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This final rule is published under authority of Federal hazardous materials transportation law (Federal hazmat law; 49 U.S.C. 5101 et seq.). Section 5103(b) of Federal hazmat law authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce. To this end, as discussed in detail earlier in this preamble, the final rule proposes to revise current HMR requirements applicable to aluminum cylinders manufactured using aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services. The purpose of the final rule is to adopt a standard for early detection of SLC to reduce the risk of a cylinder rupture and to establish a service life for cylinders manufactured of aluminum alloy 6351–T6 and used in SCUBA, SCBA, and oxygen services.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. The final rule is not considered a significant rule under the Regulatory Policies and Procedures of the Department of Transportation [44 FR 11034].

The compliance costs associated with this rule are minimal. The regulatory analysis indicates the increased cost for performing an additional non-destructive examination (NDE) and implementing operational controls is small compared to the cost and safety risks of doing nothing; it is significantly less than the cost of immediately removing all cylinders from service. We estimate the cost of the hydrostatic test and internal visual inspection required under the current regulation to be $5 per cylinder for each 5-year periodic requalification. We estimate the cost to conduct the additional visual inspection and eddy current testing required under this final rule combined with the current hydrostatic and visual inspection to be $7.25 per cylinder for each periodic requalification. Therefore, we estimate the additional annual cost associated with this final rule to be $0.45 per cylinder ($2.25 additional requalification costs/5-year requalification period). A number of cylinder owners and retesters are voluntarily utilizing NDE as part of the 5-year requalification testing process for these cylinders. We estimate about 1 million of the total population of 3.7 million cylinders are already subject to enhanced inspection and testing requirements because of voluntary actions by cylinder owners and retesters. Further, annual costs to industry will diminish with time as cylinders are condemned or voluntarily removed from service. Over the next five years, we expect the population of cylinders manufactured of aluminum alloy 6351–T6 to decrease by 500,000, decreasing the number of cylinders not currently subject to voluntary NDE to 2.2 million.

Based on the foregoing analysis, we estimate initial annual costs to comply with the test and inspection requirements of this final rule to be $1.215 million (2.7 million cylinders not currently subject to NDE × $.45 NDE test costs = $1.215 million). Over a 5-year period, compliance costs will decrease to $990,000 (2.2 million cylinders × $.45 NDE test costs). Thus, the total five year compliance cost to industry will be $4.22 million.

The benefits of implementing the provisions of this final rule include avoided fatalities, injuries, and damages resulting from cylinder ruptures caused by SLC. The annual benefits associated with this final rule total $1,183,125, or $5.9 million over 5 years.

The cost-benefit analysis is based on information obtained from cylinder manufacturers, industrial gas companies, cylinder inspectors, and metallurgical evaluation of the ruptured cylinders. A regulatory analysis is available for review in the docket.

C. Executive Order 13132

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This final rule preempts State, local and Indian tribe requirements, but does not adopt any regulation with direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazardous materials transportation law, 49 U.S.C. 5101 *et seq.*, contains an express preemption provision (49 U.S.C. 5125(b)) preempting State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacturing, fabricating, marking, maintenance, reconditioning, repairing, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This final rule covers items 2 and 5 and would preempt any State, local, or Indian tribe requirements not meeting the ''substantively the same'' standard.

Pursuant to § 5125(b)(2) of the Federal hazmat law, if the Secretary of Transportation issues a regulation concerning any of the covered subjects, the Secretary must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. PHMSA has determined the effective date of Federal preemption for these requirements will be one year from the date of publication of a final rule in the **Federal Register**.

D. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this final rule does not have tribal implications, does not impose substantial direct compliance costs, and is not required by statute, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Regulatory Policies and Procedures

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines a rule is not expected to have a significant economic impact on a substantial number of small entities. This rule imposes only minimal new costs of compliance on the regulated industry. Based on the assessment in the regulatory evaluation, I hereby certify that while this rule applies to a substantial number of small entities, there will not be a significant economic impact on those small entities. A

detailed Regulatory Flexibility analysis is available for review in the docket.

This final rule has been developed in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's policies and procedures to promote compliance with the Regulatory Flexibility Act to ensure potential impacts of draft rules on small entities are properly considered.

F. Paperwork Reduction Act

PHMSA currently has an approved information collection under OMB Control No. 2137–0022, Testing, Inspection, and Marking Requirements for Cylinders with 168,431 burden hours, and an expiration date of August 31, 2008. This final rule results in an increase in annual burden and costs based on a new information collection requirement. The amendments regarding the shipment of aluminum cylinders which resulted in a new information collection requirement were submitted to the Office of Management and Budget (OMB) for review and approval at the NPRM stage. At the request of OMB, we are re-submitting this new information collection burden request for final OMB approval at the final rule stage. Upon approval of this information collection by OMB, we will publish a separate notice in the **Federal Register**.

PHMSA has developed burden estimates to reflect changes in this final rule. PHMSA estimates the total information collection and recordkeeping burden would be as follows:

OMB No. 2137–0022:

Total Annual Number of Responders: 103,779.

Total Annual Responses: 168,879.

Total Annual Burden Hours: 271,461.

Total Annual Burden Cost: $2,614,396.

Total One-Time Start-Up Cost: $964,000.

Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it has been approved by OMB and displays a valid OMB control number. Section 1320.8(d), Title 5, Code of Federal Regulations requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. PHMSA specifically requested comments on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these requirements for approval under this final rule.

Direct your requests for a copy of the information collection to Deborah Boothe or T. Glenn Foster, Office of Hazardous Materials Standards (PHH–10), Pipeline and Hazardous Materials Safety Administration (PHMSA), Room 8102, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone (202) 366–8553. In addition, you may submit comments specifically related to the information collection burden to the PHMSA Desk Officer, OMB, at fax number 202–395–6974.

G. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

H. Unfunded Mandates Reform Act

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $120.7 million or more to either State, local or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the rule.

I. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4347), requires Federal agencies to consider the consequences of major federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment. There are no significant environmental impacts associated with this final rule. PHMSA is amending requirements in the HMR pertaining to DOT 3AL aluminum cylinders. The purpose of this rulemaking initiative is to minimize personal injury during the filling process and to adopt a standard for early detection of sustained load cracking of cylinders manufactured of aluminum alloy 6351–T6 in order to reduce the risk of a cylinder rupture. Adopting a standard for early detection of sustained load cracking in order to reduce the risk of a cylinder rupture has no potential for environmental damage or contamination.

J. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

List of Subjects

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 180

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

■ In consideration of the foregoing, we are amending 49 CFR Chapter I, Subchapter C as follows:

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENT AND PACKAGES

■ 1. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.45, 1.53.

■ 2. In § 173.301, paragraph (d) is revised and a new paragraph (o) is added to read as follows:

§ 173.301 General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels.

* * * * *

(d) *Gases capable of combining chemically.* A filled cylinder may not contain any gas or material capable of combining chemically with the cylinder's contents or with the cylinder's material of construction, so as to endanger the cylinder's serviceability.

* * * * *

(o) *DOT 3AL cylinders made of aluminum alloy 6351–T6.* A DOT 3AL cylinder manufactured of aluminum alloy 6351–T6 may not be filled and offered for transportation or transported with pyrophoric gases.

■ 3. In § 173.302, a new paragraph (e) is added to read as follows:

§ 173.302 Filling of cylinders with nonliquefied (permanent) compressed gases.

* * * * *

(e) *DOT 3AL cylinders manufactured of 6351–T6 aluminum alloy.* Suitable safeguards should be provided to

protect personnel and facilities should failure occur while filling cylinders manufactured of aluminum alloy 6351–T6 used in self-contained underwater breathing apparatus (SCUBA), self-contained breathing apparatus (SCBA) or oxygen service. The cylinder filler should allow only those individuals essential to the filling process to be in the vicinity of the cylinder during the filling process.

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 4. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.53.

■ 5. In § 180.205, paragraph (f)(4) is revised to read as follows:

§ 180.205 General requirements for requalification of specification cylinders.

* * * * *

(f) * * *

(4) In addition to other requirements prescribed in this paragraph (f), each specification cylinder manufactured of aluminum alloy 6351–T6 and used in self-contained underwater breathing apparatus (SCUBA), self-contained breathing apparatus (SCBA), or oxygen service must be inspected for sustained load cracking in accordance with Appendix C of this part at the first scheduled 5-year requalification period after January 1, 2007, and every five years thereafter.

* * * * *

■ 6. In § 180.209, in paragraph (a), in the ''Requalification of Cylinders table'' the entry ''DOT 3AL'' is revised, and a new paragraph (m) is added to read as follows:

§ 180.209 Requirements for requalification of specification cylinders.

* * * * *

(a) * * *

TABLE 1.—REQUALIFICATION OF CYLINDERS [1]

Specification under which cylinder was made	Minimum test pressure (psig.) [2]	Requalification period (years)
* * *	* *	* *
DOT 3AL	5/3 times service pressure	5 or 12 (see § 180.209(j) and § 180.209(m) [3]).
* * *	* *	* *

[1] Any cylinder not exceeding 2 inches outside diameter and less than 2 feet in length is excepted from volumetric expansion test.
[2] For cylinders not marked with a service pressure, see § 173.301(e)(1) of this subchapter.
[3] This provision does not apply to cylinders used for carbon dioxide, fire extinguisher or other industrial gas service.

* * * * *

(m) *DOT–3AL cylinders manufactured of 6351–T6 aluminum alloy.* In addition to the periodic requalification and marking described in § 180.205, each cylinder manufactured of aluminum alloy 6351–T6 used in self-contained underwater breathing apparatus (SCUBA), self-contained breathing apparatus (SCBA), or oxygen service must be requalified and inspected for sustained load cracking in accordance with the non-destructive examination method described in the following table. Each cylinder with sustained load cracking that has expanded into the neck threads must be condemned in accordance with § 180.205(i). This provision does not apply to cylinders used for carbon dioxide, fire extinguisher or other industrial gas service.

REQUALIFICATION AND INSPECTION OF DOT–3AL CYLINDERS MADE OF ALUMINUM ALLOY 6351–T6

Requalification requirement	Examination procedure [1]	Sustained Load Cracking Condemnation Criteria [2]	Requalification period (years)
Eddy current examination combined with visual inspection.	Eddy current—In accordance with Appendix C of this part. Visual inspection—In accordance with CGA Pamphlet C–6.1 (IBR; see § 171.7 of this subchapter).	Any crack in the neck or shoulder of 2 thread lengths or more.	5

[1] The requalifier performing eddy current must be familiar with the eddy current equipment and must standardize (calibrate) the system in accordance with the requirements provided in Appendix C to this part.
[2] The eddy current must be applied from the inside of the cylinder's neck to detect any sustained load cracking that has expanded into the neck threads.

■ 7. In § 180.213, paragraph (d) is revised and a new paragraph (f)(9) is added to read as follows:

§ 180.213 Requalification markings.

* * * * *

(d) *Requalification markings.* Each cylinder successfully passing requalification must be marked with the RIN set in a square pattern, between the month and year of the requalification date. The first character of the RIN must appear in the upper left corner of the square pattern; the second in the upper right; the third in the lower right; and the fourth in the lower left. Example: A cylinder requalified in September 2006, and approved by a person who has been issued RIN ''A123'', would be marked plainly and permanently into the metal of the cylinder in accordance with location requirements of the cylinder specification or on a metal plate permanently secured to the cylinder in accordance with paragraph (b) of this section. An example of the markings prescribed in this paragraph (d) is as follows:

A1
9 06 X
32

Where:

''9'' is the month of requalification

''A123'' is the RIN

''06'' is the year of requalification, and ''X'' represents the symbols described in paragraphs (f)(2) through (f)(9) of this section.

* * * * *

(f) * * *

(9) For designation of the eddy current examination combined with a visual inspection, the marking is as illustrated in paragraph (d) of this section, except the ''X'' is replaced with the letters ''VE.''

■ 8. In part 180, Appendix C is added to read as follows:

Appendix C to Part 180—Eddy Current Examination With Visual Inspection for DOT 3AL Cylinders Manufactured of Aluminum Alloy 6351–T6

1. *Examination Procedure.* Each facility performing eddy current examination with visual inspection must develop, update, and maintain a written examination procedure applicable to the test equipment it uses to perform eddy current examinations.

2. *Visual examinations.* Visual examinations of the neck and shoulder area of the cylinder must be conducted in accordance with CGA pamphlet C–6.1 (IBR; see § 171.7 of this subchapter).

3. *Eddy Current Equipment.* A reference ring and probe for each DOT–3AL cylinder manufactured of aluminum alloy 6351–T6 to be inspected must be available at the examination facility. Eddy current equipment must be capable of accurately detecting the notches on the standard reference ring.

4. *Eddy Current Reference Ring.* The reference ring must be produced to represent each cylinder to be tested. The reference ring must include artificial notches to simulate a neck crack. The size of the artificial notch (depth and length) must have a depth less than or equal to 1/3 of the wall thickness of the neck and a length greater than or equal to two threads. The standard reference must have a drawing that includes the diameter of the ring, and depth and length of each notch.

5. *Condemnation Criteria.* A cylinder must be condemned if the eddy current examination combined with visual examination reveals any crack in the neck or shoulder of 2 thread lengths or more.

6. *Examination equipment records.* Records of eddy current inspection equipment shall contain the following information:

(i) Equipment manufacturer, model number and serial number.

(ii) Probe description and unique identification (*e.g.*, serial number, part number, etc.).

7. *Eddy current examination reporting and record retention requirements.* Daily records of eddy current examinations must be maintained by the person who performs the requalification until either the expiration of the requalification period or until the cylinder is again requalified, whichever occurs first. These records shall be made available for inspection by a representative of the Department on request. Eddy current examination records shall contain the following information:

(i) Specification of each standard reference ring used to perform the eddy current examination.

(ii) DOT specification or exemption number of the cylinder; manufacturer's name or symbol; owner's name or symbol, if present; serial number; and, date of manufacture.

(iii) Name of test operator performing the eddy current examination.

(iv) Date of eddy current examination.

(vi) Acceptance/condemnation results (*e.g.* pass or fail).

(vii) Retester identification number.

8. *Personnel Qualification Requirements.* Each person who performs eddy current and visual examinations, and evaluates and certifies retest results must be certified by the employer that he/she has been properly trained and tested in the eddy current and visual examination procedures.

9. *Training Records.* A record of current training must be maintained for each employee who performs eddy current and visual examinations in accordance with § 172.704(d).

Issued in Washington, DC, on August 22, 2006, under authority delegated in 49 CFR part 1.

Thomas J. Barrett,

Administrator.

[FR Doc. E6–14255 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2005–21244]

RIN 2127–AJ59

Federal Motor Vehicle Safety Standards; Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule; delay of compliance date.

SUMMARY: Under the current version of Federal Motor Vehicle Safety Standard (FMVSS) No. 208, vehicles that are manufactured on or after September 1, 2006, are certified to the suppression requirements and have a child restraint anchorage system, commonly referred to as a Lower Anchors and Tethers for Children or ''LATCH'' system, in the right front passenger seating position must suppress the air bag for that position when a child restraint is installed at that position with the LATCH system. However, the standard does not yet specify detailed procedures for installing that type of child restraint in order to conduct the suppression test. In a notice of proposed rulemaking (NPRM) published May 19, 2005, NHTSA proposed the needed installation procedures and proposed an effective date for the final rule following the NPRM. The agency anticipated in the NPRM that a final rule would be issued by September 1, 2006, that provided sufficient leadtime for vehicles to meet the suppression requirements with LATCH-equipped child restraints.

Because we have not completed our response to the comments to the NPRM, this final rule delays, for one year, the compliance date of the requirement for vehicles to meet the air bag suppression requirement with LATCH-equipped child restraints. This delay allows us additional time to publish our final action on the rulemaking.

DATES: The amendments made by this final rule are effective September 1, 2006. The compliance date for the requirement for vehicles to meet the air bag suppression requirements with LATCH-equipped child restraints is delayed until September 1, 2007.

Petitions for reconsideration: Petitions for reconsideration of this final rule must be received not later than October 13, 2006.

ADDRESSES: Petitions for reconsideration of this final rule must refer to the docket and notice number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590, with a copy to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Note that all comments received will be posted without change to *http://dms.dot.gov*, including any personal information provided. Please see the Privacy Act heading under Rulemaking Analyses and Notices.

Docket: For access to the docket to read background documents, go to *http://dms.dot.gov*, or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Carla Cuentas, Office of Crashworthiness Standards, Light Duty Vehicle Division (telephone 202–366–1740, fax 202–493–2739); or Deirdre Fujita, Office of Chief Counsel (telephone 202–366–2992, fax 202–366–3820). Both of these officials can be reached at the National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

Federal Motor Vehicle Safety Standard (FMVSS) No. 208, ''Occupant crash protection'' (49 CFR 571.208), requires passenger vehicles to be equipped with safety belts and frontal air bags for the protection of vehicle occupants in crashes. On May 12, 2000, NHTSA published a final rule to require that air bags be designed to provide improved frontal crash protection for all occupants, by means that include advanced air bag technology (''Advanced Air Bag Rule,'' 65 FR 30680, Docket No. NHTSA 00–7013). Under the Advanced Air Bag Rule, manufacturers are provided several compliance options in order to minimize the risk to infants and small children from deploying air bags, including an option to suppress an air bag in the presence of a child restraint system (CRS).

Manufacturers choosing to rely on an air bag suppression system to minimize the risk to children in a CRS must ensure that the vehicle complies with the suppression requirements when tested with the CRSs specified in Appendix A of the standard (see S19, S21 and S23 of FMVSS No. 208). On November 19, 2003, NHTSA revised Appendix A by adding two CRSs that are equipped with components that attach to a vehicle's LATCH [1] system (68 FR 65179, Docket No. NHTSA 03–16476). On August 20, 2004, the agency responded to a request for additional leadtime by extending the compliance date (from September 1, 2004 to September 1, 2006). Thus, under that final rule, vehicles manufactured on or after September 1, 2006, and certified as meeting the suppression requirements must meet the requirements when tested with the LATCH-equipped CRSs installed on a LATCH system (69 FR 51598; Docket No. NHTSA 2004–18905).

The NPRM

FMVSS No. 208 currently does not provide a specific procedure for installing a LATCH-equipped CRS in a vehicle in order to conduct air bag suppression testing. To address this, NHTSA published an NPRM on May 19, 2005, proposing a specific procedure for installing LATCH-equipped CRSs (70 FR 28878, Docket 21244; extension of comment period, July 13, 2005, 70 FR 40280). The agency believed that the procedure, which was based on how CRSs are installed in the real world, would provide for repeatable and reproducible installation of the child restraints (70 FR 28878; Docket 21244).

II. Extension of Compliance Date

The Alliance of Automobile Manufacturers (the Alliance) submitted several comments on the NPRM. General Motors, a member of the Alliance, also commented separately. These commenters expressed concerns that aspects of the proposed test procedure allowed for ''too much variability to be a suitable test procedure'' (Alliance comment, August 17, 2005), and recommended a number of modifications to improve the procedure.

Because we have not completed our response to the comments to the NPRM, and due to the closeness of the September 1, 2006 compliance date, this final rule delays, for one year, the effective date of the requirement that vehicles manufactured certify that their vehicles comply with the suppression requirements when tested with the LATCH-equipped CRSs. This delay allows us additional time to take final action on the proposal. As to whether additional lead time beyond that provided by the September 1, 2007 date is needed to allow for manufacturer implementation of the test procedures, that issue will be addressed by the final rule completing this rulemaking action (RIN 2127–AJ59).

We find good cause for making this rule delaying the current September 1, 2006 compliance date effective in less than 30 days, *i.e.*, September 1, 2006. For reasons discussed in our proposal, we tentatively concluded that certain amendments should be made that would provide needed guidance to manufacturers, and also that the compliance date of the relevant requirements should be delayed. If the September 1, 2006 compliance date were not changed, the absence of any established test procedures would affect the ability of manufacturers to certify compliance with those requirements.

III. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This rulemaking document was not reviewed by the Office of Management and Budget under E.O. 12866. It is not considered to be significant under E.O. 12866 or the Department's Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). This document delays the date on which a requirement that certain vehicles meet the air bag suppression requirements with LATCH-equipped CRSs is to become effective. Since the delay maintains the status quo, manufacturers will incur no costs as a result of this document The impacts of today's amendment are so minimal so as not to warrant preparation of a regulatory evaluation.

B. Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, 5 U.S.C. 60l *et seq.*, NHTSA has evaluated the effects of this action on small entities. I hereby certify that this final rule will not have a significant impact on a substantial number of small entities. The delay of the effective date preserves the status quo and will not affect the responsibilities of small entities.

C. Executive Order No. 13132

NHTSA has analyzed this final rule in accordance with the principles and criteria set forth in Executive Order 13132, Federalism, and has determined that this rule does not have sufficient Federal implications to warrant consultation with State and local officials or the preparation of a Federalism summary impact statement. The rule will not have any substantial impact on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. However, under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use.

D. National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

[1] ''LATCH'' stands for ''Lower Anchors and Tethers for Children,'' a term that was developed by child restraint manufacturers and retailers to refer to the standardized child restraint anchorage system that vehicle manufacturers must install in vehicles pursuant to FMVSS No. 225 *Child Restraint Anchorage Systems (49 CFR 571.225).* The Latch system is comprised of two lower anchorages and one tether anchorage. Each lower anchorage is a rigid round rod or bar onto which the connector of a child restraint system can be attached. FMVSS No. 225 does not permit vehicle manufacturers to install LATCH systems in front designated seating positions unless the vehicle has an air bag on-off switch meeting the requirements of S4.5.4 of FMVSS No. 208.

E. Paperwork Reduction Act

Under the new procedures established by the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This final rule does not establish any new information collection requirements.

F. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' There are no voluntary consensus standards affecting this final rule.

G. Civil Justice Reform

This final rule will not have any retroactive effect. As noted above in the discussion of Executive Order No. 13132, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). This final rule will not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually.

I. Executive Order 13045

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental, health, or safety risk that NHTSA has reason to believe may have a disproportionate effect on children. This final rule is not subject to the Executive Order because it is not economically significant as defined in E.O. 12866.

J. Executive Order 13211

Executive Order 13211 (66 FR 28355, May 18, 2001) applies to any rule that: (1) Is determined to be economically significant as defined under E.O. 12866, and is likely to have a significantly adverse effect on the supply of, distribution of, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This final rule is not subject to E.O. 13211.

K. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

L. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

■ In consideration of the foregoing, NHTSA amends chapter V of title 49 of the Code of Federal Regulations by amending 49 CFR part 571 as follows:

PART 571—[AMENDED]

■ 1. The authority citation for part 571 of Title 49 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50.

■ 2. Section 571.208 is amended by revising section C of Appendix A, to read as follows:

§ 571.208 Standard No. 208; Occupant crash protection.

* * * * *

Appendix A to § 571.208—Selection of Child Restraint Systems

* * * * *

C. Any of the following forward facing toddler and forward-facing convertible child restraint systems, manufactured on or after December 1, 1999, may be used by the National Highway Traffic Safety Administration to test the suppression system of a vehicle that is manufactured on or after the effective date and prior to the termination date specified in the table below and that has been certified as being in compliance with 49 CFR 571.208 S19, or S21. (Note: Any child restraint listed in this subpart that is not recommended for use in a rear-facing position by its manufacturer is excluded from use in S20.2.1.4):

	Effective and termination dates	
	January 17, 2002	September 1, 2007
Britax Roundabout 161	Effective	Remains Effective.
Britax Expressway		Effective.
Century Encore 4612	Effective	Remains Effective.
Century STE 1000 4416	Effective	Remains Effective.
Cosco Olymp ian 02803	Effective	Remains Effective.
Cosco Touriva 02519	Effective	Remains Effective.
Evenflo Horizon V 425	Effective	Remains Effective.
Evenflo Medallion 254	Effective	Remains Effective.
Safety 1st Comfort Ride 22–400		Effective.

* * * * *

Issued: August 22, 2006.

Nicole R. Nason,

Administrator.

[FR Doc. E6–14256 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA 2006–24497]

RIN 2127–AI93

Federal Motor Vehicle Safety Standards; Occupant Protection in Interior Impact

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule; delay of compliance date.

SUMMARY: Our safety standard on occupant protection in interior impact requires, in part, that light vehicles provide head protection when an occupant's head strikes upper interior components, such as pillars, side rails, headers, and the roof during a crash. While these requirements already apply to most vehicles, the compliance date for altered vehicles and vehicles built in two or more stages is September 1, 2006. In April 2006, we responded to two petitions for rulemaking by proposing certain amendments to the head protection requirements as they apply to these vehicles. We also proposed to delay the compliance date of the requirements for these vehicles until September 1, 2008. Given the short period of time until the current September 1, 2006 compliance date, and as a partial step toward completing action on the April 2006 proposal, we are, by this final rule, delaying the compliance date for one year. This will give us time to fully analyze the comments and reach a decision on other aspects of the proposal, including the proposed additional delay in the compliance date.

DATES: The amendments made by this final rule are effective September 1, 2006. The compliance date for the head impact protection requirements for altered vehicles and vehicles built in two or more stages is delayed until September 1, 2007.

Petitions for reconsideration: Petitions for reconsideration of this final rule must be received not later than October 13, 2006.

ADDRESSES: Petitions for reconsideration of this final rule must refer to the docket and notice number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590, with a copy to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Note that all documents received will be posted without change to *http://dms.dot.gov*, including any personal information provided. Please see the Privacy Act heading under Rulemaking Analyses and Notices.

Docket: For access to the docket to read background documents, go to *http://dms.dot.gov*, or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: The following persons at the National Highway Traffic Safety Administration, 400 7th Street, SW., Washington, DC 20590:

For technical and policy issues: Lori Summers, Office of Crashworthiness Standards, telephone: (202) 366–4917, facsimile: (202) 366–4329, e-mail: *Lori.Summers@dot.gov*.

For legal issues: Edward Glancy, Office of the Chief Counsel, telephone: (202) 366–2992, facsimile: (202) 366–3820.

SUPPLEMENTARY INFORMATION: Federal Motor Vehicle Safety Standard (FMVSS) No. 201, *Occupant Protection in Interior Impact*, requires, in part, that light vehicles provide head protection when an occupant's head strikes upper interior components, such as pillars, side rails, headers, and the roof during a crash. While these requirements already apply to most vehicles, the compliance date for altered vehicles and vehicles built in two or more stages is September 1, 2006.

The Recreation Vehicle Industry Association (RVIA) and the National Truck Equipment Association (NTEA) petitioned the agency to exclude permanently certain types of altered vehicles and vehicles manufactured in two or more stages from these requirements. On April 24, 2006, NHTSA published in the **Federal Register** (71 FR 20932) a document responding to these petitions for rulemaking and proposing certain amendments to the standard.

Based on a careful consideration of both the safety benefits of the upper interior protection requirements, and practicability concerns relating to vehicles built in two or more stages and certain altered vehicles, we proposed to limit these requirements to only the front seating positions of those vehicles. Further, we tentatively concluded that it is appropriate to exclude a narrow group of multi-stage vehicles delivered to the final stage manufacturer without an occupant compartment because of impracticability concerns.

We also proposed to delay the effective date of the head impact protection requirements as they apply to final stage manufacturers and alterers until September 1, 2008.

We received two comments on the proposal, from RVIA and NTEA. Both commenters supported delaying the existing compliance date. The two commenters also each raised a number of issues about certain aspects of our proposal, and asked the agency to provide additional relief.

Given the short period of time until the current September 1, 2006 compliance date, and as a partial step toward completing action on the April 2006 proposal, we have decided, at this time, to delay the compliance date for one year. This will give us time to fully analyze the comments and reach a decision on other aspects of the proposal, including the proposed additional delay in the compliance date.

We find good cause for making this rule delaying the current September 1, 2006 compliance date effective in less than 30 days, i.e., September 1, 2006. For reasons discussed in our April 2006 proposal, we have tentatively concluded that certain amendments should be made that would provide relief to final stage manufacturers and alterers, and also that the compliance date of the relevant requirements should be delayed. If the September 1, 2006 compliance date were not changed, it is likely that some final stage manufacturers and alterers would need to immediately stop producing or altering some of the specialty vehicles they provide.

Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President'spriorities, or the principles set forth in the Executive Order.

This final rule was not reviewed under Executive Order 12866. It is not significant within the meaning of the DOT Regulatory Policies and Procedures. It does not impose any new burdens on manufacturers of vehicles built in two or more stages or vehicle alterers. It only delays the compliance date for certain existing requirements as they apply to multistage vehicles and alterers.

The agency believes that this impact is so minimal as to not warrant the preparation of a full regulatory evaluation.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires agencies to evaluate the potential effects of their rules on small businesses, small organizations and small governmental jurisdictions. I have considered the effects of this rulemaking action under the Regulatory Flexibility Act and certify that it will not have a significant economic impact on a substantial number of small entities.

Under 13 CFR 121.201, the Small Business Administration (SBA) defines small business (for the purposes of receiving SBA assistance) as a business with less than 750 employees. Most of the manufacturers of recreation vehicles, conversion vans, and specialized work trucks are small businesses that alter completed vehicles or manufacture vehicles in two or more stages. While the number of these small businesses is substantial, the economic impact upon these entities will not be significant because this document only delays the compliance date of certain existing requirements as they apply to multistage vehicles and alterers.

C. National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action will not have any significant impact on the quality of the human environment. Accordingly, no environmental assessment is required.

D. Executive Order 13132 (Federalism)

The agency has analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 and has determined that it does not have sufficient federal implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The rule will not have any substantial impact on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. However, under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use.

E. Unfunded Mandates Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually ($120.7 million as adjusted annually for inflation with base year of 1995). The assessment may be combined with other assessments, as it is here.

This rule will not result in expenditures by State, local or tribal governments or automobile manufacturers and/or their suppliers of more than $120.7 million annually. It will not impose any new burdens on manufacturers of vehicles built in two or more stages or vehicle alterers.

F. Executive Order 12988 (Civil Justice Reform)

This rule will not have any retroactive effect. As noted above in the discussion of Executive Order No. 13132, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the State requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending, or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file a suit in court.

G. Paperwork Reduction Act

There are no information collection requirements in this rule.

H. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

I. Privacy Act

Anyone is able to search the electronic form of all documents received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

Regulatory Text

List of Subjects in 49 CFR Part 571

Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

■ In consideration of the foregoing, NHTSA amends chapter V of title 49 of the Code of Federal Regulations by amending 49 CFR part 571 as follows:

PART 571—[AMENDED]

■ 1. The authority citation of part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 2011, 30115, 30166 and 30117; delegation of authority at 49 CFR 1.50.

■ 2. Section 571.201 is amended by revising S6.1.4 through S6.1.4.2 to read as follows:

§ 571.201 Standard No. 201; Occupant protection in interior impact.

* * * * *

S6.1.4 *Phase-in Schedule #4.* A final stage manufacturer or alterer may, at its option, comply with the requirements set forth in S6.1.4.1 and S6.1.4.2.

S6.1.4.1 Vehicles manufactured on or after September 1, 1998 and before September 1, 2007 are not required to comply with the requirements specified in S7.

S6.1.4.2 Vehicles manufactured on or after September 1, 2007 shall comply with the requirements specified in S7.

* * * * *

Issued on: August 22, 2006.

Nicole R. Nason,

Administrator.

[FR Doc. E6–14259 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 404

[Docket No. 060824225–6225–01]

RIN 0648–AU82

Northwestern Hawaiian Islands Marine National Monument

AGENCIES: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC); United States Fish and Wildlife Service (USFWS), Department of the Interior (DOI).

ACTION: Final rule.

SUMMARY: NOAA and the USFWS are issuing final regulations for the Northwestern Hawaiian Islands Marine National Monument. This action codifies the prohibitions and management measures set forth in Presidential Proclamation 8031 establishing the Monument. The rule is effective immediately.

DATES: *Effective date:* These regulations are effective August 25, 2006. Written comments on the information collection requirement must be received by October 30, 2006.

ADDRESSES: Submit written comments regarding the burden-hour estimates or other aspects of the information collection requirements contained in this proposed rule by e-mail to Diana Hynek at *dHynek@noaa.gov.*

Coordinates for the outer boundary of the Monument, the Special Preservation Areas, the Ecological Reserves, and the Midway Atoll Special Management Area can be found at: *http://hawaiireef.noaa.gov/management/.*

FOR FURTHER INFORMATION CONTACT: *NOAA contact:* T. Aulani Wilhelm, Monument Superintendent (NOAA); 6600 Kalanianaole Highway, #300, Honolulu, HI 96825; (808) 397–2657.

FWS contact: Barry Stieglitz, Monument Project Leader (USFWS); Hawaiian and Pacific Islands NWR Complex, 300 Ala Moana Boulevard, Box 50167, Honolulu, HI 96850–5000; 808–792–9540.

State of Hawaii contact: Athline Clark, Special Projects Manager, Department of Land and Natural Resources, Division of Aquatic Resources; 1151 Punchbowl Street, Room 330, Honolulu, HI 96813; (808) 587–0099.

SUPPLEMENTARY INFORMATION: On June 15, 2006, President Bush established the Northwestern Hawaiian Islands Marine National Monument by issuing Presidential Proclamation 8031 (71 FR 36443, June 26, 2006) under the authority of the Antiquities Act (Act) (16 U.S.C. 431). The Proclamation reserves all lands and interests in lands owned or controlled by the Government of the United States in the Northwestern Hawaiian Islands (NWHI), including emergent and submerged lands and waters, out to a distance of approximately 50 nautical miles (nmi) from the islands. The outer boundary of the Monument is approximately 100 nmi wide and extends approximately 1200 nmi around coral islands, seamounts, banks, and shoals. The area includes the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, the Midway Atoll National Wildlife Refuge/Battle of Midway National Memorial, and the Hawaiian Islands National Wildlife Refuge.

The Proclamation appropriated and withdrew the area from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including, but not limited to, withdrawal from location, entry, and patent under mining laws, and from disposition under all laws relating to mineral and geothermal leasing.

The Proclamation provides that the Secretary of Commerce, through NOAA, has primary responsibility regarding the management of the marine areas of the Monument, in consultation with the Secretary of the Interior. The Secretary of the Interior, through the USFWS, has sole responsibility for management of the areas of the Monument that overlay the Midway Atoll National Wildlife Refuge, the Battle of Midway National Memorial, and the Hawaiian Islands National Wildlife Refuge, in consultation with the Secretary of Commerce. Further, the Proclamation provides that nothing in the Proclamation diminishes or enlarges the jurisdiction of the State of Hawaii. The Monument includes state waters, including the Northwestern Hawaiian Islands State Marine Refuge and Kure Atoll Wildlife Sanctuary. The State currently holds the submerged and ceded lands of the NWHI in trust. This public trust is overseen by the Office of Hawaiian Affairs through an amendment to the Constitution of the State of Hawaii. The State of Hawaii has primary responsibility for managing the State waters of the Monument.

The three principal entities with responsibility for managing lands and waters of the Monument—NOAA, USFWS, and the State of Hawaii (collectively, the Co-Trustees)—are working cooperatively and will consult to administer the Monument. The Co-Trustees have established a goal to provide unified management in the spirit of cooperative conservation. This relationship will be further described in a Memorandum of Agreement among the Co-Trustees.

The Proclamation requires restrictions and prohibitions regarding activities in the Monument consistent with the authority provided by the Act. The Proclamation shall be applied in accordance with international law. No restrictions shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law. NOAA and USFWS are promulgating as final regulations the management measures and prohibitions set forth in the Proclamation to codify them in the Code of Federal Regulations. This action will provide additional notice to the public and other interested parties of the terms of the Proclamation and activities that are prohibited or regulated and thereby facilitate improved compliance. Interested parties may view Hawaii Administrative Rules also applicable within the Monument at *http://www.hawaii.gov/dlnr/dar/fish_regs/nwhi.htm.*

These regulations address the requirement in the Proclamation that the Secretaries shall ensure, in addition to other things, that commercial fishing for bottomfish and other associated pelagic species may continue in the Monument for no more than 5 years. Section 404.10 sets out the conditions under which such fishing may continue to be conducted. However, commercial fishing remains prohibited in areas of the Monument not open to such fishing prior to issuance of the Proclamation.

Classification

Administrative Procedure Act

The Secretaries find good cause to waive notice and comment on these regulations, pursuant to 5 U.S.C. 533(b)(B), and the 30-day delay in effective date pursuant to 5 U.S.C. 553(d). Notice and comment are unnecessary and contrary to the public interest because these regulations do not expand on the action already taken by the President in the Proclamation. The Proclamation became effective upon issuance on June 15, 2006. These regulations codify the prohibitions and management measures set forth in the Proclamation. Therefore, these regulations are being published as final regulations and are effective August 25, 2006.

E.O. 12866

This rule has been determined to be significant for purposes of E.O. 12866.

Paperwork Reduction Act

This rule contains a collection-of-information requirement that was submitted to OMB for emergency approval under the Paperwork Reduction Act (PRA). The collection-of-information requirement was approved by OMB and granted OMB control number 0648–0548 which expires on February 28, 2007. We are now requesting comment on this information collection requirement for OMB's subsequent review and approval on a non-emergency basis.

The public reporting burden for this information collection is described in the table below. The public reporting burden for permit applications and associated reporting requirements is estimated to average 1 hour per response. The public reporting burden for entry and exit notification is expected to average 15 minutes per response. The public reporting burden for VMS checklist certification is estimated to average 5 minutes per response. Each of these public reporting burdens includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

APPLICANT BURDEN

Permit type	Permits and other reporting per year	Responses per requirement	Total responses	Hours/response	Total hours	Annual record-keeping/reporting cost per response (dollar)	Total annual cost (dollar)
(a) General	33	3	99	1	99	1.00	99.00
(b) Special Ocean Use	5	3	15	24	360	1.00	15.00
(c) Native Hawaiian Practices.	2	2	4	4	16	1.00	4.00
(d) Recreation	2	3	6	1	6	1.00	6.00
(e) Entry & Exit Notice	174	2	348	5 minutes	29	0.00	0.00
(f) Purchase and installation of VMS.	50	NA	NA	4 hours	50	899 (initial cost: $3595).	44,950.00
(g) VMS maintenance	50	NA	NA	4 hours	200	0	0
(h) VMS Certification	50	0.25	12.5	5 minutes	4	0.25	13.00
(i) Hourly VMS reports	50	3805	190,224	5 seconds	264	1.28/day	10,145.00
Total	124		190,709		1028		55,232.00

Note: VMS installation and activation hours and purchase costs are annualized by dividing by 4 years, the expected service life.

Public comment is sought regarding: whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230, or via e-mail at *dHynek@noaa.gov.*

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

List of Subjects in 50 CFR Part 404

Administrative practice and procedure, Coastal zone, Fish, Fisheries, Historic preservation, Intergovernmental relations, Marine resources, Monuments and memorials, Natural resources, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

Dated: August 24, 2006.

Conrad C. Lautenbacher Jr.,

Vice Admiral, U.S. Navy (Ret.), Undersecretary of Commerce for Oceans and Atmosphere.

Dated: August 24, 2006.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

■ Accordingly, NOAA and USFWS add part 404, title 50 of the Code of Federal Regulations as follows:

PART 404—NORTHWESTERN HAWAIIAN ISLANDS MARINE NATIONAL MONUMENT

Sec.

404.1 Scope and purpose.
404.2 Boundary.
404.3 Definitions.
404.4 Access to the Monument.
404.5 Requirements for a vessel monitoring system.
404.6 Prohibited activities.
404.7 Regulated activities.
404.8 Emergencies and law enforcement activities.
404.9 Armed Forces actions.
404.10 Commercial fishing.
404.11 Permitting procedures and criteria.
404.12 International law.
Appendix A to Part 404—Map of the Monument Outer Boundary and Ecological Reserves, Special Preservation Areas, and Midway Atoll Special Management Area
Appendix B to Part 404—Approved Vessel Monitoring Systems

Authority: 16 U.S.C. 431 *et seq.*; 16 U.S.C. 460k–3; 16 U.S.C. 1801 *et seq.*; 16 U.S.C. 742f, 16 U.S.C. 742*l*, and 16 U.S.C. 668dd–

ee; 16 U.S.C. 1361 *et seq.*; 16 U.S.C. 1531 *et seq.*, Pub. L. No. 106–513, § 6(g) (2000).

§ 404.1 Scope and purpose.

The regulations in this part codify the provisions of Presidential Proclamation 8031, and govern the administration of the Northwestern Hawaiian Islands Marine National Monument. These regulations are jointly implemented by the Secretaries of the Interior, through the U.S. Fish and Wildlife Service (USFWS), and Commerce, through the National Oceanic and Atmospheric Administration (NOAA). Nothing in these regulations shall be deemed to diminish or enlarge the jurisdiction of the State of Hawaii.

§ 404.2 Boundary.

The Northwestern Hawaiian Islands Marine National Monument consists of all lands and interest in lands owned or controlled by the Government of the United States within the boundaries of the Monument, including emergent and submerged lands and waters of the Northwestern Hawaiian Islands. The map in Appendix A to this part 404 depicts the outer boundary of the Monument, which consists of the geodetic lines connecting the coordinates specified in the Proclamation.

§ 404.3 Definitions.

The following definitions are applicable only to this Part.

Attract or Attracting means luring or attempting to lure a living resource by any means, except the mere presence of human beings (e.g., swimmers, divers, boaters).

Bottomfish Species means Bottomfish management unit species as defined at 50 CFR 665.12.

Commercial Bottomfishing means commercial fishing for bottomfish species.

Commercial passenger vessel means a vessel that carries individuals who have paid for such carriage.

Commercial pelagic trolling means commercial fishing for pelagic species.

Deserting a vessel means:

(1) Leaving a vessel aground or adrift:

(i) Without notifying the Secretaries of the vessel going aground or adrift within 12 hours of its discovery and developing and presenting to the Secretaries a preliminary salvage plan within 24 hours of such notification;

(ii) After expressing or manifesting intention to not undertake or to cease salvage efforts; or

(iii) When the Secretaries are unable, after reasonable efforts, to reach the owner/operator within 12 hours of the vessel's condition being reported to authorities.

(2) Leaving a vessel at anchor when its condition creates potential for a grounding, discharge, or deposit and the owner/operator fails to secure the vessel in a timely manner.

Ecological Reserve means the areas of the Monument, identified in the Proclamation, consisting of contiguous, diverse habitats that provide natural spawning, nursery, and permanent residence areas for the replenishment and genetic protection of marine life, and also to protect and preserve natural assemblages of habitats and species within areas representing a broad diversity of resources and habitats found within the Monument. Specific coordinates for Ecological Reserves within the Monument are found in the Proclamation, and the Ecological Reserves consist of the areas within the geodetic lines connecting these coordinates. The Ecological Reserves are depicted on the map in Appendix A to part 404.

Ecological integrity means a condition determined to be characteristic of an ecosystem that has the ability to maintain the function, structure, and abundance of natural biological communities, including rates of change in response to natural environmental variation.

Fishing year means the year beginning at 0001 local time on January 1 and ending at 2400 local time on December 31.

Introduced Species means:

(1) A species (including, but not limited to, any of its biological matter capable of propagation) that is non-native to the ecosystem(s) protected by the Monument; or

(2) Any organism into which genetic matter from another species has been transferred in order that the host organism acquires the genetic traits of the transferred genes.

Landing means offloading fish from a fishing vessel or causing fish to be offloaded from a fishing vessel.

Midway Atoll Special Management Area means the area of the Monument surrounding Midway Atoll out to a distance of 12 nautical miles, established for the enhanced management, protection, and preservation of Monument wildlife and historical resources. The geographic coordinates of this area, which consists of the area within the geodetic lines connecting these coordinates, are found in the Proclamation. The Midway Atoll Special Management Area is depicted on the map in Appendix A to part 404.

Mobile transceiver unit means a vessel monitoring system or VMS device, as described in Appendix E to this Part, installed on board a vessel that is used for vessel monitoring and transmitting the vessel's position as required by this Part.

Monument means the Northwestern Hawaiian Islands Marine National Monument.

Native Hawaiian Practices means cultural activities conducted for the purposes of perpetuating traditional knowledge, caring for and protecting the environment and strengthening cultural and spiritual connections to the Northwestern Hawaiian Islands that have demonstrable benefits to the Native Hawaiian community. This may include, but is not limited to, the non-commercial use of Monument resources for direct personal consumption while in the Monument.

Ocean-based ecotourism means a class of fee-for-service activities that involves visiting the Monument for study, enjoyment, or volunteer assistance for purposes of conservation and management.

Office for Law Enforcement (OLE) refers to NOAA, National Marine Fisheries Service, Office for Law Enforcement.

Pelagic Species means Pacific Pelagic Management Unit Species as defined at 50 CFR 665.12.

Pono means appropriate, correct, and deemed necessary by traditional standards in the Hawaiian culture.

Proclamation means Presidential Proclamation 8031, dated June 15, 2006 (71 FR 36443).

Recreational activity means an activity conducted for personal enjoyment that does not result in the extraction of Monument resources and that does not involve a fee-for-service transaction. This includes, but is not limited to, wildlife viewing, SCUBA diving, snorkeling, and boating.

Secretaries means the Secretary of Commerce and the Secretary of the Interior or their designees.

Special Preservation Area (SPA) means discrete, biologically important areas of the Monument, identified in the Proclamation, within which uses are subject to conditions, restrictions, and prohibitions, including but not limited to access restrictions. SPAs are used to avoid concentrations of uses that could result in declines in species populations or habitat, to reduce conflicts between uses, to protect areas that are critical for sustaining important marine species or habitats, or to provide opportunities for scientific research. Specific coordinates for Special Preservation Areas within the Monument are found in the Proclamation, and the Special Preservation Areas consist of the areas within the geodetic lines connecting these coordinates. The Special

Preservation Areas are depicted on the map in Appendix A to part 404.

Special ocean use means an activity or use of the Monument that is engaged in to generate revenue or profits for one or more of the persons associated with the activity or use, and does not destroy, cause the loss of, or injure Monument resources. This includes ocean-based ecotourism and other activities such as educational and research activities that are engaged in to generate revenue, but does not include commercial fishing for bottomfish or pelagic species conducted pursuant to a valid permit issued by NOAA.

Stowed and not available for immediate use means not readily accessible for immediate use, *e.g.,* by being securely covered and lashed to a deck or bulkhead, tied down, unbaited, unloaded, or partially disassembled (such as spear shafts being kept separate from spear guns).

Sustenance fishing means fishing for bottomfish or pelagic species in which all catch is consumed within the Monument, and that is incidental to an activity permitted under this part.

Vessel monitoring system or VMS means a vessel monitoring system or mobile transceiver unit as described in § 404.5 and approved by Office for Law Enforcement for use on vessels permitted to access the Monument, as required by this Part.

§ 404.4 Access to the Monument.

(a) Entering the Monument is prohibited and thus unlawful except:

(1) As provided in §§ 404.8 and 404.9;

(2) Pursuant to a permit issued under §§ 404.10 or 404.11; or

(3) When conducting passage without interruption in accordance with paragraph (b) of this section.

(b) Any person passing through the Monument without interruption is subject to the prohibitions in §§ 404.5, 404.6, and 404.7 and must provide notification prior to entering and after leaving the Monument. Notification of entry must be provided at least 72 hours, but no longer than 1 month, prior to the entry date. Notification of departure from the Monument must be provided within 12 hours of leaving. Notification under this paragraph may be made via e-mail, telephone or fax by contacting:

(1) E-mail: *nwhi.notifications@commat;noaa.gov;* or

(2) Telephone: 1–866–478–NWHI (6944); or (808) 395–NWHI (6944).

(c) A person providing notice under this paragraph must provide the following information, as applicable:

(1) Position when making report.

(2) Vessel name and International Maritime Organization identification number.

(3) Name, address, and telephone number of owner and operator.

(4) USCG documentation, state license, or registration number.

(5) Home port.

(6) Intended and actual route through the Monument.

(7) General categories of any hazardous cargo on board.

(8) Length of vessel and propulsion type (e.g., motor or sail).

§ 404.5 Requirements for a vessel monitoring system.

(a) *Requirement for use.* Effective August 28, 2006, an owner or operator of a vessel that has been issued a permit for accessing the Monument must ensure that such vessel has an OLE-approved, operating VMS on board when voyaging within the Monument. An operating VMS includes an operating mobile transmitting unit on the vessel and a functioning communication link between the unit and OLE as provided by an OLE-approved communication service provider. Appendix B to this part 404 provides information regarding OLE-approved transmitting units.

(b) *Installing and activating the VMS.* Only a VMS that has been approved by OLE may be used. When installing and activating the OLE-approved VMS, or when reinstalling and reactivating such VMS, the vessel owner or operator must:

(1) Follow procedures indicated on an installation and activation checklist, which is available from OLE; and

(2) Submit to OLE a statement certifying compliance with the checklist, as prescribed on the checklist.

(c) *Interference with the VMS.* No person may interfere with, tamper with, alter, damage, disable, or impede the operation of the VMS, or attempt any of the same.

(d) *Interruption of operation of the VMS.* When a vessel's VMS is not operating properly, the owner or operator must immediately contact OLE, and follow instructions from that office. If notified by OLE that a vessel's VMS is not operating properly, the owner and operator must follow instructions from that office. In either event, such instructions may include, but are not limited to, manually communicating to a location designated by OLE the vessel's positions or returning to port until the VMS is operable.

(e) *Access to position data.* As a condition of authorized access to the Monument, a vessel owner or operator subject to the requirements for a VMS in this section must allow OLE, the USCG, and their authorized officers and designees access to the vessel's position data obtained from the VMS. Consistent with other applicable laws, including the limitations on access to, and use of, VMS data collected under the Magnuson-Stevens Fishery Conservation and Management Act, the Secretaries may have access to, and use of, collected data for scientific, statistical, and management purposes.

(f) *Authority for installation and operation.* OLE has authority over the installation and operation of the VMS unit. OLE may authorize the connection or order the disconnection of additional equipment, including a computer, to any VMS unit when deemed appropriate by OLE.

(g) *Activities Regarding Vessel Monitoring Systems.* Effective August 28, 2006, the following activities regarding vessel monitoring systems are prohibited and thus unlawful for any person to conduct or cause to be conducted:

(1) Operating any vessel within the Monument without an OLE type-approved mobile transceiver unit described in this section;

(2) Failing to install, activate, repair, or replace a mobile transceiver unit prior to leaving port;

(3) Failing to operate and maintain a mobile transceiver unit on board the vessel at all times as specified in this section;

(4) Tampering with, damaging, destroying, altering, or in any way distorting, rendering useless, inoperative, ineffective, or inaccurate the VMS, mobile transceiver unit, or VMS signal required to be installed on or transmitted by a vessel as specified in this section;

(5) Failing to contact OLE or follow OLE instructions when automatic position reporting has been interrupted as specified in this section;

(6) Registering a VMS or mobile transceiver unit to more than one vessel at the same time;

(7) Connecting or leaving connected additional equipment to a VMS unit or mobile transceiver unit without the prior approval of OLE; and

(8) Making a false statement, oral or written, to an authorized officer regarding the installation, use, operation, or maintenance of a VMS unit or mobile transceiver unit or communication service provider.

§ 404.6 Prohibited activities.

The following activities are prohibited and thus unlawful for any person to conduct or cause to be conducted:

(a) Exploring for, developing, or producing oil, gas, or minerals within the Monument;

(b) Using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a Monument resource;

(c) Introducing or otherwise releasing an introduced species from within or into the Monument; and

(d) Anchoring on or having a vessel anchored on any living or dead coral with an anchor, anchor chain, or anchor rope.

§ 404.7 Regulated activities.

Except as provided in §§ 404.8, 404.9 and 404.10, the following activities are prohibited and thus unlawful for any person to conduct or cause to be conducted within the Monument without a valid permit as provided for in § 404.11:

(a) Removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging; or attempting to remove, move, take, harvest, possess, injure, disturb, or damage any living or nonliving Monument resource;

(b) Drilling into, dredging, or otherwise altering the submerged lands other than by anchoring a vessel; or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands;

(c) Anchoring a vessel;

(d) Deserting a vessel aground, at anchor, or adrift;

(e) Discharging or depositing any material or other matter into Special Preservation Areas or the Midway Atoll Special Management Area except vessel engine cooling water, weather deck runoff, and vessel engine exhaust;

(f) Discharging or depositing any material or other matter into the Monument, or discharging or depositing any material or other matter outside the Monument that subsequently enters the Monument and injures any resources of the Monument, except fish parts (i.e., chumming material or bait) used in and during authorized fishing operations, or discharges incidental to vessel use such as deck wash, approved marine sanitation device effluent, cooling water, and engine exhaust;

(g) Touching coral, living or dead;

(h) Possessing fishing gear except when stowed and not available for immediate use during passage without interruption through the Monument;

(i) Swimming, snorkeling, or closed or open circuit SCUBA diving within any Special Preservation Area or the Midway Atoll Special Management Area; and

(j) Attracting any living Monument resource.

§ 404.8 Emergencies and law enforcement activities.

The prohibitions in this part do not apply to activities necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for law enforcement purposes.

§ 404.9 Armed Forces actions.

(a) The prohibitions in this part do not apply to activities and exercises of the Armed Forces (including those carried out by the United States Coast Guard) that are consistent with applicable laws.

(b) These regulations shall not limit agency actions to respond to emergencies posing an unacceptable threat to human health or safety or to the marine environment and admitting of no other feasible solution.

(c) All activities and exercises of the Armed Forces shall be carried out in a manner that avoids, to the extent practicable and consistent with operational requirements, adverse impacts on Monument resources and qualities.

(d) In the event of threatened or actual destruction of, loss of, or injury to a Monument resource or quality resulting from an incident, including but not limited to spills and groundings, caused by a component of the Department of Defense or the United States Coast Guard, the cognizant component shall promptly coordinate with the Secretaries for the purpose of taking appropriate actions to respond to and mitigate the harm and, if possible, restore or replace the Monument resource or quality.

§ 404.10 Commercial fishing.

(a) *Lobster fishing.* Any commercial lobster fishing permit is subject to a zero annual harvest limit condition.

(b) *Fishing and bottomfish and pelagic species.* (1) Notwithstanding the prohibitions in § 404.7(a) and (h), commercial fishing for bottomfish and associated pelagic species may continue within the Monument subject to paragraph (c) of this section, until June 15, 2011, provided that:

(i) The fishing is conducted in accordance with a valid commercial bottomfish permit issued by NOAA; and

(ii) Such permit was in effect on June 15, 2006, and is subsequently renewed pursuant to NOAA regulations at 50 CFR part 665, subpart E as necessary.

(2) Total landings for each fishing year from fishing allowed under paragraph (b)(1) of this section may not exceed the following amounts:

(i) 350,000 pounds for bottomfish species; and

(ii) 180,000 pounds for pelagic species.

(3) Commercial fishing for bottomfish and associated pelagic species is prohibited in the Monument after June 15, 2011.

(c) *General requirements.* Any commercial fishing within the Monument shall be conducted in accordance with the following restrictions and conditions:

(1) A valid permit or facsimile of a valid permit shall be on board the fishing vessel and available for inspection by an authorized officer;

(2) No attempt is made to falsify or fail to make, keep, maintain, or submit any logbook or logbook form or other required record or report.

(3) Only gear specifically authorized by the relevant permit issued under the Magnuson-Stevens Fishery Conservation and Management Act is allowed to be in the possession of a person conducting commercial fishing under this section;

(4) Any person conducting commercial fishing notifies the Secretaries by telephone, facsimile, or electronic mail at least 72 hours before entering the Monument and within 12 hours after leaving the Monument in accordance with § 404.4(b) and (c);

(5) All fishing vessels must carry an activated and functioning VMS unit on board at all times whenever the vessel is in the Monument;

(6) All fishing vessels must carry an observer when requested to do so by the Secretaries;

(7) The activity does not take place within any Ecological Reserve, any Special Preservation Area, or the Midway Atoll Special Management Area.

§ 404.11 Permitting procedures and criteria.

(a) *Issuance.* Subject to such terms and conditions as the Secretaries deem appropriate, a person may conduct an activity prohibited by § 404.7 if such activity is specifically authorized by a permit issued under this section.

(b) *Application requirements.* Applicants for permits under this section shall submit applications to: Northwestern Hawaiian Islands Marine National Monument, 6600 Kalanianaole Highway, Suite 300, Honolulu, HI 96825.

(c) *Permit Types.* A permit under this subpart may be issued if the Secretaries find that the activity:

(1) Is research designed to further understanding of Monument resources and qualities;

(2) Will further the educational value of the Monument;

(3) Will assist in the conservation and management of the Monument;

(4) Will allow Native Hawaiian practices subject to paragraph (e) of this section;

(5) Will allow a special ocean use subject to paragraph (f) of this section; or

(6) Will allow recreational activities subject to paragraph (g) of this section.

(d) *Findings.* A permit may not be issued under this section unless the Secretaries find:

(1) The activity can be conducted with adequate safeguards for the resources and ecological integrity of the Monument;

(2) The activity will be conducted in a manner compatible with the purposes of the Proclamation, considering the extent to which the conduct of the activity may diminish or enhance Monument resources, qualities, and ecological integrity, any indirect, secondary or cumulative effects of the activity, and the duration of such effects;

(3) There is no practicable alternative to conducting the activity within the Monument;

(4) The end value of the activity outweighs its adverse impacts on Monument resources, qualities, and ecological integrity;

(5) The duration of the activity is no longer than necessary to achieve its stated purpose;

(6) The applicant is qualified to conduct and complete the activity and mitigate any potential impacts resulting from its conduct;

(7) The applicant has adequate financial resources available to conduct and complete the activity and mitigate any potential impacts resulting from its conduct;

(8) The methods and procedures proposed by the applicant are appropriate to achieve the proposed activity's goals in relation to their impacts to Monument resources, qualities, and ecological integrity;

(9) The applicant's vessel has been outfitted with a mobile transceiver unit approved by OLE and complies with the requirements of § 404.5; and

(10) There are no other factors that would make the issuance of a permit for the activity inappropriate.

(e) *Additional findings for Native Hawaiian practice permits.* In addition to the findings listed in paragraph (d) of this section, a permit to allow Native Hawaiian practices under paragraph (c)(4) of this section, may not be issued unless:

(1) The activity is non-commercial and will not involve the sale of any organism or material collected;

(2) The purpose and intent of the activity are appropriate and deemed necessary by traditional standards in the Native Hawaiian culture (*pono*), and demonstrate an understanding of, and background in, the traditional practice, and its associated values and protocols;

(3) The activity benefits the resources of the Northwestern Hawaiian Islands and the Native Hawaiian community;

(4) The activity supports or advances the perpetuation of traditional knowledge and ancestral connections of Native Hawaiians to the Northwestern Hawaiian Islands; and

(5) Any Monument resource harvested from the Monument will be consumed in the Monument.

(f) *Additional findings, criteria, and requirements for special ocean use permits.* (1) In addition to the findings listed in paragraph (d) of this section, the following requirements apply to the issuance of a permit for a special ocean use under paragraph (c)(5) of this section:

(i) Any permit for a special ocean use issued under this section:

(ii) Shall authorize the conduct of an activity only if that activity is compatible with the purposes for which the Monument is designated and with protection of Monument resources;

(A) Shall not authorize the conduct of any activity for a period of more than 5 years unless renewed;

(B) Shall require that activities carried out under the permit be conducted in a manner that does not destroy, cause the loss of, or injure Monument resources; and

(iii) Shall require the permittee to purchase and maintain comprehensive general liability insurance, or post an equivalent bond, against claims arising out of activities conducted under the permit and to agree to hold the United States harmless against such claims;

(iv) Each person issued a permit for a special ocean use under this section shall submit an annual report to the Secretaries not later than December 31 of each year which describes activities conducted under that permit and revenues derived from such activities during the year.

(2) In addition to the findings listed in paragraph (d) of this section, a permit may not be issued for a special ocean use unless the activity has been determined to be consistent with the findings made pursuant to paragraph (f) of this section.

(3) Categories of special ocean use being permitted for the first time under this section will be restricted in duration and permitted as a special ocean use pilot project. Subsequent permits for any category of special ocean use may only be issued if a special ocean use pilot project for that category meets the requirements of this section, and any terms and conditions placed on the permit for the pilot project.

(4) Public notice shall be provided prior to requiring a special ocean use permit for any category of activity not previously identified as a special ocean use.

(5) The following requirements apply to permits for a special ocean use for an activity within the Midway Atoll Special Management Area.

(i) A permit for a special ocean use for activities within the Midway Atoll Special Management Area may be issued provided:

(A) The activity furthers the conservation and management of the Monument; and

(B) The Director of the United States Fish and Wildlife Service or his or her designee has determined that the activity is compatible with the purposes for which the Midway Atoll National Wildlife Refuge was designated.

(ii) As part of a permit issued pursuant to this paragraph (f)(5), vessels may be allowed to transit the Monument as necessary to enter the Midway Atoll Special Management Area.

(6) A permit for a special ocean use for activities outside the Midway Atoll Special Management Area may be issued provided:

(i) The activity will directly benefit the conservation and management of the Monument;

(ii) The purpose of the activity is for research or education related to the resources or qualities of the Monument;

(iii) Public notice of the application and an opportunity to provide comments is given at least 30 days prior to issuing the permit; and

(iv) The activity does not involve the use of a commercial passenger vessel.

(g) *Additional findings for recreation permits.* A permit for recreational activities under paragraph (c)(6) of this section may be issued for activities to be conducted within the Midway Atoll Special Management area if, in addition to the findings listed in paragraph (d) of this section:

(1) The activity is for the purpose of recreation as defined in section 404.3;

(2) The activity is not associated with any for-hire operation; and

(3) The activity does not involve any extractive use.

(h) *Sustenance fishing.* Sustenance fishing, as defined in 404.3, may be allowed outside of any Special Preservation Area as a term or condition of any permit issued under this part. Sustenance fishing in the Midway Atoll

Special Management Area shall not be allowed unless the activity has been determined by the Director of the U.S. Fish and Wildlife Service or his or her designee to be compatible with the purposes for which the Midway Atoll National Wildlife Refuge was established. Sustenance fishing must be conducted in a manner compatible with the Proclamation and this part, including considering the extent to which the conduct of the activity may diminish Monument resources, qualities, and ecological integrity, as well as any indirect, secondary, or cumulative effects of the activity and the duration of such effects. Sustenance fishing is subject to systematic reporting requirements when developed by the Secretaries.

§ 404.12 International law.

These regulations shall be applied in accordance with international law. No restrictions shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law.

Appendix A to Part 404—Map of the Monument Outer Boundary and Ecological Reserves, Special Preservation Areas, and Midway Atoll Special Management Area

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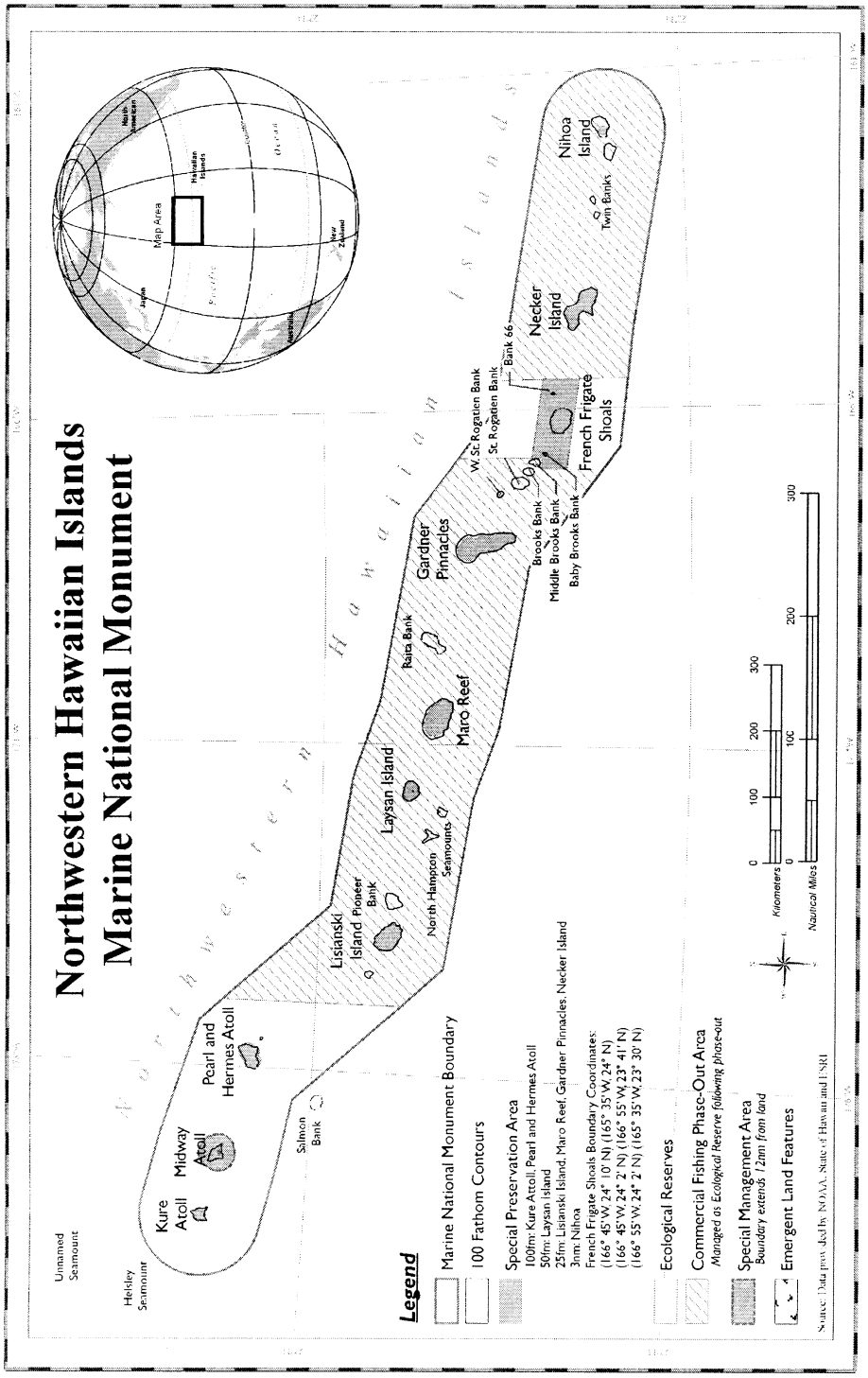

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Appendix B to Part 404—Approved VMS

I. VMS Mobile Transceiver Unit

Thrane & Thrane Sailor 3026D Gold VMS

The Thrane & Thrane Sailor 3026D Gold VMS (TT–3026D) has been found to meet the minimum technical requirements for vessels issued permits to operate in the Northwestern Hawaiian Islands Marine National Monument. The address for the Thrane & Thrane distributor contact is provided in this notice under the heading VMS Provider Address.

The TT–3026D Gold VMS features an integrated GPS/Inmarsat-C unit and a marine grade monitor with keyboard and integrated mouse. The unit is factory pre-configured for NMFS VMS operations (non-Global Maritime Distress & Safety System (non-GMDSS)). Satellite commissioning services are provided by Thrane & Thrane personnel.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is an integrated transceiver/antenna/GPS design using a floating 10 to 32 VDC power supply. The unit is configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port). It allows for port stays without power drain or power shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The TT–3026D provides operation down to +/−15 degree angles. The unit has the capability of two-way communications to send formatted forms and to receive e-mail and other messages. A configuration option is available to automatically send position reports to a private address, such as a fleet management company.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading ''VMS Provider Address''. The owner should identify himself or herself as a vessel owner issued a permit to operate in the Northwestern Hawaiian Islands Marine National Monument, so the transceiver set can be properly configured. To use the TT–3026D the vessel owner will need to establish an Inmarsat-C system use contract with an approved Inmarsat-C communications service provider. The owner will be required to complete the Inmarsat-C ''Registration for Service Activation for Maritime Mobile Earth Station.'' The owner should consult with Thrane & Thrane when completing this form.

Thrane & Thrane personnel will perform the following services before shipment: (1) Configure the transceiver according to OLE specifications for vessels issued permits to operate in the Northwestern Hawaiian Islands Marine National Monument; (2) download the predetermined NMFS position reporting and broadcast command identification numbers into the unit; (3) test the unit to ensure operation when installation has been completed on the vessel; and (4) forward the Inmarsat service provider and the transceiver identifying information to OLE.

II. Inmarsat-C Communications Providers

It is recommended, for vendor warranty and customer service purposes, that the vessel owner keep for his or her records and that Telenor and Xantic have on record the following identifying information: (1) Signed and dated receipts and contracts; (2) transceiver serial number; (3) Telenor or Xantic customer number, user name and password; (4) e-mail address of transceiver; (5) Inmarsat identification number; (6) owner name; (7) vessel name; (8) vessel documentation or registration number; and (9) mobile earth station license (FCC license).

The OLE will provide an installation and activation checklist that the vessel owner must follow. The vessel owner must sign a statement on the checklist certifying compliance with the installation procedures and return the checklist to OLE. Installation can be performed by an experienced crew or by an electronics specialist, and the installation cost is paid by the owner.

The owner may confirm the TT–3026D operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on a trip under VMS. The OLE does not regard the vessel as meeting requirements until position reports are automatically received. For confirmation purposes, contact the NOAA Fisheries Office for Law Enforcement, 8484 Georgia Ave., Suite 415, Silver Spring, MD 20910, phone 888–219–9228, fax 301–427–0049.

Telenor Satellite Services

Inmarsat-C is a store-and-forward data messaging service. Inmarsat-C allows users to send and receive information virtually anywhere in the world, on land, at sea, and in the air. Inmarsat-C supports a wide variety of applications including Internet, e-mail, position and weather reporting, a free daily news service, and remote equipment monitoring and control. Mariners can use Inmarsat-C free of charge to send critical safety at sea messages as part of the U.S. Coast Guard's Automated Mutual-Assistance Vessel Rescue system and of the NOAA Shipboard Environmental Acquisition System programs. Telenor Vessel Monitoring System Services is being sold through Thrane & Thrane, Inc. For the Thrane & Thrane and Telenor addresses, look inside this notice under the heading ''VMS Provider Address''.

Xantic

Xantic is a provider of Vessel Monitoring Services to the maritime industry. By installing an approved OLE Inmarsat-C transceiver on the vessel, vessels can send and receive e-mail, to and from land, while the transceiver automatically sends vessel position reports to OLE, and is fully compliant with the International Coast Guard Search and Rescue Centers. Xantic Vessel Monitoring System Services are being sold through Thrane & Thrane, Inc. For the Thrane & Thrane and Xantic addresses, look in this notice under the heading ''VMS Provider Address''.

For Telenor and Xantic, Thrane & Thrane customer service supports the security and privacy of vessel accounts and messages with the following: (a) Password authentication for vessel owners or agents and for OLE to prevent unauthorized changes or inquiries; and (b) separation of private messages from OLE messages. (OLE requires VMS-related position reports, only.)

Billing is separated between accounts for the vessel owner and the OLE. VMS position reports and vessel-initiated messaging are paid for by the vessel owner. Messaging initiated from OLE operations center is paid for by NOAA.

Thrane & Thrane provides customer service for Telenor and Xantic users to support and establish two-way transmission of transceiver unit configuration commands between the transceiver and land-based control centers. This supports OLE's message needs and, optionally, the crew's private message needs.

The vessel owner can configure automatic position reports to be sent to a private address, such as to a fleet management company.

Vessel owners wishing to use Telenor or Xantic services will need to purchase an Inmarsat-C transceiver approved for vessels issued permits to operate in the Northwestern Hawaiian Islands Marine National Monument. The owner will need to complete an Inmarsat-C system use contract with Telenor or Xantic, including a mobile earth station license (FCC requirement). The transceiver will need to be commissioned with Inmarsat according to Telenor or Xantic's instructions. The owner should refer to and follow the configuration, installation, and service activation procedures for the specific transceiver purchased.

III. VMS Provider Address

For TT–3026D, Telenor, or Xantic information, contact Ronald Lockerby, Marine Products, Thrane & Thrane, Inc., 509 Viking Drive, Suite K, L & M, Virginia Beach, VA 23452; voice: 757–463–9557; fax: 757–463–9581, e-mail: *rdl@tt.dk.com*; Web site: *http://www.landseasystems.com*.

[FR Doc. 06–7235 Filed 8–25–06; 12:24 pm]

BILLING CODE 3510–NK–P

Proposed Rules

Federal Register
Vol. 71, No. 167
Tuesday, August 29, 2006

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 HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. 2006D–0331]

Conduct of Emergency Clinical Research; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing on emergency research conducted without informed consent under FDA's emergency research rule. The public hearing announced in this document is part of FDA's Human Subject Protection and Bioresearch Monitoring Initiative. We are particularly interested in hearing the views of individuals and groups who have encountered challenges in the conduct of emergency research in the absence of informed consent, including patient advocacy groups, individuals who have participated in clinical studies, institutional review board members (IRBs), sponsors, clinical investigators, medical societies, ethicists, and other interested parties. We are seeking input on a number of specific questions regarding aspects of emergency research and additional human subject protections. Elsewhere in this issue of the **Federal Register**, we are also issuing a draft guidance entitled ''Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research.'' We will consider comments received on this draft guidance together with comments and suggestions received at the hearing to determine whether the current framework is adequate for the ethical conduct of emergency research, or whether modifications would be appropriate.

DATES: The public hearing will be held on October 11, 2006, from 8 a.m. to 6 p.m. However, depending upon the level of public participation, the meeting may end early. Submit written or electronic comments by November 27, 2006. The administrative record of the hearing will remain open for 45 days following the hearing.

ADDRESSES: The public hearing will be held at the University System of Maryland Shady Grove Center, 9630 Gudelsky Dr., Rockville, MD 20850.

Submit written comments 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.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

See section I. of the **SUPPLEMENTARY INFORMATION** section for information on how to participate in the meeting.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of the Commissioner (HF–18), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–7864, FAX: 301–443–9718, *terrie.crescenzi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meeting

All individuals wishing to make a presentation at the hearing must indicate their intent, the question to be addressed, and also provide an abstract of the presentation by September 20, 2006. Submit written or electronic comments by November 27, 2006, at the Division of Dockets Management (see **ADDRESSES**).

The procedures governing the hearing are found in part 15 (21 CFR part 15). If you wish to make an oral presentation during the hearing, you must state your intention on your submission to the docket (see **ADDRESSES**). To present, submit your name, title, business affiliation, address, telephone number, fax number, and e-mail address. FDA has identified questions and subject matter of special interest in section V of this document. You should also identify by number each question you wish to address in your presentation, although presentations do not have to be limited to those questions. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. FDA will prepare the hearing schedule indicating which persons will be making oral presentations and the time allotted to each person, which will be filed with the Division of Dockets Management (see **ADDRESSES**) and mailed or telephoned before the hearing to each participant. Persons making oral presentations should arrive early to be sure that they are present to make their presentation in case the schedule advances. Individuals who are not present when called upon will likely lose their ability to make their oral presentation. However, the administrative record of the hearing will remain open for 45 days following the hearing and individuals may submit written comments to the docket as described in section VII of this document. Presenters should submit two copies of each presentation given. All participants are encouraged to attend the entire hearing.

If you need special accommodations due to a disability, please contact Terrie L. Crescenzi (see **FOR FURTHER INFORMATION CONTACT**).

II. Background

On October 2, 1996, FDA issued a final rule providing a narrow exception from the requirement of obtaining and documenting informed consent from each human subject prior to initiation of a clinical investigation. The intent of the regulation was to facilitate certain emergency research while ensuring adequate protection of human subjects (61 FR 51498, October 2, 1996). In the decade following issuance of the regulation, we have received approximately 60 requests to conduct a clinical investigation under § 50.24 (21 CFR 50.24) with an exception from the informed consent requirements. Now that we have received a sizeable number of requests, we have reviewed our experience with emergency clinical research under the 1996 regulatory framework. We have heard informally from some individuals that the additional safeguards in § 50.24 are either insufficient or too poorly defined to protect subjects; others have said that

the safeguards in the regulation are too onerous and interfere with important research; still others have said that the regulation contains the appropriate safeguards, but that further guidance is needed. In addition, some have asserted that important emergency research is not being carried out for a variety of reasons. These reasons include the difficulties inherent in emergency research trial designs, and the challenges and cost of applying specific aspects of § 50.24.

III. Purpose and Scope of the Hearing

The purpose of this hearing is to provide patient advocacy groups, individuals who have participated in clinical studies, IRBs, sponsors, clinical investigators, medical societies, ethicists, and other interested parties with an opportunity to discuss their experiences and concerns in the conduct of emergency research without informed consent under § 50.24, and to determine whether the current framework is adequate for the ethical conduct of emergency research or needs modification. The hearing will give us the opportunity to hear these parties' concerns related to the challenges of conducting scientifically rigorous emergency research while maintaining human subject protections and their suggestions for improving the process. We hope to obtain information that will help in developing strategies to address the identified challenges.

IV. Summary of Regulatory Requirements for Emergency Research

The regulation at § 50.24(a) describes the following criteria that must be met for a clinical investigation to be eligible for an exception from the informed consent requirements. The responsible IRB must find and document the following:

(1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

(2) Obtaining informed consent is not feasible because:

(a) The subjects will not be able to give their informed consent as a result of their medical condition;

(b) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and

(c) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

(3) Participation in the research holds out the prospect of direct benefit to the subjects because:

(a) Subjects are facing a life-threatening situation that necessitates intervention;

(b) Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and

(c) Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

(4) The clinical investigation could not practicably be carried out without the exception from informed consent.

(5) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

(6) The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with § 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with § 50.25(a)(7)(v).

(7) Additional protections of the rights and welfare of the subjects will be provided, including, at least:

(a) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;

(b) Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits:

(c) Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;

(d) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and

(e) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

V. Issues for Discussion

At this part 15 hearing, we will be specifically inviting comments on the questions discussed in sections V.A and V.B of this document.

A. Scientific Aspects of Emergency Research and Human Subject Protection

In studies conducted under Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications without an exception from the informed consent requirements, the products tested need not show particular promise of being superior to existing treatments in order for a clinical investigation to proceed. This is acceptable because the subject has the opportunity to make an informed decision and choose whether to participate in the clinical investigation. In the special case where a clinical investigation is permitted to proceed with an exception from the informed consent requirements, however, the regulation demands that participation hold out the prospect of direct benefit

for participants, as suggested by animal data, other preclinical studies, and related evidence. We recognize that it can be difficult to determine whether a new treatment holds out enough of a prospect of direct benefit to allow a clinical investigation to go forward and to determine whether available treatment is ''unproven or unsatisfactory''.

Therefore, FDA would like interested parties to address the following questions:

(1) Are the criteria for allowing studies conducted under § 50.24 adequate to protect human subjects and to promote scientifically rigorous research? Are any additional criteria warranted?

(2) Are the following criteria easily understood and, if not, how can they be clarified?

(a) ''Available treatments are unsatisfactory or unproven'' (§ 50.24(a)(1))

(b) ''Prospect of direct benefit'' (§ 50.24(a)(3))

(c) ''Practicably'' (§ 50.24(a)(4))

(3) Are there other criteria in the regulation, besides those identified in criteria (2)(a) through (c), that need to be clarified?

(4) Are there challenges that have not been explicitly addressed in the regulation in designing scientifically rigorous and ethically sound emergency research protocols (e.g., pediatric protocols)? If there are such challenges, should they be addressed and how?

B. Additional Human Subject Protections

Recognizing that emergency research presents unique human subject protection and ethical challenges, § 50.24 requires that additional human subject protections be provided. In particular, in order to ensure that emergency research is conducted with respect for the human subjects as discussed in the Belmont Report,[1] FDA recognizes that it is important to inform and consult with the communities involved (which include the communities where the clinical investigation will be conducted and from which the subjects will be drawn). Therefore, § 50.24 contains a number of additional human subject protections, several of which are specifically designed to provide relevant information to the involved communities. Such additional protections include: (1) Community consultation, (2) public disclosure prior to initiation of the clinical investigation of plans for the investigation and its risks and expected benefits, and (3) public disclosure following completion of the clinical investigation of information to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.

Community Consultation

The regulation (§ 50.24 (a)(7)(i)) requires consultation with representatives of the communities described previously, but provides few details about how to do this or what would constitute adequate consultation. We are aware that community consultation poses challenges and therefore invite comments on the following questions.

(5) What are the costs, benefits, and feasibility of community consultation as currently required under § 50.24?

(6) What aspects of community consultation as currently practiced are effective mechanisms for human subject protection? Are there additional practices that could enhance human subject protection?

(7) Are there elements of community consultation, both procedural and substantive, that should, at a minimum, be required (e.g., types of information presented, number and types of meetings or interactions, number of people reached)?

(8) Would opt-out mechanisms (e.g., advanced directives, jewelry similar to medical alert bracelet/necklace, and driver's license indicators) to identify individuals who do not wish to be included as subjects in particular emergency research studies provide a necessary protection for human subjects? If so, are they feasible?

(9) Who should use the information obtained from the community consultation process and how should they use it? Should the regulation be more specific on this point, and if so, what should it provide?

(10) Are there others besides the IRB (e.g., sponsors, clinical investigators, community leaders, advisory committees, ethicists) who should play a role in determining the adequacy of the plan for community consultation and the material to be publicly disclosed?

(11) The community consultation process typically includes meetings and discussions about the study with the community.

(a) Should the regulation require documentation of meeting activities and discussions in sufficient detail to show the information that was disclosed and the community reaction to the clinical investigation? If so, who should be responsible for such documentation (e.g., clinical investigator, sponsor)?

(b) The regulations (see 21 CFR 312.54(a) and 812.47(a)) currently require the sponsor to submit the information publicly disclosed prior to study initiation and after completion to FDA Docket Number 1995S–0158 (formerly 95S–0158). Should the regulation also require that documentation of community consultation activities be submitted to FDA, for example by being placed in the public docket? If so, who should be responsible for doing this?

(c) Should this information also be available elsewhere such as on *clinicaltrials.gov*?[2]

Public Disclosure Prior to Initiation

The regulation requires public disclosure, before the study begins, of plans for the investigation and its risks and expected benefits (§ 50.24(a)(7)(ii)) as an important protection for human subjects. We ask for comments on the following questions regarding such public disclosure.

(12) Are there certain types of information (e.g., adverse event reports, study protocol, informed consent document) that should, at a minimum, be publicly disclosed to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn?

(13) Should the full protocol, or other information such as the investigator's brochure, for emergency research be available (e.g., through FDA's public docket, *clinicaltrials.gov*) to the general public before initiation of the clinical investigation? If so, should protocols or other information be available for all emergency research or only for certain emergency research?

Public Disclosure Following Completion

The regulation requires public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including demographic characteristics of the research population and the study results (§ 50.24(a)(7)(iii)).

(14) Is there information regarding study results that, at a minimum, should always be disclosed after the clinical investigation is completed? If so, what is that information?

(15) How can this disclosure best be accomplished? Who should be responsible for this disclosure?

[1] The Belmont Report—Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (44 FR 23192, April 18, 1979).

[2] (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

(16) When should a clinical investigation be considered ''completed?'' How soon after a clinical investigation is completed should the results be disclosed?

(17) How can we assure timely disclosure of study results after completion of a study?

Public Discussion of Emergency Research

Currently, all emergency research protocols are subject to IRB review and community consultation. FDA has received some suggestions that it may be important, at least in some cases, to have additional public discussion, such as during an open meeting of an advisory committee or other expert panel. We invite comment on the following questions. Is there a need for such additional review and public discussion? If so, what criteria would be used to determine which protocols should be subject to this additional review and discussion?

(18) What type of venue would be best for this additional review and public discussion?

(19) What information should be included in this review?

Additional Challenges

(20) Are there any additional challenges to the conduct of emergency research that have not been identified in the preceding questions?

(21) If so, what are they and how should they be addressed?

VI. Notice of Hearing Under 21 CFR Part 15

The Acting Commissioner of Food and Drugs (the Acting Commissioner) is announcing that the public hearing will be held in accordance with part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Office of Policy, and the Office of Human Research Protection.

Persons who wish to participate in the part 15 hearing must file a written or electronic submission with the Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number found in brackets in the heading of this document, along with the statement ''Emergency Research.'' Requests to make a presentation should contain the potential presenter's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation (including the discussion questions identified by number that will be addressed).

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open for 45 days following the hearing. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions identified by number to which they refer (see section V of this document). Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number at the heading of this document. Received comments may be seen in Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the hearing. You may place orders for copies of the transcript at the meeting or through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: August 18, 2006.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. E6–14264 Filed 8–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 1978N–0065 (formerly Docket No. 78N–0065)]

RIN 0910–AF53

Skin Bleaching Drug Products For Over-the-Counter Human Use; Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal of previous proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would establish that over-the-counter (OTC) skin bleaching drug products are not generally recognized as safe and effective (GRASE) and are misbranded. FDA is also withdrawing the previous proposed rule on skin bleaching drug products for OTC human use, which was issued in the form of a tentative final monograph (TFM). FDA is issuing this proposed rule after considering new data and information on the safety of hydroquinone, the only active ingredient that had been proposed for inclusion in a monograph for these products. This proposal is part of FDA's ongoing review of OTC drug products. Further, upon issuance of a final rule, FDA intends to consider all skin bleaching drug products, whether currently marketed on a prescription or OTC basis, to be new drugs requiring an approved new drug application (NDA) for continued marketing.

DATES: Submit written or electronic comments by December 27, 2006; submit written or electronic comments on FDA's economic impact determination by December 27, 2006. The September 3, 1982, proposed rule (47 FR 39108) is withdrawn as of August 29, 2006. See section IX for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 1978N–0065 and RIN number 0910–AF53, 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). and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 addtional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.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: Michelle M. Jackson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5486, Silver Spring, MD 20993–0002, 301–796–0923.

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I. Background

In the **Federal Register** of November 3, 1978 (43 FR 51546), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC skin bleaching drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The data and information considered by the Panel were put on display in the Division of Dockets Management (see **ADDRESSES**).

FDA's TFM for OTC skin bleaching drug products was published in the **Federal Register** of September 3, 1982 (47 FR 39108). In that TFM, FDA proposed that hydroquinone (1.5 to 2.0 percent) be GRASE as an active ingredient in OTC skin bleaching drug products. Six manufacturers, one cosmetic manufacturers' association, and one drug manufacturers' association submitted comments in response to the 1982 TFM. These comments and additional information that has come to FDA's attention since publication of the 1982 TFM are also on public display in the Division of Dockets Management (see **ADDRESSES**).

FDA is now proposing a rule that would classify OTC skin bleaching drug products as not GRASE, misbranded, and new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). This proposed rule would amend part 310 (21 CFR part 310), subpart E by adding new § 310.545(a)(17)(ii). Accordingly, the proposed monograph that published in the **Federal Register** of September 3, 1982, which would have added hydroquinone as a GRASE skin bleaching agent (part 358 (21 CFR part 358)), is withdrawn (see **DATES**).

If this proposal becomes a final rule, FDA advises that the conditions under which the drug products that are subject to this rule are not GRASE and are misbranded (nonmonograph conditions) will be effective 30 days after the date of publication of the final rule in the **Federal Register**. On or after that date, no OTC drug product that is subject to the rule may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the final rule that is repackaged or relabeled after the effective date of the final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

The comments to the TFM were primarily labeling comments related to skin bleaching drug products being GRASE. Because FDA is proposing in this current notice that there are no GRASE skin bleaching drug products, discussion of the submitted comments is unnecessary at this time. Instead, FDA is only discussing the new data that are the basis for the current proposal.

II. New Data

A significant amount of research has been conducted on the skin bleaching ingredient hydroquinone, and a number of reports have appeared in the literature since publication of the TFM in 1982. As a result, FDA has evaluated significant additional new data on the safety of hydroquinone. Toxicology and carcinogenesis studies on orally administered hydroquinone conducted under the support of the National Toxicology Program (NTP) (Refs. 1 and 2) have indicated ''some evidence'' of carcinogenicity in male and female rats and in female mice. FDA's Center for Drug Evaluation and Research (CDER) Carcinogenicity Assessment Committee (CAC) has evaluated the design, results, and NTP interpretation of these studies, and concurs with the NTP's assessment. The CAC determined that additional safety studies are needed and, to date, those studies have not been submitted to FDA. Based on the evidence of carcinogenicity in animals, FDA cannot rule out the potential carcinogenic risk from topically applied hydroquinone in humans. In addition, hydroquinone has been shown to cause disfiguring effects (ochronosis) after use of concentrations as low as 1 to 2-percent.

A. Fertility Studies

The Environmental Protection Agency (EPA) has been evaluating the safety of hydroquinone since 1979. In the **Federal Register** of December 7, 1979 (44 FR 70664), the Interagency Testing Committee (ITC), in its Fifth Report,

designated hydroquinone for priority consideration. The ITC recommended that hydroquinone be considered for testing for carcinogenicity and teratogenicity, and that epidemiology, human metabolism, and environmental fate studies also be considered. Under section 4(a) of the Toxic Substances Control Act (15 U.S.C. 2603), EPA published two notices for manufacturers and processors of hydroquinone to perform studies to evaluate hydroquinone's: (1) Toxicokinetics and (2) potential nervous system, reproductive, and teratogenic effects. EPA did not propose oncogenicity testing of hydroquinone because the NTP was conducting a 2-year bioassay on hydroquinone. EPA's proposal was published in the **Federal Register** of January 4, 1984 (49 FR 438), and its final rule for hydroquinone testing requirements was published in the **Federal Register** of December 30, 1985 (50 FR 53145).

EPA stated in its final rule (50 FR 53145 at 53148) (references omitted): ''Developmental toxicity and reproductive effects. At oral doses of 50 mg/kg/day [milligram/kilogram/day] and higher, Racz reported that hydroquinone prolonged the diestrus period of the sexual cycle in female albino rats. Skalka, subcutaneously injecting male rats at a dose of 100 mg/kg/day for 51 days, reported decreased weights in testes, epididymides, seminal vesicles and adrenal glands; histological changes in testes indicating disrupted spermiogenesis; and diminished DNA content of sperm heads. * * *''

EPA provided FDA copies of several studies (Refs. 1 through 9) that had been submitted to EPA by the Chemical Manufacturers Association (CMA). These studies addressed the evaluation guidelines outlined in EPA's final rule for hydroquinone testing requirements. The data included the 2-year bioassay study of hydroquinone that was conducted by NTP. FDA has evaluated the data on hydroquinone provided by EPA, along with other new data submitted to FDA and found the following:

In a study by Salzgeber (Ref. 3), hydroquinone was shown to inhibit the normal growth of ovaries from 10-day chick embryos cultured in vitro. Seven of the 15 ovaries were abnormal when examined histologically. The cortex was partially or totally inhibited. Only a medullary region remained, and it was poorly differentiated.

Hydroquinone increased the resorption (pregnant rats reabsorbing their fetus as a marker for unsuccessful pregnancy) rate when given in the diet to pregnant rats (Ref. 4). One hundred percent of all hydroquinone-treated litters had resorptions, compared with 40.8 percent for control litters; 26.8 percent of implantations resulted in resorptions in treated animals compared with 10.6 percent in control rats. In a developmental toxicity study submitted by CMA (Ref. 5), hydroquinone given orally at doses of 30, 100, and 300 milligrams (mg)/kilograms (kg) to pregnant rats did not produce embryotoxic, fetotoxic, or teratogenic effects. Measurement of resorption rate was not reported in the study. Maternal toxicity was observed in the form of a slight, but statistically significant, reduction in maternal body weight gain and feed consumption in rats receiving the high dose (300 mg/kg).

In a similar protocol, the embryotoxic, fetotoxic, and teratogenic potential of hydroquinone was evaluated in pregnant rabbits (Ref. 6). Hydroquinone was dissolved in degassed distilled water and administered by gastric intubation. A dose level of 25 mg/kg/day was without maternal toxic effects and was not considered to be embryotoxic, fetotoxic, or teratogenic. In the mid-dose group (75 mg/kg/day), the only maternal toxic effect seen was a statistically significant reduction (when compared to controls) in food consumption on days 11 and 12 of gestation. In the high dose group (150 mg/kg/day), maternal toxicity was evident from the following statistically significant differences from the control data:

- Lower weights for days 16 and 18 of gestation
- Greater magnitude of weight loss over the treatment interval for days 6 to 18 of gestation
- Reduced food consumption for days 6 to 14 and 17 of gestation.

An increase in incidence of fetuses with external, visceral, and skeletal malformations was seen in the high dose group, and the incidence of litters containing affected fetuses was also increased. These incidences did not differ statistically from the controls, and malformations seen were considered to be associated with the maternal toxicity evident at the same dose level.

A reproduction study in rats was designed to assess the long-term effects of hydroquinone administered daily in an aqueous solution via gastric intubation at dose levels of 15, 50, and 150 mg/kg/day through two consecutive generations of rats (Ref. 7). The results showed that hydroquinone did not adversely affect the following:

- Maternal body weights (gestation/lactation periods)
- Gestational feed consumption
- Reproductive performance
- Fertility of parental animals
- Body weight or feed consumption during pre-mating treatment periods.

No adverse effects of treatment were evident during either generation on pup body weight, pup sex distribution, or pup survival to weaning, including doses of hydroquinone as high as 150 mg/kg/day.

Because some studies showed fertility was impaired and others did not, FDA cannot make a final determination on hydroquinone's potential to impair fertility related to decreased spermatogenesis or prolonged reproductive cycle in animals or humans. Additional studies are needed to make a better assessment.

B. Toxicokinetic Studies

Toxicokinetic studies with hydroquinone were conducted in rats following oral gavage and dermal administration (Ref. 8). Elimination (87 to 92-percent) of a single oral dose of hydroquinone occurred primarily within the first 8 hours after dosing. Using the cumulative 48 to 72 hour urine recovery data, dermal absorption was estimated to be 10.5 to 11.5 percent. All groups had similar chemical profiles following oral and dermal administration of hydroquinone.

Hydroquinone (2-percent) in an alcoholic vehicle was found to penetrate readily in human forehead skin following a single topical exposure in vivo for a 24-hour duration (Ref. 9). The average percutaneous absorption of hydroquinone was 57 percent. The addition of azone (a penetration enhancer) increased the absorption to 66 percent. Addition of Escalol 507 (a sunscreen), with and without azone, decreased the absorption of hydroquinone (35 and 26 percent, respectively).

C. Carcinogenicity Studies

The NTP 2-year bioassay studies (Refs. 1 and 2) were conducted by administering 0, 25, or 50 mg/kg hydroquinone in deionized water by gavage to groups of 65 Fischer 344/N rats of each sex, 5 days per week. Groups of 65 B6C3F1 mice of each sex were administered 0, 50, or 100 mg/kg on the same schedule. Nearly all male rats and most female rats in all vehicle control and dosed groups had nephropathy. The severity of this disease was greater in the high dose male rat group. Hyperplasia of the renal pelvic transitional epithelium and renal cortical cysts, changes which are observed with advanced renal disease, were increased in male rats. Renal tubular hyperplasia was seen in 2/55 high dose male rats, and renal tubular

adenomas were seen in 4/55 low dose and 8/55 high dose male rats; none were seen in the vehicle controls.

Mononuclear cell leukemia in female rats occurred with a dose-related trend and the incidences in the dosed groups were greater than in the vehicle controls (vehicle control, 9/55; low dose, 15/55; high dose, 22/55; $p < 0.05$). The historical incidence of leukemia in water gavage vehicle control female F344/N rats is 25 ± 15 percent and in untreated controls is 19 ± 7 percent.

Compound-related lesions observed in the liver of male mice given 0, 50, and 100 mg/kg hydroquinone included anisokaryosis (0/55, 2/54, 12/55)[1], syncytial alteration (5/55, 3/54, 25/55), and basophilic foci (2/55, 5/54, 11/55). The incidences of hepatocellular adenomas were increased in dosed male mice (9/55, 21/54, 20/55), but the increases were offset by decreases in the incidences of hepatocellular carcinomas (13/55, 11/54, 7/55). The incidences of hepatocellular neoplasms, primarily adenomas, were increased in dosed female mice (3/55, 16/55, 13/55).

Follicular cell hyperplasia of the thyroid gland was increased in dosed mice (male: 5/55, 15/53, 19/54; female: 13/55, 47/55, 45/55). Follicular cell adenomas were seen in male mice (2/55, 1/53, and 2/54) and female mice (3/55, 5/55, and 6/55). A follicular cell carcinoma was seen in a seventh high dose female mouse. The highest observed incidence of follicular cell adenomas or carcinomas (combined) in historical water gavage vehicle control female B6C3F1 mice is 3/48 (6 percent).

In conclusion, these studies showed ''some evidence'' of carcinogenic activity of hydroquinone as follows:

- Male F344/N rats: Marked increases in tubular cell adenomas of the kidney
- Female F344/N rats: Increases in mononuclear cell leukemia
- Female B6C3F1 mice: Increases in hepatocellular neoplasms, mainly adenomas
- Female and male B6C3F1 mice: Thyroid follicular cell hyperplasia
- Male B6C3F1 mice: Anisokaryosis, multinucleated hepatocytes, and basophilic foci of the liver.

NTP interprets the findings of each bioassay with regard to the strength of the experimental evidence. NTP defines ''some evidence'' of carcinogenicity as demonstrated by studies that are interpreted as showing a chemically related increased incidence of neoplasms (malignant, benign, or combined) in which the strength of the response is less than that required for clear evidence. ''Clear evidence'' of carcinogenicity is considered demonstrated by studies that are interpreted as showing one of the following:

- A dose-related increase of malignant neoplasms
- An increase of a combination of malignant and benign neoplasms
- A marked increase of benign neoplasms if there is an indication from this or other studies of the ability of such tumors to progress to malignancy.

NTP's conclusion for these studies is that there was ''some evidence'' of carcinogenic activity in male and female rats and in female mice.

On February 11, 1992, the Nonprescription Drug Manufacturers Association (NDMA) requested to meet with FDA to discuss the safety of hydroquinone, specifics of the NTP study, and its research plans related to that study (Ref. 10). That meeting was held on May 20, 1992 (Ref. 11). NDMA presented a research program to further evaluate hydroquinone's carcinogenic potential based on the oral bioassay studies NTP performed. NDMA also discussed projected timelines for completing the proposed safety studies of hydroquinone. FDA also received additional data (Refs. 12 and 13) from NDMA, containing updates on chronic health effects testing for hydroquinone. These updates provided results of completed studies, including preliminary results for ongoing studies, and an outline of studies in the planning phase. FDA evaluated the studies and concluded that the available data are insufficient to rule out the potential carcinogenic risk from topically applied hydroquinone.

On July 10, 1996 (Ref. 14), FDA and NDMA met to discuss the safety of hydroquinone as an active ingredient in OTC skin bleaching drug products. Safety discussion points included the following:

- Mechanism of action of hydroquinone in tumor formation,
- Two year gavage study of hydroquinone in rats,
- Genotoxicity test results, and
- In vitro percutaneous absorption of hydroquinone through human skin.

FDA and NDMA agreed to present the data concerning the safety of hydroquinone with respect to an oral carcinogenicity study to FDA's CDER CAC. Subsequently, on December 4, 1996 (Ref. 15), information from the July 10, 1996, meeting and the 1989 NTP draft technical report were discussed at a CAC meeting. A majority of the CAC members agreed that the available data are insufficient to rule out the potential carcinogenic risk from topically applied hydroquinone and recommended that additional studies be performed to assess the safety of skin bleaching drug products containing 2-percent hydroquinone. The CAC indicated that a dermal carcinogenicity study, conducted in an appropriate model with functioning mellanocytes, must be performed on hydroquinone to assess both its topical and systemic tumorgenicity. In a December 7, 1998, letter (Ref. 16), FDA informed NDMA of our findings on its previous data submissions and the CAC recommendations. FDA also requested NDMA to provide an implementation schedule, which should include the timeframe for protocol development, protocol submission, study initiation and completion, and analysis of data. In an April 13, 1999, letter (Ref. 17), the Consumer Healthcare Products Association (CHPA; formerly NDMA) provided the following projected dates for additional safety studies of hydroquinone:

- May 1999—submit draft protocols for FDA review
- August 1999—initiate 4-week range-finding study
- November 1999—submit revised 2-year study protocol to FDA
- January 2000—initiate the 2-year study
- January 2002—conduct terminal sacrifice and necropsy

Since April 13, 1999, CHPA has not provided any additional information.

D. Occurrence of Exogenous Ochronosis

Ochronosis refers to the deposition of polymerized homogentisic acid (HGA; 2,5-dihydroxyphenylacetic acid) as a grossly blue-black pigment in all collagen-containing structures. Ochronosis is classically associated with the autosomal recessively inherited metabolic disorder, alkaptonuria, in which the hepatic and renal enzyme HGA oxidase is absent (Refs. 18 and 19). Exogenous (acquired) ochronosis is a condition involving the deposition of blue-black pigment in the skin and is associated with the topical application of various chemicals. In severe cases, ochronosis may cause disfiguring and irreversible effects. FDA is aware that the occurrence of ochronosis has been reported following the topical application of hydroquinone.

Studies have shown that exogenous ochronosis caused by short- or long-term use of high or low concentrations of hydroquinone-containing bleaching creams has been well described in African blacks (Refs. 20 through 28). In 1975, Findlay, Morrison, and Simson (Ref. 20) first reported the development of exogenous ochronosis and pigmented

[1] Numbers reported for the vehicle control, low dose, and high dose groups, respectively.

colloid milium on the faces of black women in South Africa caused by prolonged use of skin bleaching creams containing hydroquinone (5 percent or greater). These lesions usually appeared after about 3 years of using the bleaching creams. The Panel reviewed this study and concluded that prolonged use of high concentrations (5 percent or more) of hydroquinone with exposure to sun may produce disfiguring effects (43 FR 51546 at 51549). Findlay and Beers (Ref. 21) found that up to 30 percent of outpatients in a dermatology clinic in South Africa wanted treatment of ochronosis following the use of skin lightening preparations containing hydroquinone for 3 years on average.

Phillips et al. (Ref. 22) reported 395 of 5,128 black patients who had used skin lightening products had ochronosis. The ochronosis was categorized as mild (darkening and thickening of the skin), moderate (large black bumps), or severe (larger intensively black caviar-like bumps).

According to Hardwick et al. (Ref. 23), in 1983 South Africa passed legislation that limited the concentration of hydroquinone in OTC skin lightening products to 2-percent in response to the severity of exogenous ochronosis in its black population. In addition, all skin lightening products had to contain a sunscreen with a minimum Sun Protection Factor of 5. In 1986, Hardwick et al. conducted a survey of adult South African blacks (both sexes) to investigate the relationship between exogenous ochronosis and the use of skin lightening products containing hydroquinone. Of 12 individuals who had begun using skin lightening products after 1983, seven (58 percent) had developed exogenous ochronosis.

Olumide, Odunowo, and Odiase (Ref. 24) discussed the common causes of facial hyperpigmentation in the black African population. One of the causes discussed was hydroquinone-induced exogenous ochronosis from bleaching creams containing hydroquinone. The physical signs included darkening and thickening of the skin, yellow-to-brown dome-shaped tiny bumps, and grayish-brown spots. Jordaan and Mulligan (Ref. 25) presented a case of a 39-year-old black South African woman with skin lesions on her face and neck. She had been using a skin bleaching cream containing an unknown concentration of hydroquinone for many years. Physical examination showed severe ochronosis on the cheeks, forehead, and neck. Weiss, de Fabbro, and Kolisang (Ref. 26) conducted a survey on black South African women, ages 16 to 40 years, to determine the prevalence of exogenous ochronosis caused by skin lightening products containing hydroquinone. Of 65 women who had used skin lightening products after 1983, 42 (65 percent) had developed exogenous ochronosis.

Levin and Maibach (Ref. 27) presented some reasoning for the high prevalence of exogenous ochronosis among South African blacks. The high concentrations of hydroquinone used in South Africa skin-lightening products prior to 1984 were linked with increased incidence of exogenous ochronosis. Since the South African Government mandated a limit of 2-percent hydroquinone in skin bleaching creams in 1983, exogenous ochronosis still continues to occur and appears to be on the increase. Causes may be due to several factors in addition to hydroquinone. There was a marketed growth for use of an antiacne product containing resorcinol, also known as an ochronotic agent. Hydroquinone and resorcinol are often used together for a more rapid skin lightening agent. The predominant formulation for skin bleaching in South Africa includes hydroquinone and hydroalcoholic acid, which may contribute to the high incidence of exogenous ochronosis.

Mahe et al. (Ref. 28) conducted a questionnaire study on cosmetic use of bleaching creams on 368 dark-skinned women from sub-Saharan Africa who were patients at the dermatological center in Senegal. Also in a separate study, Mahe et al. recorded information on 425 women who actually used bleaching creams on a regular basis. Of the 368 women questioned, 194 (52.7 percent) were current users of bleaching products. Of the 425 users enrolled, 92-percent used products on the body. The active ingredients used included hydroquinone (89 percent of users), glucocorticoids (70 percent), mercury iodide (10 percent), caustic agents (17 percent), and products of unknown composition (13-percent). Complete skin examination of women using skin bleaching products revealed 14 cases of exogenous ochronosis.

Exogenous ochronosis was not extensively reported in the United States or the United Kingdom as a result of using OTC skin bleaching drug products containing 2-percent hydroquinone until after publication of the TFM for these drug products in 1982. In 1983, Cullison, Abele, and O'Quinn reported blue-black darkening of the face of a 50-year-old black woman (Ref. 18). This condition started on the right cheek and soon thereafter involved the entire face. For over 2 years, the woman had used a proprietary bleaching cream containing 2-percent hydroquinone to ''brighten'' her complexion. When the darkening of the skin began to appear, the woman increased the application of the bleaching cream from twice a day to five or six times a day. Physical examination revealed a sooty blue-black darkening of the face without involvement of the eyes or ears. The darkening of the skin was relatively uniform, with some spots on the upper cheeks and the skin creases of the cheeks and forehead. A 2-millimeter (mm) biopsy specimen was taken and stained. The biopsy demonstrated a yellow-brown pigment present within mixed and swollen collagen bundles in the upper skin layer. These findings were interpreted as ochronosis.

Hoshaw, Zimmerman, and Menter (Ref. 29) described two black American women who had ochronosis-like pigmentation and colloid milium formation following the topical use of a 2-percent hydroquinone bleaching cream. The first black woman was a 75-year-old who had a 10-year history of pigmentation of the cheeks and nose in association with minimal itching. For the previous 2 years, she had used a 2-percent hydroquinone skin bleaching product to treat the pigmented areas. Physical examination disclosed multiple pigmented papules situated predominantly on the cheeks and extending around the lateral area of the eyes onto the forehead. There was an associated melasma-type macular pigmentation. The woman's condition was relatively unchanged 1 year later.

The second black woman was a 49-year-old who had a 2-year history of dark blotches on the face. During the previous 3-months, she had used a variety of 2-percent hydroquinone skin bleaching products to lighten her skin color. Instead of lightening, she noticed progressive darkening of the treated areas. Physical examination disclosed sharply separated areas of blue-black darkening of the skin over the cheeks, nose, and chin. The pigment was located essentially in discrete spots of less than 0.5 mm in size. In both cases, histological examination of a biopsy was consistent with ochronosis.

Tidman, Horton, and MacDonald (Ref. 30) reported a case of a 45-year-old Nigerian woman, resident in the United Kingdom for 7 years, who had a 7-month history of localized darkening of the face. This condition had been transiently preceded by erythema. Over a period of 10 years, the woman had intermittently applied to her face a proprietary depigmenting cream which contained 2-percent hydroquinone. Physical examination revealed a pronounced symmetrical darkening of the skin involving the cheek regions and, to a lesser extent, the nose and

chin. There was no evidence of spontaneous resolution after 11 months.

Conner and Braunstein (Ref. 31) reported a case of a 72-year-old black woman with a 1-month history of progressive darkening of her face. Since childhood, the woman had been applying a bleaching cream containing hydroquinone to her face in an attempt to lighten her complexion. Physical examination revealed blue-black spots along with patches on the forehead, cheek, and temporal regions. A biopsy specimen from the darkened skin led to a diagnosis of exogenous ochronosis.

Lawrence, et al. (Ref. 32) described two middle aged black women who reported unusual darkening of the face after using bleaching creams containing hydroquinone. One woman (62 years old) had applied a 1-percent hydroquinone bleaching cream for 2 to 3 years to the cheek area for mild darkening of the skin. The woman noted mild lightening of her skin during the first few months of use. After extended use, she noticed the return of the pigmentation, followed by diffuse darkening of the skin that was limited to the areas treated with the cream. Physical examination revealed dark spots across her cheeks.

The second woman (45 years old) had darkening of the skin on her face of 2 months' duration. The woman had used a 1-percent hydroquinone cream to lighten several post inflammatory lesions. After some initial lightening, she noted progressive darkening of the skin. Physical examination revealed a dark spot eruption extending over the bridge of her nose, the cheek, the eye areas, and across the forehead. The histopathologic findings of a biopsy specimen were consistent with ochronosis.

Howard and Furner (Ref. 33) presented a case of a 36-year-old Mexican-American woman with symptoms of darkening of the skin on her face after she used an OTC skin bleaching cream containing 2-percent hydroquinone for 4 months. Physical examination of the woman's face showed even blue-black, dark spots on her cheeks, chin, and forehead, as well as several dark spots on her gum line and inner cheek area. A biopsy specimen was consistent with exogenous ochronosis.

Diven, et al. (Ref. 34) reported a case of a 53-year-old black woman who noticed a progressive darkening of her face after applying a ''skin whitener cream'' and a cream containing 2-percent hydroquinone for a 2 to 3 month duration. Examination showed sooty blue-black spots and patches, which were prominent around the eye and cheek areas. A biopsy specimen from the pigmented area showed the yellow-brown deposits in the skin characteristic of exogenous ochronosis.

Jordaan and Van Niekerk (Ref. 35) reported two cases of severe ochronosis with superimposed papilar lesions after long-term application of skin lightening creams containing hydroquinone. The first case (a 56-year-old black man) had been using 6.5 to 7.5 percent hydroquinone periodically for many years. The second case (a 39-year-old black woman) had been using a skin lightening cream containing an unknown concentration of hydroquinone for 5 years. The woman had severe papular ochronosis on her face, forehead, and neck.

Martin, et al. (Ref. 36) reported two cases of exogenous ochronosis secondary to the topical use of hydroquinone containing bleaching creams. The first case (a 44-year-old woman) noticed progressive darkening of her skin for 3 years while using OTC bleaching creams. She had a grayish-black pigmentation localized to her cheeks, forehead, and the bridge of her nose, which corresponded to tiny grayish-black bumps. The second case (a 56-year-old black woman) had a history of facial pigmentation for 30 years while using many OTC skin bleaching creams. She had round dark spots localized to both temples and a purplish-black spot on the left lower eye area.

Snider and Thiers (Ref. 37) reported a case of exogenous ochronosis in a 59-year-old black woman who had a 5-year history of progressive darkening of the skin around her eyes. She had been using 2-percent hydroquinone skin bleaching cream once daily for many years. About 9 months before examination she had used 3-percent hydroquinone twice daily for 3 months, then 4-percent hydroquinone twice daily for 3 months, and then 4-percent hydroquinone with a sunscreen twice daily for 3 months. Examination showed numerous pinpoint blue-black spots around the eye area. A biopsy specimen revealed multiple scattered, elongated, curved, and oval deposits of ochronotic pigment within the collagen bundles.

Camarasa and Serra-Baldrich (Ref. 38) reported a case of a 45-year-old woman who had a 9-month history of darkening of the cheeks and eye area from using a skin lightening cream containing 2-percent hydroquinone. She was patch tested with a standard series, cosmetics, vehicles, and hydroquinone. The results showed this woman's reaction was consistent with the diagnosis of exogenous ochronosis.

Bowman and Lesher (Ref. 39) reported a 75-year-old black woman with numerous discrete, 2- to 3-mm, firm, yellowish bumps on her forehead, cheeks, and chin; many had surrounding areas of dark spots. She was diagnosed with a case of primary multiple miliary osteoma cutis (MMOC), a rare disorder characterized by the appearance of numerous bony nodules on the face. She had used OTC topical acne medications and bleaching creams for 3 years in an attempt to treat the disorder. Several biopsies showed collections of homogenous yellow-brown pigment in the upper dermis, which also led to the diagnosis of exogenous ochronosis.

III. FDA's Tentative Conclusions on Skin Bleaching Drug Products

A significant amount of research has been conducted on the skin bleaching ingredient hydroquinone, and a number of reports have appeared in the literature since publication of the TFM in 1982. As a result, FDA evaluated significant additional new data on the safety of hydroquinone. Although we cannot make a final determination on hydroquinone's potential to impair fertility, toxicology and carcinogenesis studies on orally administered hydroquinone conducted under the support of NTP (Refs. 1 and 2) have indicated ''some evidence'' of carcinogenicity in male and female rats and in female mice after gavage administration. ''Some evidence'' of carcinogenic activity is defined as studies that are interpreted as showing a chemically related increased incidence of neoplasms (malignant, benign, or combined) in which the strength of the response is less than that required for ''clear evidence'' (e.g., same finding in two of the four sex/species groups, extensive malignancy, etc.). In these studies:

- Male rats had increased renal tubular cell adenomas without associated increases in nonneoplastic findings or bladder lesions;
- Female rats had increased mononuclear cell leukemia; and
- Female mice had increased hepatocellular neoplasms, mainly adenoma.

FDA's CDER CAC has evaluated the design, results, and NTP interpretation of these studies, and concurs with the NTP assessment. The CAC recommended additional studies, which have not been submitted to date. The evidence of carcinogenicity in animals in combination with the high absorption rate (57 percent) of hydroquinone demonstrated in humans does not allow FDA to rule out the potential carcinogenic risk from topically applied hydroquinone in humans. Further,

hydroquinone has been shown to cause disfiguring effects (ochronosis) after use of high concentrations (5 percent or greater) and at concentrations as low as 1 to 2-percent.

Skin bleaching products are drugs under section 201(g)(1)(C) of the act if they are intended to affect the structure or function of the body (e.g., products intended to suppress melanin pigment formation within skin cells). In evaluating the suitability of such drug products for OTC use, FDA considers, among other factors, the benefit-to-risk ratio of the drug. For OTC skin bleaching drug products, FDA tentatively concludes that there is no benefit to physical health that would justify the continued marketing of these products. Because the choice to use a drug is not considered an inadvertent exposure, risks may be outweighed by benefits, where they exist. Where the benefit appears low and use of the drug is proposed for an otherwise healthy target population, the risks should be minimal. For these OTC drug products, the sole intended benefit would be to improve the user's appearance by bleaching the skin.

The actual risk to humans from the use of hydroquinone has yet to be fully determined. There is, however, evidence of carcinogenicity related to hydroquinone in animals and disfiguring effects (ochronosis) in humans. Under these circumstances, the use of hydroquinone as an active ingredient in OTC skin bleaching drug products cannot be justified. Therefore, in light of the new data discussed in this document, FDA has reassessed the position stated in the 1982 TFM (47 FR 39108).

FDA now proposes that skin bleaching drug products should not be available OTC. FDA finds that because of the carcinogenic and ochronotic potential of hydroquinone, its use in skin bleaching drug products should be restricted to prescription use only, and users of such products should be closely monitored under medical supervision. FDA now tentatively concludes that skin bleaching drug products, including but not limited to those that contain hydroquinone, which have been reviewed by the Panel and FDA should be considered not GRASE. Accordingly, the proposed monograph (TFM) published in the **Federal Register** of September 3, 1982, which proposed 21 CFR part 358, subpart A (Skin Bleaching Drug Products for Over-The-Counter Human Use), is hereby withdrawn.

FDA emphasizes that this withdrawal does not in any way denigrate the scientific content of the Panel's report on these products or negate the excellent work of the Panel in its long efforts to produce it. FDA recognizes that OTC skin bleaching drug products constitute a very small segment of the marketplace and that withdrawal of the proposed monograph does not affect FDA's authority to take action against OTC skin bleaching drug products that are unsafe and misbranded.

The only other skin bleaching active ingredient evaluated in this rulemaking was ammoniated mercury, which FDA declared to be not GRASE in the **Federal Register** of November 7, 1990 (55 FR 46914 at 46919). FDA now proposes that all skin bleaching drug products be considered new drugs within the meaning of section 201(p) of the act (21 U.S.C. 321(p)), for which approved NDAs under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314) are required for marketing. In the absence of an approved NDA, such a product would also be misbranded under section 502 of the act (21 U.S.C. 352). This proposal applies only to drugs marketed OTC, and it would amend § 310.545, which applies only to OTC drugs. However, FDA emphasizes that it regards all skin bleaching drug products, whether marketed on a prescription or OTC basis, to be new drugs. This does not preclude other OTC drugs from being considered for the OTC drug monograph on skin bleaching drug products (e.g., under the procedures in 21 CFR 330.14).

IV. Analysis of Impacts

FDA has examined the impacts 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 net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement and economic analysis 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.''

FDA concludes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product.

The purpose of this proposed rule is to establish that OTC skin bleaching drug products are not GRASE and are misbranded. Most skin bleaching drug products that contain hydroquinone as an active ingredient are currently marketed as OTC drug products. Some such products (usually those containing above 2-percent hydroquinone) are marketed by prescription. FDA's Drug Listing System identifies approximately 200 products containing hydroquinone in strengths from 0.4 to 5.0 percent (Table 1).

TABLE 1.—NUMBER OF SKIN BLEACHING DRUG PRODUCTS CONTAINING VARIOUS CONCENTRATIONS OF THE ACTIVE INGREDIENT HYDROQUINONE

Percent Hydroquinone	Number of Products
5	2
4	65
3	8
2	110
<2	21

About two-thirds of these products appear to be marketed as OTC drugs. These products are marketed by approximately 65 different manufacturers, most of which are considered to be small entities, using the U.S. Small Business Administration designations for this industry (750 employees). FDA believes that any other unidentified manufacturer of these products is also likely to be a small entity.

FDA tentatively concludes that the benefits of OTC skin bleaching drug products are insignificant when compared to the potential risks and that this proposed rule would benefit society because it would eliminate a potentially unsafe drug product. The proposed rule would prohibit the continued marketing of hydroquinone as an OTC drug product and require a NDA under 21 CFR part 314 for marketing.

FDA acknowledges that this proposed rule would have an impact on consumers who use OTC skin bleaching drug products containing hydroquinone to lighten limited areas of hyperpigmented skin. They will no longer be able to purchase these OTC drug products after current inventories are depleted.

The benefit of removing OTC skin bleaching drug products from the market will be a reduction in the number of cases of ochronosis that would otherwise occur each year. However, FDA has limited information to assign a monetary value to the prevention and treatment of ochronosis and the direct medical costs and indirect costs, such as psychological suffering, resulting from disfigurement due to ochronosis.

The 65 manufacturers of these products will incur the majority of the costs of this proposed rule, in the form of lost sales. They would also incur the costs of obtaining an approved NDA if they wished to continue to market their product(s) by prescription. Manufacturers who have followed the FDA-NDMA (CHPA) dialogue on these hydroquinone drug products should have known for some time that if additional adequate data were not provided to support safety, a nonmonograph status for these products would occur. Thus, this economic analysis, together with other relevant sections of this document, serves as FDA's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

V. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) 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.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 751 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379r) is an express preemption provision. Section 751(a) of the act (21 U.S.C. 379r(a)) provides that ''* * * no State or political subdivision of a State may establish or continue in effect any requirement-- * * * that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).''

Currently, this provision operates to preempt States from imposing requirements related to the regulation of nonprescription drug products. (See Section 751(b) through (e) of the act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.) This proposed rule, if finalized as proposed, would establish that OTC skin bleaching drug products are not GRASE and are misbranded. Although any final rule would have a preemptive effect, in that it would preclude States from promulgating requirements related to OTC skin bleaching drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule, this preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision is not applicable, implied preemption may arise. See *Geier* v. *American Honda Co.*, 529 US 861 (2000).

FDA believes that the preemptive effect of the proposed rule, if finalized as proposed, would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA is providing an opportunity for State and local officials to comment on this rulemaking.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document and on FDA's economic impact determination. 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Proposed Effective Date

Because there will be no need to reformulate or relabel any of these products, FDA is proposing that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 1978N–0065 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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7. Bio/dynamics Inc., ''A Two-Generation Reproduction Study in Rats With Hydroquinone,'' Project No. 87–3219, 1989, in OTC Vol. 16ATFM2.

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9. Bucks, D. A. W. et al., ''Percutaneous Absorption of Hydroquinone in Humans: Effect of 1-Dodecylazacycloheptan-2-One (Azone) and the 2-Ethylhexyl Ester of 4-(Dimethylamino)Benzoic Acid (Escalol 507),'' *Journal of Toxicology and Environmental Health*, 24:279–288, 1988.

10. Comment No. LET2.

11. Comment No. MM1.

12. Comment No. RPT3.

13. Comment No. RPT5.

14. Comment No. MM2.

15. Comment No. MM3.

16. Comment No. LET16.

17. Comment No. C24.

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19. Fisher, A. A., ''Exogenous Ochronosis from Hydroquinone Bleaching Cream,'' *Cutis*, 62:11–12, 1998.

20. Findlay, G. H., J. G. L. Morrison, and I. W. Simson, ''Exogenous Ochronosis and Pigmented Colloid Milium From Hydroquinone Bleaching Creams,'' *British Journal of Dermatology*, 93:613–622, 1975.

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22. Phillips, J. I., C. Isaacson, and H. Carman, ''Ochronosis in Black South Africans Who Used Skin Lighteners,'' *The American Journal of Dermatopathology*, 8:14–21, 1986.

23. Hardwick, N. et al., ''Exogenous Ochronosis: An Epidemiological Study,'' *British Journal of Dermatology*, 120:229–238, 1989.

24. Olumide, Y. M., B. D. Odunowo, and A. O. Odiase, ''Regional Dermatoses in the African. Part I. Facial Hypermelanosis,'' *International Journal of Dermatology*, 30:186–189, 1991.

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List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the proposed rule that published on September 3, 1982 (47 FR 39108), is withdrawn and it is proposed that 21 CFR part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by revising paragraphs (a)(17), (d) introductory text, and (d)(1) and by adding new paragraph (d)(41) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(17) *Skin bleaching drug products*—(i) *Ingredient—Approved as of May 7, 1991.*

Mercury ammoniated

(ii) *Ingredients—Approved as of* [date 30 days after date of publication in the **Federal Register**].

Hydroquinone

Any other ingredient

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(41) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4)(i), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), (a)(16), (a)(17)(i), and (a)(18)(i)(A) of this section.

* * * * *

(41) [30 days after date of publication in the **Federal Register**], for products subject to paragraph (a)(17)(ii) of this section.

Dated: August 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14263 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–121509–00]

RIN 1545–AY54

Exclusion From Gross Income of Previously Taxed Earnings and Profits, and Adjustments to Basis of Stock in Controlled Foreign Corporations and of Other Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance relating to the exclusion from gross income of previously taxed earnings and profits under section 959 of the Internal Revenue Code (Code) and related basis adjustments under section 961 of the Code. These regulations reflect relevant statutory changes made in years subsequent to 1983. These regulations also address a number of issues that the current section 959 and section 961 regulations do not clearly answer. These regulations, in general, will affect United States shareholders of controlled foreign corporations and their successors in interest.

DATES: Written or electronic comments and requests for a public hearing must be received by November 27, 2006.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–121509–00), Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044 or send electronically, via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–121509–00).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Ethan Atticks, (202) 622–3840; concerning submissions of comments, Kelly Banks, (202) 622–0392 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to 26 CFR part 1 under sections 959 and 961. Section 959(a)(1) generally provides an exclusion from the gross income of a United States shareholder for distributions of earnings and profits of a foreign corporation attributable to amounts which are, or have been, included in a United States shareholder's gross income under section 951(a). Section 959(a)(2) excludes from the gross income of a United States shareholder earnings and profits attributable to amounts which are, or have been, included in the gross income of a United States shareholder under section 951(a) which would, but for section 959(a)(2), be again included in gross income of a United States shareholder under section 951(a)(1)(B) as an amount determined under section 956 (section 956 amounts). Earnings and profits of a foreign corporation included in a United States shareholder's gross income under section 951(a) are referred to as previously taxed earnings and profits or previously taxed income (PTI).

Section 959(b) generally provides that for purposes of section 951(a), PTI shall not, when distributed through a chain of ownership described in section 958(a), be included in the gross income of a controlled foreign corporation (CFC) in such chain for purposes of the application of section 951(a) to such CFC.

Section 959(c) generally provides for the allocation of distributions by a foreign corporation to three different categories of the corporation's earnings and profits: (1) PTI attributable to section 956 amounts that are included in the gross income of a United States shareholder under section 951(a)(1)(B) and section 956 amounts that would have been so included but for section 959(a)(2), (2) PTI attributable to amounts included in gross income under section 951(a)(1)(A), and (3) other earnings and profits (non-PTI). Section 959(f) provides for the allocation of section 956 amounts first to PTI arising from a United States shareholder's income inclusions under section 951(a)(1)(A) and then to non-PTI. In addition, section 959(f) provides a priority rule under which actual distributions of earnings and profits are taken into account before section 956 amounts.

Certain amounts are treated as amounts included in the gross income of a United States shareholder under section 951(a)(1)(A) for purposes of section 959. For example, section 959(e) generally provides that any amount included in the gross income of any person as a dividend by reason of subsection (a) or (f) of section 1248 is treated for purposes of section 959 as an amount included in the gross income of such person under section 951(a)(1)(A).

Section 961 authorizes the Secretary of the Treasury to promulgate regulations adjusting the basis of stock in a foreign corporation, as well as the basis of other property by reason of which a United States person is considered under section 958(a) to own stock in a foreign corporation. Section 961(a) generally provides for an increase in a United States shareholder's basis in its CFC stock, or in the property by reason of which it is considered to own such stock, by the amount required to be included in its gross income under section 951(a) with respect to such stock.

Under section 961(b), and the regulations thereunder, when a United States person receives an amount which is excluded from gross income under section 959(a), the adjusted basis of the foreign corporation stock or the property by reason of which the shareholder is considered to own such stock is reduced by the amount of the exclusion. In addition, section 961(c) generally provides for regulations under which adjustments similar to those provided for under section 961(a) and (b) are made to the basis of stock in a CFC which is owned by another CFC (and certain other CFCs in the chain) for the purpose of determining the amount included under section 951 in the gross income of a United States shareholder.

Section 959 was enacted so that PTI is excluded from gross income and, thus, not taxed again when distributed by the foreign corporation. Moreover, section 959 effects the relevant gross income exclusion at the earliest possible point. Thus, the ''allocation of distribution'' rules of section 959(c) ensure that distributions from the foreign corporation are to be paid first out of earnings and profits attributable to amounts that have been previously included in income by the United States shareholders. Accordingly, as a result of its section 951(a)(1) inclusion, a United States shareholder is made whole by receiving, without further U.S. tax, PTI attributable to its stock in a foreign corporation before it receives any taxable distributions from the foreign corporation. Section 961, which adjusts basis in the stock in a foreign corporation for PTI attributable to such stock, also ensures that PTI is not taxed twice if the stock in the foreign corporation is sold before the PTI is distributed.

The existing regulations under sections 959 and 961 were published in 1965. See TD 6795 (1965–1 CB 287). Minor amendments were made to the regulations in 1974, 1978, and 1983. See TD 7334 (1975–1 CB 246); TD 7545 (1978–1 CB 245); TD 7893 (1983–1 CB 132). The regulations have not been updated since 1983 to reflect relevant

statutory changes in subsequent years. For example, section 959(e) (described above) was added by the Deficit Reduction Act of 1984 (Pub. L. 98–369). Section 304(b)(6) was enacted by the IRS Restructuring and Reform Act of 1998 (Pub. L. 105–206) and provides that in the case of a section 304 transaction in which the acquiring corporation or the issuing corporation is a foreign corporation, the Secretary of the Treasury is to prescribe regulations providing rules to prevent the multiple inclusion of any item in income and to provide appropriate basis adjustments, including rules modifying the application of sections 959 and 961. The determination of the amount includible in a United States shareholder's gross income as a result of a CFC's investments in United States property under section 956 was modified by the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66). Congress enacted section 961(c) (described in this preamble) as part of the Taxpayer Relief Act of 1997 (Pub. L. 105–34) and further modified the provision in the Gulf Opportunity Zone Act of 2005 (Pub. L. 109–135). Section 986 was added to the Code by the Tax Reform Act of 1986 (Pub. L. 99–514) and provides that earnings and profits of foreign corporations are maintained in the foreign corporation's functional currency and translated into United States dollars when taken into account by a United States person at the appropriate exchange rate specified in section 989.

Further, in addition to raising issues about the complexities of section 959 in cross-chain stock sales subject to section 304(a)(1), commentators and taxpayers have raised a number of other issues that the current section 959 regulations do not clearly answer. For example, issues have been raised about distributions of PTI through a chain of CFCs and the status of PTI when a United States shareholder's stock in a foreign corporation is sold to a foreign person. There are numerous other examples where the existing section 959 regulations simply do not provide sufficient guidance. As a result, additional regulatory guidance is needed to address these and other section 959 issues. In addition, the IRS and Treasury Department are currently studying the new section 954(c)(6) rule enacted by the Tax Increase Prevention and Reconciliation Act of 2005 (Pub. L. 109–222), which provides for look-through treatment of payments between related CFCs under the foreign personal holding company rules of section 954(c), to determine whether that rule requires any additional regulatory guidance under section 959. Any such guidance will be included in a subsequent project.

Explanation of Provisions

These proposed regulations provide guidance with respect to a number of issues that are not specifically addressed in the current regulations and also resolve some of the complexities raised regarding the application of sections 959 and 961. The guidance needed to answer open issues under sections 959 and 961 is intended to be consistent with the legislative intent of avoiding double taxation and allowing United States persons to receive the full benefit of their PTI at the earliest possible time.

In order to carry out this legislative intent, these regulations propose new rules that are primarily based on maintaining shareholder accounts for PTI. As described in this preamble, maintaining shareholder accounts for PTI will better ensure that taxpayers are able to receive distributions of PTI before receiving taxable distributions, provide consistency for treatment of PTI by taxpayers and also, provide more rational and clear rules for resolving many of the issues that have been raised by taxpayers since the current section 959 regulations were issued. Under the proposed rules, earnings and profits will still be maintained at the foreign corporation level in the PTI and non-PTI categories described in section 959(c) on an aggregate basis with respect to all of the foreign corporation's outstanding shares.

The proposed rules also would modify the current regulations to reflect amendments to the law since 1965, such as the addition of section 959(e) and section 961(c), and the modification of sections 304 and 956. Minor changes have also been proposed to reflect changes in IRS titles and organizational units used in the current regulations.

A. Shareholder-Level Exclusion Under Section 959(a)

1. In General

Section 959 provides rules for the exclusion from gross income of PTI. Prop. Reg. § 1.959–1 describes the scope and purpose of the proposed regulations under section 959 in paragraph (a), and provides definitions in paragraph (b). Paragraph (c) generally provides for the exclusion from a covered shareholder's gross income of a distribution or section 956 amount based upon the amount of adjustments made to a shareholder's PTI accounts with respect to the relevant stock under Prop. Reg. § 1.959–3 because of that distribution or section 956 amount, as discussed below. A covered shareholder is defined to mean a person who is (1) a United States person who owns stock (within the meaning of section 958(a)) in a foreign corporation and who has had a section 951(a) inclusion with respect to its stock in such corporation, (2) a ''successor in interest'' (defined in this preamble), or (3) a corporation that is not described in (1) or (2) and that owns stock (within the meaning of section 958(a)) in a foreign corporation in which another corporation is a covered shareholder described in (1) or (2), if both corporations are members of the same consolidated group.

2. Shareholder PTI Accounts

Prop. Reg. § 1.959–1(d)(1) requires each covered shareholder of a foreign corporation to maintain a PTI account for each share of stock in a foreign corporation that the shareholder owns directly, or indirectly under section 958(a). Although the PTI account is share specific, as a matter of administrative convenience, Prop. Reg. § 1.959–1(d)(1) permits a shareholder to maintain the account with respect to an entire block of stock in foreign corporation if the PTI attributable to each share in the block is the same. For a discussion of the rules for maintaining a PTI account, see Part C of this discussion.

3. Successors in Interest

Section 959(a) extends the exclusion from gross income for PTI to any United States person who acquires from any person any portion of the interest of a United States shareholder (as the term is defined in section 951(b) or section 953(c)(1)(A)) in a foreign corporation, but only to the extent of that portion and subject to such proof of the identity of such interest as the Secretary of the Treasury may by regulations prescribe. Consequently, Prop. Reg. § 1.959–1(d)(2)(i) provides that a transferee of stock in a foreign corporation acquires the PTI account of the transferor for such stock and may exclude PTI from gross income under section 959(a) by reference to the PTI account for the stock acquired, if the transferee is a United States person that can prove the right to the exclusion (successor in interest).

In order to establish a United States person's right to the exclusion, the proposed regulations provide that a person must attach a statement to its return that provides that it is excluding amounts from gross income because it is a successor in interest and that provides the name of the foreign corporation.

Further, a person must be prepared to provide, within 30 days upon the request of the Director of Field Operations, certain additional information (e.g., evidence showing that the earnings and profits for which an exclusion is claimed are PTI and that such amounts were not previously excluded from the gross income of a United States person). The information that may be required under these proposed regulations remains substantially unchanged from the information that is currently required to be included in a statement with the United States person's return under § 1.959–1(d).

Moreover, Prop. Reg. § 1.959–1(d)(2)(ii) provides that the amount of the PTI account for stock that is transferred to someone who is not a successor in interest (e.g., a foreign person) is preserved unchanged during the period of such person's ownership of such stock. However, section 959(a) extends the section 959(a) exclusion to a United States person who acquires a United States shareholder's interest in a foreign corporation from any person. Accordingly, Prop. Reg. § 1.959–1(d)(2)(i) provides that if a United States person acquires stock in a foreign corporation from a person that is not a successor in interest, such as a foreign person, and the United States person qualifies as a successor in interest, the United States person acquires the PTI account attributable to the foreign corporation stock acquired and may exclude PTI from gross income under section 959(a) by reference to the PTI account for such stock.

B. CFC-Level Exclusion Under Section 959(b)

The earnings and profits of a CFC (lower-tier CFC) attributable to amounts which are, or have been, included in the gross income of a United States shareholder under section 951(a) shall not, when distributed through a chain of ownership described in section 958(a), be also included in the gross income of the CFC receiving the distribution (upper-tier CFC) in such chain for purposes of the application of section 951(a) to such upper-tier CFC with respect to such United States shareholder. Prop. Reg. § 1.959–2 contains rules relating to the section 959(b) exclusion. These rules are intended to reflect the holding of Rev. Rul. 82–16 (1982–1 CB 106) as well as rules regarding cross-chain sales of stock in a foreign corporation by a CFC subject to section 304(a)(1).

In Rev. Rul. 82–16, an upper-tier CFC, 70 percent owned by a United States shareholder (USP) and 30 percent owned by a foreign person, received a distribution of $200x of earnings and profits from a lower-tier CFC wholly-owned by the upper-tier CFC. The lower-tier CFC had earned $100x of subpart F income for the year of the distribution ($70x of which was included in USP's gross income under section 951(a)) and a $100 of non-subpart F income. The ruling held that $100x, rather than $70x, was excluded from the gross income of the upper-tier CFC under section 959(b). If only $70x were excluded, USP would be required to include in gross income $21x of subpart F income with respect to the remaining $30x included in the upper-tier CFC's gross income, resulting in a total inclusion in USP's gross income of $91x ((70% × $30) + (70% × $100)).

Prop. Reg. § 1.959–2(a) addresses the issue raised in Rev. Rul. 82–16, and accordingly, provides that, the amount of the exclusion provided under section 959(b) is the entire amount distributed by the lower-tier CFC to the upper-tier CFC that gave rise (in whole or in part) to an adjustment of the United States shareholder's PTI accounts with respect to the stock it owns (within the meaning of section 958(a)) in the lower-tier and upper-tier CFC under Prop. Reg. § 1.959–3(e)(3) (discussed in this preamble). This amount shall not exceed the earnings and profits of the distributor CFC attributable to amounts described in section 951(a). Such amount is not limited to the amount of the adjustment to the United States shareholder's PTI account.

For example, under the facts of Rev. Rul. 82–16, the amount excluded from the upper-tier CFC's gross income for purposes of applying section 951(a) to USP under Prop. Reg. § 1.959–2(a) is $100x. That is, the entire amount of the earnings and profits distributed by the lower-tier CFC that were attributable to amounts described in section 951(a) and that caused an adjustment to USP's PTI accounts in both the upper- and lower-tier CFCs under Prop. Reg. § 1.959–3(e)(3).

Prop. Reg. § 1.959–2(a) produces results consistent with Rev. Rul. 82–16, while ensuring that section 959(b) does not inappropriately prevent taxation under section 951(a) of a United States shareholder that has acquired stock in a CFC from a person who was not taxed on the subpart F income of a lower-tier CFC in the year such income was earned (e.g., a foreign person). For example, assume the same facts as those of Rev. Rul. 82–16, except that: (1) The subpart F income was earned by the lower-tier CFC in year 1, (2) another United States shareholder (DC) acquired the 30 percent interest in the upper-tier CFC in year 2 from the foreign person with a zero PTI account, and (3) the lower-tier CFC did not distribute any property until year 3. Under Prop. Reg. § 1.959–2(a), the section 959(b) exclusion for the upper-tier CFC for purposes of calculating USP's section 951(a) inclusion is still $100. In contrast, Prop. Reg. § 1.959–2(a) provides that the section 959(b) exclusion for the upper-tier CFC for purposes of determining DC's section 951(a) inclusion is zero because none of the earnings and profits distributed were attributable to amounts included in income under section 951(a) with respect to DC or the person to whom DC is a successor in interest. Therefore, DC may have an income inclusion under section 951(a).

In addition, Prop. Reg. § 1.959–2(b) provides guidance with respect to the application of section 959(b) in the context of stock sales subject to section 304(a)(1) where the selling corporation is a CFC. The proposed regulations clarify that in the case of a deemed redemption resulting from a transaction described in section 304(a)(1) in which earnings and profits of an acquiring foreign corporation or an acquired foreign corporation or both are deemed distributed to a selling CFC, the selling CFC is deemed for purposes of section 959(b) to receive such distributions through a chain of ownership described under section 958(a).

C. Maintenance of PTI Accounts

The proposed regulations contain detailed rules regarding the maintenance of shareholder PTI accounts and the maintenance of pools of PTI and non-PTI earnings and profits with respect to a foreign corporation, including rules for adjusting PTI accounts as a result of certain transactions. In addition, the proposed regulations provide rules for covered shareholders that have more than one share of stock in a foreign corporation and covered shareholders that are members of a consolidated group.

1. Shareholder-Level Accounting of PTI

The proposed regulations provide that a covered shareholder's PTI account with respect to its stock in a foreign corporation shall identify the amounts included in gross income by a United States shareholder under section 951(a)(1)(A) with respect to the stock (PTI described in section 959(c)(2)), and amounts that are included in the gross income of a United States shareholder under section 951(a)(1)(B) and section 956 amounts that would have been so included but for section 959(a)(2) (PTI described in section 959(c)(1)) by such shareholder who owns the stock or by

a successor in interest. A shareholder account must also reflect these amounts in the functional currency of the foreign corporation and the annual dollar basis of each category of PTI in the account.

2. Corporate-Level Accounting of PTI

The proposed regulations also provide that separate aggregate categories (with respect to all of the shareholders of a foreign corporation) of PTI described in section 959(c)(1) and section 959(c)(2) and non-PTI shall be maintained with respect to foreign corporations. These categories of earnings and profits of a foreign corporation shall be maintained in the functional currency of the foreign corporation.

The proposed regulations reflect the basic allocation rules under section 959(c) and (e). Those rules provide that distributions are considered to be made on a last-in first-out basis under section 316(a), first from any PTI described in section 959(c)(1), then from PTI described in section 959(c)(2), and finally from non-PTI earnings and profits. In addition, section 956 amounts are allocated first to section 959(c)(2) earnings and profits and then to non-PTI earnings and profits. Consequently, PTI resulting from section 956 amounts in a prior year cannot exclude section 956 amounts in a later year from otherwise being included in a United States shareholder's gross income under section 951(a)(1)(B).

The proposed regulations also provide that these allocations to PTI are made in conjunction with the shareholder-level adjustments to shareholder-level PTI accounts. In addition, any adjustments to earnings and profits required under section 312 or other sections of the Code or Treasury regulations shall generally be made only to non-PTI.

3. Foreign Currency and Foreign Tax Credit Rules

The proposed regulations also contain several rules that reflect the significant changes made to the foreign currency translation rules since the existing section 959 regulations were issued. The proposed regulations also contain rules regarding the foreign tax credit rules relating to PTI.

a. Dollar Basis Pooling Election

The proposed regulations provide that a shareholder account must reflect the annual dollar basis of each category of PTI in the account. However, Prop. Reg.§ 1.959–3(b)(2)(ii) allows taxpayers to elect to treat distributions as being made from a single pool of post-1986 PTI for purposes of computing foreign currency gain or loss under section 986(c) and basis adjustments under section 961 with respect to distributions of PTI. Thus, the reduction of the basis of shares in a foreign corporation and the foreign currency gain (or loss) attributable to a PTI distribution may both be determined by assigning a pro rata portion of the shareholder's aggregate dollar basis in its PTI account to a distribution of PTI. Notice 88–71 (1988–2 C.B. 374) makes this pooled approach available to taxpayers for purposes of section 986(c) at the taxpayer's election, but it does not provide guidance as to how this election is made. The proposed regulations provide that the election is made by using a dollar basis pool to compute foreign currency gain or loss under section 986(c) with respect to distributions of PTI of a foreign corporation, or to compute gain or loss with respect to its stock in the foreign corporation, whichever occurs first. Any subsequent change in the taxpayer's method of assigning dollar basis may only be made with the consent of the Commissioner.

b. Taxes and Other Expenses Attributable to PTI

Prop. Reg. § 1.959–3(c) provides that the corporate-level and shareholder-level PTI accounts are reduced by the functional currency amount of any income, war profits, or excess profits taxes imposed by any foreign country or a possession of the United States on or with respect to PTI as it is distributed by a foreign corporation to another foreign corporation through a chain of ownership described in section 958(a). The proposed regulations further provide that such taxes are not added to the foreign corporation's post-1986 foreign income taxes pool, which is maintained with respect to the foreign corporation's post-1986 undistributed earnings. Rather, such taxes are maintained in a separate account and allowed as a credit pursuant to section 960(a)(3) when the associated PTI is distributed to a United States shareholder (or its successor in interest). This rule ensures that amounts previously included in income that are used to pay creditable foreign taxes and so are unavailable for distribution to covered shareholders reduce the amount of PTI available for distribution but may be claimed as a foreign tax credit at the appropriate time. The proposed regulations also provide for corresponding adjustments to the covered shareholder's dollar basis of the PTI account.

Prop. Reg. § 1.959–3(d) provides that no expenses of a foreign corporation, other than creditable foreign income taxes described in Prop. Reg. § 1.959–3(c), shall be allocated and apportioned to reduce PTI. By allocating all such expenses to non-PTI, this rule preserves the amount of PTI that may be distributed to a United States shareholder (or its successor in interest) in a non-taxable manner.

4. Adjustment of Shareholder PTI Accounts

The proposed regulations generally provide rules for the adjustment of a covered shareholder's PTI account upon an inclusion of income by the shareholder under section 951, an actual distribution of earnings and profits to the shareholder, or a determination of a section 956 amount with respect to the shareholder. The proposed regulations provide that the adjustment of PTI accounts occur according to the ordering rules of section 959 to determine the tax consequences of the various events. For purposes of determining the tax consequences to a covered shareholder in a foreign corporation, the proposed regulations provide that with respect to a foreign corporation's taxable year, and for the taxable year of the covered shareholder in which or with which such taxable year of the foreign corporation ends, the following events are taken into account in the following order: (1) The covered shareholder's inclusion of subpart F income or other amounts in gross income under section 951(a)(1)(A) for a taxable year, (2) any actual distributions of current or accumulated earnings and profits by a foreign corporation during the year, including redemptions treated as distributions of property to which section 301 applies pursuant to section 302(d); and (3) any investments in United States property by a CFC during the year resulting in a section 956 amount for one or more United States shareholders for the year. For purposes of the proposed regulations, amounts included in the gross income of any person as a dividend under section 1248(a) or (f) are generally treated as section 951(a)(1)(A) inclusions.

Thus, under Prop. Reg. § 1.959–3(e)(2), at the end of the foreign corporation's taxable year, a shareholder's PTI account is first adjusted upward by the amount of any subpart F income included in gross income by the shareholder under section 951(a) with respect to the shareholder's stock in the foreign corporation. Next, a shareholder's PTI account is adjusted downward by the amount of any distributions of PTI to the shareholder with respect to the stock during the year. However, a PTI account can never be reduced below zero. Third, to the extent that any section 956

amount for the year is equal to (or less than) the amount of PTI described in section 959(c)(2), an amount of such PTI equal to the section 956 amount is reclassified as PTI described in section 959(c)(1), but does not decrease the shareholder's PTI account. Finally, the shareholder's PTI account is adjusted upward by any section 956 amount in excess of the PTI described in section 959(c)(2) for the year. Corresponding adjustments are made to the dollar basis of the PTI account.

This sequence of adjustments may be affected by the PTI sharing rules discussed below. Although the sharing rules are described in greater detail in Prop. Reg. §§ 1.959–3(f) and (g), the order of the adjustments described in these sections are provided for in the steps described in Prop. Reg. § 1.959–3(e)(2).

The amount of a downward adjustment to the covered shareholder's PTI account under the second step described above is excluded from the shareholder's gross income under section 959(a)(1) and Prop. Reg. § 1.959–1(c)(1). Similarly, the amount of section 959(c)(2) PTI which is reclassified as section 959(c)(1) PTI under the third step described above is excluded from the covered shareholder's gross income under section 959(a)(2) and Prop. Reg. § 1.959–1(c)(2).

5. Adjustment to PTI Accounts Upon Distributions to Intermediary CFCs

Where stock in a lower-tier CFC is owned indirectly by a United States shareholder (or successor in interest) through one or more upper-tier CFCs in a chain of ownership under section 958(a), the shareholder's PTI accounts with respect to stock in the relevant foreign corporations in the chain must be adjusted when the lower-tier CFC makes a distribution of PTI to an upper-tier CFC in the chain. Prop. Reg. § 1.959–3(e)(3) provides that the shareholder's PTI account with respect to stock in the distributing foreign corporation is decreased by the amount of PTI distributed with respect to such stock, and the shareholder's PTI account with respect to stock in the recipient foreign corporation is increased by the same amount (in addition to being increased by any non-PTI portion of the distribution that results in an inclusion in the shareholder's gross income under section 951(a) as subpart F income of the receiving CFC). Prop. Reg. § 1.959–3(e)(3) provides a spot rate translation convention for cases in which the distributing and receiving corporations use different functional currencies.

6. Effect of Deficits in Earnings and Profits

Prop. Reg. § 1.959–3(e)(5) provides that a shareholder's PTI account is not adjusted to take into account any deficit in earnings and profits of the corporation for the taxable year. Deficits will reduce only the non-PTI of the corporation under section 312.

7. Distribution in Excess of the PTI Account

Under Prop. Reg. § 1.959–3(e)(5), when a foreign corporation distributes to a shareholder an amount exceeding the PTI account with respect to the relevant stock, the treatment of the excess amount depends on the facts and circumstances. Subject to the PTI sharing rules discussed below, the excess amount of a distribution generally is treated as a dividend under section 316 to the extent of the distributing corporation's non-PTI, and thereafter as a return of capital (reducing the shareholder's basis in its stock in the foreign corporation) under section 301(c)(2). Any portion of the distribution remaining after the shareholder's basis of the stock in the foreign corporation is reduced to zero is treated as capital gain under section 301(c)(3).

8. PTI Sharing Rules

The purpose of section 959 is to prevent double taxation of amounts that have been previously included in gross income by a United States shareholder under section 951(a) and, importantly, to prevent such double taxation at the earliest possible time. Section 951 subjects a United States shareholder to tax on undistributed income of a CFC, so the ordering rule of section 959(c) effectuates this statutory purpose by treating actual distributions to the shareholder as coming first out of PTI. As one of the goals of section 959 is to treat distributions as first coming from PTI, the IRS and Treasury Department believe that a United States shareholder (or successor in interest) should be entitled to exclude from gross income under section 959(a) all of a foreign corporation's distributions of earnings and profits and section 956 amounts to the extent of PTI associated with any of the United States person's stock in the foreign corporation, before that person is required to include additional distributions of earnings and profits or section 956 amounts of the foreign corporation in gross income.

The IRS and Treasury Department believe that similar rules should apply with respect to members of a consolidated group. Although the taxation of a consolidated group represents a hybrid of single and separate entity treatment, consolidated attribute utilization is generally based on single entity treatment. For example, when determining consolidated taxable income for a given year, subject to certain limitations, the group is entitled to offset its income with any consolidated net operating losses that are carried forward to such year (regardless of which member or members recognized the income or incurred the losses). Given the broad regulatory authority of section 1502 and the statutory mandate in section 959 to allow United States shareholders (or successors in interest) to recover PTI at the earliest possible time, the IRS and Treasury Department believe that PTI is an attribute for which single entity treatment of United States consolidated groups is appropriate. As a result, the IRS and Treasury Department have concluded that a shareholder of a foreign corporation that is a member of a consolidated group should be entitled to exclude from gross income under section 959(a) all of a foreign corporation's distributions of earnings and profits, and section 956 amounts, to the extent of PTI associated with any stock in the foreign corporation owned by any member of the consolidated group (with appropriate adjustments). Therefore, the proposed regulations provide for sharing of PTI between accounts of different members of a consolidated group in a manner similar to the sharing of PTI between multiple accounts of a single shareholder, as described below.

a. Shareholder With Multiple PTI Accounts

Prop. Reg. § 1.959–3(f) provides a special rule that applies when a United States shareholder has more than one PTI account with respect to stock in a foreign corporation, and during its taxable year, the foreign corporation distributes earnings and profits in an amount that exceeds one or more of such PTI accounts. In that case, the shareholder's PTI accounts with respect to all of its other stock in the foreign corporation that it owns at the end of the foreign corporation's taxable year shall be reduced, in the aggregate, by the amount of the excess, on a pro rata basis by reference to the level of such PTI accounts (after such PTI accounts have first been adjusted to reflect any distributions of earnings and profits with respect to those blocks of stock).

The aggregate reduction in such PTI accounts produces a corresponding increase in the PTI account that would have been exceeded by the amount

distributed but for the operation of this sharing rule. That PTI account is then reduced to zero to reflect the amount of earnings and profits distributed with respect to that block of stock during the year.

Similarly, if the section 959(c)(2) portion of a PTI account for a share in a foreign corporation is exceeded by the section 956 amount attributable to the share, the aggregate amount of the section 959(c)(2) portion of the PTI accounts for all other stock of the foreign corporation owned by the shareholder on the last day of the foreign corporation's taxable year is available for purposes of excluding the section 956 amount from gross income under section 959(a)(2).

b. Shareholder That Is a Member of a Consolidated Group

Prop. Reg. § 1.959–3(g) provides similar sharing rules where stock in a foreign corporation is owned by two or more members of a consolidated group. For purposes of administrative convenience, however, this rule focuses on whether the shareholders are members of the same consolidated group at the end of the foreign corporation's taxable year and not at the time the PTI in question was generated. Specifically, if the total amount of a United States shareholder's PTI account or accounts for stock in a foreign corporation is exceeded by the amount of earnings and profits distributed by the corporation to the shareholder during the year, the PTI accounts of other members of the shareholder's consolidated group who own stock in the corporation are decreased on a pro rata basis (after adjustment) and the shareholder's PTI accounts or account, as the case may be, will be correspondingly increased and then adjusted downward to zero.

Similarly, if the total amount of the section 959(c)(2) portion of a shareholder's PTI account or accounts for stock in a foreign corporation is exceeded by the shareholder's section 956 amount for the year, the aggregate amount of the section 959(c)(2) portions of the PTI accounts of other member's of the shareholder's consolidated group at the end of the foreign corporation's taxable year who own stock in the foreign corporation will be available to the shareholder for purposes of excluding the section 956 amount from gross income under section 959(a)(2).

9. Redemptions, Including Section 304 Transactions

The proposed regulations provide rules for the adjustment of PTI accounts and the effect on the corporation's non-PTI when a foreign corporation redeems its stock. The effect of a distribution in redemption of stock (redemption distribution) depends on whether the redemption distribution is treated as a payment in exchange for the stock under sections 302(a) or 303, or as a distribution of property to which section 301 applies pursuant to section 302(d).

a. Redemptions Treated as Sales or Exchanges

If a redemption distribution is treated as a sale or exchange, generally the amount chargeable to the earnings and profits of the redeeming corporation is limited by section 312(n)(7) to a ratable share of the earnings and profits. Where the redeeming corporation is a foreign corporation and there is a PTI account with respect to the redeemed stock, the proposed regulations provide that section 312(n)(7) is applied by limiting the reduction of the redeeming corporation's earnings and profits to an amount which does not exceed the sum of (1) the amount in the PTI account for the redeemed stock and (2) a ratable share of the corporation's non-PTI attributable to the redeemed shares, if any. This sum first reduces the PTI account with respect to the redeemed stock and then reduces the corporation's non-PTI.

The IRS and Treasury Department believe that, in the case where a foreign corporation redeems stock in a transaction treated as a sale or exchange for an amount that is less than the PTI account for that stock, it would be inappropriate to transfer the remainder of the PTI account to any other PTI accounts with respect to stock in the foreign corporation. Under section 961(a) and the regulations thereunder, the basis of stock in a foreign corporation is increased by the amount included in the shareholder's gross income under section 951(a), which is reflected in the PTI account with respect to such stock. The shareholder recovers this increase in basis upon a sale of the stock, preventing the shareholder from suffering double taxation on gain attributable to PTI (or in appropriate cases enabling the shareholder to recognize a loss). Consequently, under the proposed regulations, the remainder of the PTI account in the situation described above is not transferred to any other PTI account because it was already accounted for in the treatment of the redemption as a sale or exchange. Any corporate-level PTI attributable to the redeemed stock that remains after the reduction under section 312(n)(7) loses its character as PTI and is reclassified as non-PTI of the corporation. The IRS and Treasury Department believe that because the redeemed shareholder is able to use the loss resulting from the redemption to offset other income, its excess PTI must become other earnings and profits that remain with the foreign corporation so that those earnings and profits can be subject to tax.

b. Redemptions Treated as Section 301 Distributions

If, under section 302(d), a redemption distribution is treated as a distribution of property to which section 301 applies, the proposed regulations provide that the rules of Prop. Reg. §§ 1.959–1 and –3 shall apply in the same manner as they do to any other distribution to which section 301(c) applies. The PTI account with respect to the redeemed stock is reduced by the amount of the redemption distribution. If the redemption distribution exceeds such PTI account, the sharing rules described above regarding nonredemptive distributions of earnings and profits will be applicable. If, instead, the PTI account with respect to the redeemed shares exceeds the amount of the redemption distribution, the excess PTI is reallocated to the PTI accounts with respect to the remaining stock in the foreign corporation in a manner consistent with, and in proportion to, the proper adjustments of the basis in the remaining shares of the foreign corporation pursuant to § 1.302–2(c). Accordingly, the proposed regulations also require proper adjustment of the basis of the shareholder's remaining stock in the redeeming corporation, and of stock in the redeeming corporation held by related persons (not limited to members of the shareholder's consolidated group).

c. Deemed Redemptions Under Section 304

With respect to amounts paid to acquire stock in a transaction described in section 304(a)(1) and to which section 301(c) applies, the rules of Prop. Reg. §§ 1.959–1 and –3 shall apply in the same manner as they do to any other distribution to which section 301(c) applies. As discussed below, the sharing rules described above are applicable to such redemption distributions that are treated as distributions of property to which section 301 applies. In addition, a covered shareholder receiving such a distribution of earnings and profits shall have a PTI account with respect to the stock of each foreign corporation deemed to have distributed its earnings and profits under section 304(b)(2).

The Senate Report on the IRS Restructuring and Reform Act of 1998 states with respect to the Secretary's authority to prescribe regulations resulting from the enactment of section 304(b)(6), ''It is expected that such regulations will provide for an exclusion from income for distributions from earnings and profits of the acquiring corporation and the issuing corporation that represent previously taxed income under subpart F. It further is expected that such regulations will provide for appropriate adjustments to the basis of stock held by the corporation treated as receiving the distribution or by the corporation that had the prior inclusion with respect to the previously taxed income.'' S. Rep. No. 105–174 at 179 (1998). The Conference agreement on the Act follows the Senate amendment. H.R. Conf. Rep. No. 105–599 (1998).

In the case where members of a United States consolidated group own stock in the issuing corporation and the acquiring corporation in a section 304(a)(1) transaction, the PTI accounting and sharing rules are intended to prevent double taxation of PTI, as intended by Congress in enacting sections 304(b)(6) and 959. A lower-tier, cross-chain acquisition of stock is generally subject to section 304(a)(1) and the transferor is treated as having transferred the stock in the issuing corporation to the acquiring corporation in exchange for stock in the acquiring corporation in a transaction to which section 351(a) applies. The acquiring corporation is treated as having redeemed those shares pursuant to a redemption distribution to which section 301 applies. As a result, in accordance with these regulations, a PTI account with respect to the stock in the foreign corporation that is treated as redeemed under section 304(a)(1) would be considered to arise at the time of the transaction. Any PTI accounts with respect to stock in the foreign corporation owned by other members of the shareholder's consolidated group would be reduced, and the PTI account of the redeemed shareholder increased (and then reduced to zero), under the PTI sharing rules described above.

D. Basis Adjustments

The proposed regulations contain corresponding amendments to the regulations under section 961. These proposed regulations generally provide for increases and reductions in the basis of foreign corporation stock or other property through which foreign corporation stock is owned which match the increases and reductions in the PTI account with respect to such stock under the section 959 proposed regulations. The proposed regulations provide translation conventions for determining dollar basis adjustments under section 961 as a result of inclusions under section 951(a), distributions, and the foreign income taxes imposed on PTI as it is distributed through tiers of foreign corporations.

The proposed regulations also implement section 961(c) by providing for adjustments to the basis of stock in a CFC that is held by another CFC in a chain of ownership described in section 958(a) for the purpose of determining the amount properly includible in gross income under section 951(a) by a United States shareholder upon a sale of stock in a lower-tier CFC.

The regulations also contain rules describing basis adjustments resulting from cross-chain sales of foreign corporation stock under section 304(a)(1).

E. Basis Adjustments of Consolidated Group Members

In the case where there is sharing of PTI among members of a U.S. consolidated group, the proposed regulations also clarify the interaction of the investment adjustment provisions in the consolidated return regulations with the section 961 basis adjustment provisions. Accordingly, the proposed regulations clarify that a consolidated group member who utilizes PTI of another member shall treat the increase in its PTI account as the receipt of tax exempt income under Prop. Reg. § 1.1502–32(b)(3)(ii)(D), and a member whose PTI is utilized shall treat the reduction in its PTI account as a noncapital nondeductible expense under Prop. Reg. § 1.1502–32(b)(3)(iii)(B) for purposes of making the investment adjustments required by § 1.1502–32.

F. Proposed Effective Date and Transition Rule

These regulations are proposed to apply to taxable years of foreign corporations beginning on or after the date these regulations are published as final regulations in the **Federal Register**, and taxable years of U.S. shareholders with or within which such taxable years of foreign corporations end. After these regulations become effective, foreign corporations and shareholders who are currently accounting for PTI in a manner other than that which is provided in these regulations may use any reasonable method to conform their current accounting of PTI to the rules provided in these regulations.

Request for Comments

A. Coordination of Shareholder-Level and Corporate-Level Accounts

Prop. Reg. § 1.959–3(e)(4) requires aggregate categories of PTI to be maintained at the corporate level and to be adjusted in accordance with adjustments made to the individual shareholder-level PTI accounts. No explicit rules are provided for how shareholder-level and corporate-level PTI information is to be shared between the shareholders of a foreign corporation. Comments are requested on whether such information sharing rules are necessary, and if so, how they should operate to ensure conformity between shareholder-level and corporate-level PTI accounting.

B. PTI and Consolidated Groups

The application of the PTI sharing rules in the proposed regulations result in corresponding adjustments to the basis of stock in the sharing member corporations (and potentially higher tier members) held by other members of the shareholder's consolidated group. As noted above, the IRS and Treasury Department believe that the PTI sharing rules result in the corresponding basis adjustments under the current investment adjustment provisions. There is some tension between single and separate entity treatment of a consolidated group regarding the PTI sharing rules, and the IRS and Treasury Department are continuing to study how to balance the policy in favor of minimizing multiple income inclusions with the policy of preserving the location of attributes within a consolidated group. In particular, the IRS and Treasury Department are concerned about the potential basis shifting that may occur as a result of the PTI sharing rules. The IRS and Treasury Department request comments on the proposed rules and whether there are more appropriate rules for determining the basis of: (1) The stock in a member of the consolidated group that transfers PTI to another member of the consolidated group under the proposed regulations, (2) the stock in the member of the consolidated group that receives the transferred PTI under the proposed regulations and (3) the stock in the higher tier members of the consolidated group that directly or indirectly own the stock in the members of the consolidated group whose PTI accounts are affected by the sharing rules in the proposed regulations.

The proposed regulations do not limit the application of the PTI sharing rules between members of a consolidated group to PTI earned by a foreign

corporation while the member with excess PTI was a member of such group. The IRS and Treasury Department did not adopt such a limitation out of concern that it would be overly complex and concern that such a limitation might not be consistent with the successor in interest rule. However, the IRS and Treasury Department recognize that some may believe that such a limitation might be more consistent with other attribute sharing rules in the consolidated group context. Consequently, the IRS and Treasury Department request comments as to whether a limitation on PTI sharing between members of a consolidated group similar to those of § 1.1502–21(c) is appropriate.

The IRS and Treasury Department believe that transactions described in section 304 are generally covered by the PTI sharing rules contained in Prop. Reg. §§ 1.959–3(h)(1) through (3) that are applicable to typical redemptions. However, a specific rule has also been provided in Prop. Reg. § 1.959–3(h)(4) that makes the PTI sharing rules explicitly applicable to transactions described in section 304(a)(1) that are treated as distributions of property to which section 301 applies. The IRS and Treasury Department request comments regarding whether the PTI sharing rules should also be made explicitly applicable to transactions described in section 304(a)(1) that are treated as sales or exchanges or to transactions described in section 304(a)(2). In addition, comments are requested on whether rules should be provided to address the proper allocation of PTI after a transaction described in section 355.

C. PTI and Section 367(b) Transactions

On November 15, 2000, the IRS and Treasury Department issued proposed regulations in the **Federal Register** (65 FR 69138) (REG–116050–99) addressing (1) the carryover of certain tax attributes, such as earnings and profits and foreign income tax accounts, when two corporations combine in a section 367(b) transaction described in section 381, and (2) the allocation of certain tax attributes when a corporation distributes stock in another corporation in a section 367(b) transaction (a foreign divisive transaction). In the preamble to those proposed regulations, the IRS and Treasury Department indicated that further guidance under section 959 would be required prior to addressing PTI issues that arise under section 367(b). At that time the IRS and Treasury Department requested comments with respect to proposed § 1.367(b) regarding whether PTI should be transferable and retain its character as PTI for section 959 purposes, as well as the various implications that result from that determination. Additionally, in the 2000 proposed regulations, the IRS and Treasury Department requested comments with respect to § 1.367(b)–8 of the proposed regulations regarding the proper adjustment of the PTI of a CFC following a foreign divisive transaction.

On August 8, 2006, the IRS and Treasury Department issued final regulations under §§ 1.367(b)–3 and –7 with respect to the carryover of non-PTI amounts, among other things, while reserving final regulations under § 1.367(b)–8 with respect to the allocation of tax attributes in foreign divisive transactions.

The IRS and Treasury Department invite comments regarding the proper extension of the principles in these proposed regulations (including shareholder-level accounting of PTI and the PTI sharing rules) to §§ 1.367(b)–3 and –7, as well as Prop. Reg. § 1.367(b)—8.

D. Foreign Currency Gain or Loss and Foreign Tax Credits With Respect to PTI Distributions

Under section 986(c) of the Code, foreign currency gain or loss with respect to distributions of PTI that is attributable to movements in exchange rates between the date(s) of the income inclusion that created the PTI and the distribution of such PTI shall be recognized and treated as ordinary income or loss from the same source as the associated income inclusion. The IRS and Treasury Department invite comments regarding additional guidance that may be needed under section 986(c) in light of the proposed regulations under section 959. The IRS and Treasury Department also invite comments regarding additional guidance that is needed to ensure that section 960(a)(3) provides appropriate foreign tax credit rules with respect to taxes imposed on PTI that is distributed through tiers of foreign corporations.

E. Section 962

The IRS and Treasury Department have not determined how the proposed accounting rules and basis rules should apply to a United States individual shareholder who has elected to be taxed as a corporation under section 962. Therefore, those rules are reserved for future study. The IRS and Treasury Department, however, invite comments about how the PTI rules and basis rules should apply for purposes of section 962.

F. Section 961(c) Basis Adjustments

Section 961(c) is by its terms only applicable for purposes of determining the amount included under section 951 in gross income of a United States shareholder. Consequently, the IRS and Treasury Department have so limited the application of Prop. Reg. § 1.961–3. In the event of a sale of a lower-tier CFC by an upper-tier CFC for which the rules of section 961(c) are implicated in determining the gain on the sale, the basis created in the lower-tier CFC stock for purposes of applying section 951 would not apply, for example, to determine the earnings and profits of the upper-tier CFC. However, the IRS and Treasury Department are concerned about the potential double taxation that may result in the event of the later distribution of these earnings and profits to a United States person.

G. Transition Rule

These regulations are proposed to apply to taxable years of foreign corporations beginning on or after the date these regulations are published as final regulations in the **Federal Register**, and taxable years of U.S. shareholders with or within which such taxable years of foreign corporations end. After these regulations become effective, foreign corporations and shareholders who are currently accounting for PTI in a manner other than that which is provided in these regulations may use any reasonable method to conform their current accounting of PTI to the rules provided in these regulations. Comments are requested on whether more detailed transition rules should be provided, and, if so, how such transition rules should operate to conform existing methods of PTI accounting with the method of PTI accounting required by these regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and because the proposed regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. Ch. 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Ethan Atticks, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income Taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing all entries for § 1.1502–12 and § 1.1502–32 and by adding entries in numerical order to read, in part, as follows:

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

Section 1.959–1 also issued under 26 U.S.C. 304(b)(6), 959 and 1502.

Section 1.959–2 also issued under 26 U.S.C. 304(b)(6) and 959.

Section 1.959–3 also issued under 26 U.S.C. 304(b)(6), 959 and 1502.

Section 1.959–4 also issued under 26 U.S.C. 304(b)(6) and 959. * * *

Section 1.961–1 also issued under 26 U.S.C. 961.

Section 1.961–2 also issued under 26 U.S.C. 961.

Section 1.961–3 also issued under 26 U.S.C. 961.

Section 1.961–4 also issued under 26 U.S.C. 304(b)(6) and 961. * * *

Section 1.1502–12 also issued under 26 U.S.C. 959, 961 and 1502. * * *

Section 1.1502–32 also issued under 26 U.S.C. 301, 959, 961, 1502 and 1503. * * *

Par. 2. Section 1.959–1 is revised to read as follows:

§ 1.959–1 Exclusion from gross income of United States persons of previously taxed earnings and profits.

(a) *In general.* Section 959(a) provides an exclusion whereby the earnings and profits of a foreign corporation attributable to amounts which are, or have been, included in a United States shareholder's gross income under section 951(a) are not taxed again when distributed (directly or indirectly through a chain of ownership described in section 958(a)) from such foreign corporation to such shareholder (or any other United States person who acquires from any person any portion of the interest of such United States shareholder in such foreign corporation, but only to the extent of such portion, and subject to such proof of the identity of such interest as the Secretary may by regulations prescribe). Section 959(a) also excludes from gross income of a United States shareholder earnings and profits attributable to amounts which are, or have been, included in the gross income of such shareholder under section 951(a) which would, but for section 959(a)(2), be again included in the gross income of such shareholder (or any other United States person who acquires from any person any portion of the interest of such United States shareholder in such foreign corporation, but only to the extent of such portion, and subject to such proof of the identity of such interest as the Secretary may by regulations prescribe) under section 951(a)(1)(B). Section 959(b) provides that for purposes of section 951(a), the earnings and profits of a CFC attributable to amounts that are, or have been, included in the gross income of a United States shareholder under section 951(a) shall not, when distributed through a chain of ownership described in section 958(a), be included in the gross income of a CFC in such chain for purposes of the application of section 951(a) to such CFC with respect to such United States shareholder (or any other United States person who acquires from any person any portion of the interest of such United States shareholder in such foreign corporation, but only to the extent of such portion, and subject to such proof of the identity of such interest as the Secretary may by regulations prescribe). Section 959(c) provides rules for the allocation of distributions to the various categories of previously taxed earnings and profits of a foreign corporation and the foreign corporation's non-previously taxed earnings and profits. Section 959(d) provides that, except as provided in section 960(a)(3), any distribution excluded from gross income under section 959(a) shall be treated as a distribution which is not a dividend; except that such distributions shall immediately reduce earnings and profits. Section 959(e) provides that, for purposes of sections 959 and 960(b), any amount included in the gross income of any person as a dividend by reason of subsection (a) or (f) of section 1248 shall be treated as an amount included in the gross income of such person (or, in any case to which section 1248(e) applies, of the domestic corporation referred to in section 1248(e)(2)) under section 951(a)(1)(A). Section 959(f)(1) provides rules for the allocation of amounts which would, but for section 959(a)(2), be included in gross income under section 951(a)(1)(B) to certain previously taxed earnings and profits of a foreign corporation and non-previously taxed earnings and profits. Section 959(f)(2) provides an ordering rule pursuant to which the rules of section 959 are applied first to actual distributions and then to amounts which would, but for section 959, be included in gross income under section 951(a)(1)(B). Paragraph (b) of this section provides a list of definitions. Paragraph (c) of this section provides rules for the exclusion from gross income under section 959(a)(1) of distributions of earnings and profits by a foreign corporation and the exclusion from gross income under section 959(a)(2) of amounts which would, but for section 959, be included in gross income under section 951(a)(1)(B). Paragraph (d) of this section provides for the establishment and acquisition of previously taxed earnings and profits accounts by shareholders of foreign corporations. Section 1.959–2 provides rules for the exclusion from gross income of a CFC of distributions of previously taxed earnings and profits from another CFC in a chain of ownership described in section 958(a). Section 1.959–3 provides rules for the allocation of distributions and section 956 amounts to the earnings and profits of a CFC and for the maintenance and adjustment of previously taxed earnings and profits accounts by shareholders of foreign corporations. Section 1.959–4 provides for the treatment of actual distributions that are excluded from gross income under section 959(a).

(b) *Definitions.* For purposes of this section through § 1.959–4 and § 1.961–1 through § 1.961–4, the terms listed in this paragraph are defined as follows:

(1) *Previously taxed earnings and profits* means the earnings and profits of a foreign corporation, computed in accordance with sections 964 and 986(b) and the regulations thereunder, attributable to section 951(a) inclusions.

(2) *Previously taxed earnings and profits account* means an account reflecting the previously taxed earnings and profits of a foreign corporation (if any) that are attributable to section 951(a) inclusions.

(3) *Dollar basis* means the United States dollar amounts included in income with respect to the previously taxed earnings and profits included in a shareholder's previously taxed earnings and profits account.

(4) *Covered shareholder* means a person who is one of the following—

(i) A United States person who owns stock (within the meaning of section 958(a)) in a foreign corporation and who has had a section 951(a) inclusion with respect to its stock in such corporation;

(ii) A successor in interest, as defined in paragraph (b)(5) of this section; or

(iii) A corporation that is not described in paragraphs (b)(4)(i) or (ii) of this section and that owns stock (within the meaning of section 958(a)) in a foreign corporation in which another corporation is a covered shareholder described in paragraph (b)(4)(i) or (ii) of this section, if both corporations are members of the same consolidated group.

(5) *Successor in interest* means a United States person who acquires, from any person, ownership (within the meaning of section 958(a)) of stock in a foreign corporation, for which there is a previously taxed earnings and profits account and who establishes to the satisfaction of the Director of Field Operations the right to the exclusion from gross income provided by section 959(a) and this section. To establish the right to the exclusion, the shareholder must attach to its return for the taxable year a statement that provides that it is excluding amounts from gross income because it is a successor in interest succeeding to one or more previously taxed earnings and profits accounts with respect to shares it owns in a foreign corporation. Included in the statement shall be the name of the foreign corporation. In addition, that shareholder must be prepared to provide the following information within 30 days upon request by the Director of Field Operations—

(i) The name, address, and taxable year of the foreign corporation and of all the other corporations, partnerships, trusts, or estates in any applicable chain of ownership described in section 958(a);

(ii) The name, address, and taxpayer identification number, if any, of the person from whom the stock interest was acquired;

(iii) A description of the stock interest acquired and its relation, if any, to a chain of ownership described in section 958(a);

(iv) The amount for which an exclusion under section 959(a) and paragraph (c) of this section is claimed; and

(v) Evidence showing that the earnings and profits for which an exclusion is claimed are previously taxed earnings and profits, that such amounts were not previously excluded from the gross income of a United States person, and the identity of the United States shareholder who originally included such amounts in gross income under section 951(a). The acquiring person shall also furnish to the Director of Field Operations such other information as may be required by the Director of Field Operations in support of the exclusion.

(6) *Block of stock* shall have the meaning provided in § 1.1248–2(b) with the additional requirement that the previously taxed earnings and profits attributable to each share of stock in such block must be the same.

(7) *Consolidated group* shall have the meaning provided in § 1.1502–1(h).

(8) *Member* shall have the meaning provided in § 1.1502–1(b).

(9) *Section 951(a) inclusion* means a section 951(a)(1)(A) inclusion or an amount included in the gross income of a United States shareholder under section 951(a)(1)(B).

(10) *Section 951(a)(1)(A) inclusion* means—

(i) An amount included in a United States shareholder's gross income under section 951(a)(1)(A);

(ii) An amount included in the gross income of any person as a dividend by reason of subsection (a) or (f) of section 1248 (or, in any case to which section 1248(e) applies, an amount included in the gross income of the domestic corporation referred to in section 1248(e)(2)); or

(iii) An amount described in section 1293(c).

(11) *Section 956 amount* means an amount determined under section 956 for a United States shareholder with respect to a single share or, if a shareholder maintains a previously taxed earnings and profits account with respect to a block of stock, a block of such shareholder's stock in the CFC.

(12) *Section 959(c)(1) earnings and profits* means the previously taxed earnings and profits of a foreign corporation attributable to amounts that have been included in the gross income of a United States shareholder under section 951(a)(1)(B) (or which would have been included except for section 959(a)(2) and § 1.959–2) and amounts that have been included in gross income under section 951(a)(1)(C) as it existed prior to its repeal (or which would have been included except for section 959(a)(3) as it existed prior to its repeal).

(13) *Section 959(c)(2) earnings and profits* means the previously taxed earnings and profits of a foreign corporation attributable to section 951(a)(1)(A) inclusions.

(14) *Non-previously taxed earnings and profits* means the earnings and profits of a foreign corporation other than the corporation's previously taxed earnings and profits.

(15) *CFC* means a controlled foreign corporation within the meaning of either section 953(c)(1)(B) or section 957.

(16) *United States shareholder* means a United States person who qualifies as a United States shareholder under either section 951(b) or section 953(c)(1)(A).

(c) *Amount excluded from gross income*—(1) *Distributions.* In the case of a distribution of earnings and profits to a covered shareholder with respect to stock in a foreign corporation, an amount shall be excluded from such shareholder's gross income equal to the total amount by which such shareholder's previously taxed earnings and profits account with respect to such stock is decreased under § 1.959–3 because of the distribution.

(2) *Section 956 amounts.* In a case where a covered shareholder has a section 956 amount for a CFC's taxable year, an amount shall be excluded from such shareholder's gross income equal to the amount of section 959(c)(2) earnings and profits in any shareholder's previously taxed earnings and profits account that are reclassified as section 959(c)(1) earnings and profits under § 1.959–3 because of that section 956 amount.

(d) *Shareholder accounts*—(1) *In general.* Any person who is subject to § 1.959–3 shall maintain a previously taxed earnings and profits account with respect to each share of stock it owns (within the meaning of section 958(a)) in a foreign corporation. Although the account is share specific, the account may be maintained with respect to each block of the stock in the foreign corporation. Such account shall be maintained in accordance with § 1.959–3.

(2) *Acquisition of account*—(i) *In general.* If any person acquires, from any other person, ownership of shares of stock in a foreign corporation (within the meaning of section 958(a)) the prior shareholder's previously taxed earnings and profits account with respect to such stock becomes the previously taxed earnings and profits account of the acquirer.

(ii) *Acquisition of account by a person other than a successor in interest.* If such acquirer is not a successor in interest (a foreign person for example), the previously taxed earnings and profits account with respect to the stock acquired shall remain unchanged for the period that the stock is owned by such acquirer. See also § 1.959–3(e), providing account adjustment rules that apply only for acquired PTI accounts if the acquirer is a successors in interest.

(3) The application of this paragraph (d) is illustrated by the following examples:

Example 1. Shareholder previously taxed earnings and profits account. (i) *Facts.* DP, a United States shareholder owns all of the 100 shares of the only class of stock in FC, a CFC. The 100 shares are a block of stock. DP and FC use the calendar year as their taxable year and FC uses the U.S. dollar as its functional currency. FC earns $100x of subpart F income in year 1 and $100x of non-subpart income. DP includes $100x in gross income under section 951(a).

(ii) *Analysis.* As a result of DP's inclusion of $100x of gross income under section 951(a), DP has a previously taxed earnings and profits account with respect to each of its 100 shares equal to $1x or should DP choose to maintain its previously taxed earnings and profits account on a block basis, an account of $100x with respect to its entire interest in FC.

Example 2. Acquisition of previously taxed earnings and profits account. (i) *Facts.* Assume the same facts as *Example 1,* but that in year 2, a nonresident alien, FP, contributes property to FC to acquire 1000 newly issued shares of FC of the same class held by DP. In year 10, DP sells all of its FC shares to FP. In year 15, FP sells all of its shares in FC to USP, a United States person. Any income earned by FC after year 1 is non-subpart F income. The only distributions by FC during this period are a $100x pre-sale distribution to FP in year 15 and another $100x distribution in year 16 to USP.

(ii) *Analysis.* In year 2, DP retains its previously taxed earnings and profits account of $100x as a result of its section 951(a) inclusion in year 1 regardless of the fact that FC is no longer a CFC and DP no longer holds a sufficient interest in FC to be a United States shareholder with respect to FC. In year 10, pursuant to paragraph (d)(2)(i) of this section, FP acquires a $100x previously taxed earnings and profits account with respect to DP's block of stock in FC that FP acquired. In year 15, FP receives a distribution of $100x of earnings and profits from FC, but FP may not exclude any of this distribution from gross income because FP is a nonresident alien. Consequently, pursuant to paragraph (d)(2)(ii) of this section, even though it acquired a previously taxed earnings and profits account from DP of $100x the account remains unchanged during FP's ownership of the FC stock. However, if USP can make the showing required in paragraph (b)(5) of this section, USP may exclude the $100x distribution in year 16 under section 959(a)(1) and paragraph (c) of this section to the extent that the distribution results in a decrease of the $100x previously taxed earnings and profits account that USP acquired from FP pursuant to the account adjustment rules of § 1.959–3.

Par. 3. Section 1.959–2 is revised to read as follows:

§ 1.959–2 Exclusion from gross income of CFCs of previously taxed earnings and profits.

(a) *Exclusion from gross income*—(1) *In general.* The earnings and profits of a CFC (lower-tier CFC) attributable to amounts which are, or have been, included in the gross income of a United States shareholder under section 951(a) shall not, when distributed through a chain of ownership described in section 958(a), be also included in the gross income of the CFC receiving the distribution (upper-tier CFC) in such chain for purposes of the application of section 951(a) to such upper-tier CFC with respect to such United States shareholder. The amount of the exclusion provided under this paragraph is the entire amount distributed by the lower-tier CFC to the upper-tier CFC that gave rise (in whole or in part) to an adjustment of the United States shareholder's previously taxed earnings and profits accounts with respect to the stock it owns (within the meaning of section 958(a)) in the lower- and upper-tier CFC under § 1.959–3(e)(3). This amount shall not exceed the earnings and profits of the lower-tier CFC attributable to amounts described in section 951(a)(1) (without regard to pro rata share). The exclusion from the income of such distributee CFC also applies with respect to any other United States shareholder who is a successor in interest.

(2) *Examples.* The application of this paragraph (a) is illustrated by the following examples:

Example 1. Distribution attributable to subpart F income of lower-tier CFC. (i) *Facts.* FC, a CFC, is 70% owned by DP, a United States person, and 30% owned by FP, a nonresident alien. FC owns all the stock in FS, a CFC. DP, FP, FC and FS all use the calendar year as their taxable year and FC and FS use the U.S. dollar as their functional currency. In year 1, FS earns $100x of passive income described in section 954(c) and $50x of non-subpart F income. On the last day of year 1, FS distributes $100x to FC that would qualify as subpart F income of FC. On the last day of year 1, FC distributes $70x to DP and $30x to FP.

(ii) *Analysis.* DP is required to include $70x in its gross income under section 951(a) as a result of FS's earning $100x of subpart F income for the year. Consequently, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to its indirect ownership of stock in FS is increased to $70x. Under § 1.959–3(e)(3), as a result of the $100x distribution paid by FS to FC, DP's previously taxed earnings and profits account is reduced by its pro rata share of the distribution ($70x). In addition, FS's non-previously taxed earnings and profits are reduced by the remaining $30x. Under paragraph (a) of this section, the amount of the exclusion under paragraph (a) is equal to the amount distributed, not to exceed the amount of earnings and profits that gave rise to the previously taxed income that is being distributed. Consequently, the entire $100x distribution (as opposed to only $70x) is excluded from FC's gross income for purposes of determining whether DP has an inclusion under section 951(a) as a result of FC's receiving the distribution from FS. The receipt of the distribution from FS increases FC's earnings and profits by $100x ($70x of which is previously taxed earnings and profits and $30x of which is non-previously taxed earnings and profits).

Example 2. Transferee shareholder. (i) *Facts.* The facts are the same as in *Example 1* except that neither FS nor FC makes any distributions in year 1. In year 2, FP sells its stock in FC to DT, a United States person. On the last day of year 2, FS distributes $100x to FC that would qualify as subpart F income of FC. FS has no earnings and profits for year 2, and FC has no earnings for year 2 other than the distribution from FS.

(ii) *Analysis.* With respect to DP, the analysis is the same as that in *Example 1.* However, for purposes of DT's determination of the amount includible in its gross income under section 951(a) with respect to FC for year 2, none of the $100x distribution is excluded from FC's gross income for purposes of applying section 951(a) with respect to DT's interest in FC because none of earnings and profits distributed by FS to FC are attributable to amounts which are, or have been, included in the gross income of DT or the person to whom DT is a successor in interest (FP). Consequently, DT must include $30x in gross income under section 951(a) for year 2 as its pro rata share of FC's subpart F income of $100x ($100x × 30%). Thereafter, DT has a previously taxed earnings and profits account consisting of $30x with respect to its stock in FC and FC has $100x of previously taxed earnings and profits.

Example 3. Mixed distribution. (i) *Facts.* The facts are the same as in *Example 1,* except that on the last day of year 1, FS distributes $150x to FC that would qualify as subpart F income of FC, which in turn distributes $105x to DP and $45x to FP.

(ii) *Analysis.* Under the analysis in *Example 1* and pursuant to paragraph (a) of this section, $100x of the distribution from FS to FC is excluded from FC's gross income for purposes of determining DP's inclusion under section 951(a) with respect to FC's receipt of the distribution from FS. However, DP's pro rata share of the remaining $50, or $35 ($50 × 70%), is included in DP's gross income under section 951(a). Consequently, the previously taxed earnings and profits in DP's previously taxed earnings and profits account with respect to its stock in FC is increased from $70x to $105x pursuant to § 1.959–3(e)(2)(i). That account is then

reduced to $0, however, as a result of the distribution of $105x to DP pursuant to § 1.959–3(e)(2)(ii) and DP excludes the distribution of $105x from FC from its gross income for year 1 under section 959(a)(1) and § 1.959–1(c).

(b) *Section 304(a)(1) transactions*—(1) *Deemed redemption treated as a distribution.* In the case of a stock acquisition under section 304(a)(1) treated as a distribution to which section 301 applies, the selling CFC shall be deemed for purposes of section 959(b) and paragraph (a) of this section to receive such distributions through a chain of ownership described under section 958(a).

(2) The application of this paragraph (c) is illustrated by the following example:

Example. Cross-chain acquisition of CFC stock by a CFC from another CFC. (i) *Facts.* DP, a domestic corporation, owns all of the stock in two foreign corporations, FX and FY. FX owns all of the stock in foreign corporation FZ. DP, FX, FY, and FZ all use the calendar year as their taxable year and the U.S. dollar as their functional currency. During year 1, FY purchases all of the stock in FZ from FX for $80x in a transaction described in section 304(a)(1). At the end of year 1, before taking into account the purchase of FZ's stock, FY has section 959(c)(2) earnings and profits of $20x and non-previously taxed earnings and profits of $10x, and FZ has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $0.

(ii) *Analysis.* Under section 304(a)(1), FX is deemed to have transferred the FZ stock to FY in exchange for FY stock in a transaction to which section 351 applies, and FY is treated as having redeemed, for $80x, the FY stock deemed issued to FX. The payment of $80x is treated as a distribution to which section 301 applies. Under section 304(b)(2), the determination of the amount which is a dividend (and the source) is made as if the distribution were made, first, by FY to the extent of its earnings and profits, $30x, and then by FX to the extent of its earnings and profits, $50x. Under paragraph (c)(1) of this section, FX is deemed to receive the distributions from FY and FZ through a chain of ownership described in section 958(a). Under paragraph (a) of this section, the amount of FY's previously taxed earnings and profits, $20x, and the amount of FZ's previously taxed earnings and profits, $50x, distributed to FX are excluded from the gross income of FX. Accordingly, only $10x is included in FX's gross income.

Par. 4. Section 1.959–3 is revised to read as follows:

§ 1.959–3 Maintenance and adjustment of previously taxed earnings and profits accounts.

(a) *In general.* This section provides rules for the maintenance and adjustment of previously taxed earnings and profits accounts by shareholders and with respect to foreign corporations. Paragraph (b) of this section provides general rules governing the accounting of previously taxed earnings and profits at the shareholder level and corporate level. Paragraph (c) of this section provides rules regarding the treatment of foreign taxes when previously taxed earnings and profits are distributed by a foreign corporation through a chain of ownership described in section 958(a). Paragraph (d) of this section provides rules regarding the allocation of other expenses to previously taxed earnings and profits. Paragraph (e)(1) of this section addresses the adjustment of shareholder-level previously taxed earnings and profits accounts as a result of certain transactions. Paragraph (e)(2) of this section provides rules establishing the order in which adjustments are to be made to a covered shareholder's previously taxed earnings and profits account. Paragraph (e)(3) of this section provides rules regarding distributions of previously taxed earnings and profits in a chain of ownership described in section 958(a). Paragraph (e)(4) of this section provides for the maintenance and adjustment of aggregate categories of previously taxed and non-previously taxed earnings and profits at the corporate level with adjustments to individual shareholder-level accounts. Paragraph (e)(5) of this section provides rules for the effect of a foreign corporation's deficit in earnings and profits on previously taxed earnings and profits. Paragraph (f) of this section provides rules regarding the treatment of previously taxed earnings and profits when a shareholder has multiple previously taxed earnings and profits accounts. Paragraph (g) of this section provides rules regarding the treatment of previously taxed earnings and profits when more than one shareholder in a foreign corporation is a member of the same consolidated group. Paragraph (h) of this section provides rules governing the adjustment of previously taxed earnings and profits accounts in the case of a redemption.

(b) *Corporate-level and shareholder-level accounting of previously taxed earnings and profits*—(1) *Shareholder-level accounting.* A shareholder's previously taxed earnings and profits account with respect to its stock in a foreign corporation shall identify the amount of section 959(c)(1) earnings and profits and the amount of section 959(c)(2) earnings and profits attributable to such stock for each taxable year of the foreign corporation and shall be maintained in the functional currency of such foreign corporation. A shareholder account must also reflect the annual dollar basis of each category of previously taxed earnings and profits in the account. See § 1.959–3(e) of this section for rules regarding the adjustment of shareholder previously taxed earnings and profits accounts.

(2) *Corporate-level accounting.* Separate aggregate categories of section 959(c)(1), section 959(c)(2) and non-previously taxed earnings and profits (earnings and profits described in section 959(c)(3)) shall be maintained with respect to a foreign corporation. These categories of earnings and profits of the foreign corporation shall be maintained in the functional currency of the foreign corporation. For purposes of this section, distributions are allocated to a foreign corporation's earnings and profits under section 316(a) by applying first section 316(a)(2) and then section 316(a)(1) to each of these three categories of earnings and profits. Section 956 amounts shall be treated as attributable first to section 959(c)(2) earnings and profits and then to non-previously taxed earnings and profits. These allocations are made in conjunction with the rules for making corporate-level adjustments to previously taxed earnings and profits under § 1.959–3(e)(4).

(3) *Classification of earnings and profits*—(i) *In general.* For purposes of this section, earnings and profits are classified as to year and category of earnings and profits in the year in which such amounts are included in gross income of a United States shareholder under section 951(a) and are reclassified as to category of earnings and profits in the year in which such amounts would be so included but for the provisions of section 959(a)(2) and § 1.959–1(c)(2). Such classifications do not change by reason of a subsequent distribution of such amounts to an upper-tier corporation in a chain of ownership described in section 958(a). This paragraph shall apply to distributions by one foreign corporation to another foreign corporation and by a foreign corporation to a United States person.

(ii) *Dollar basis pooling election.* For purposes of computing foreign currency gain or loss under section 986(c) and adjustments to stock basis under section 961(b) and (c) with respect to distributions of previously taxed earnings and profits of any foreign corporation, in lieu of maintaining annual dollar basis accounts with respect to previously taxed earnings and profits described in paragraph (b)(1) of this section, a taxpayer may maintain an aggregate dollar basis pool that reflects the dollar basis of all of the corporation's previously taxed earnings

and profits described in sections 959(c)(1) and 959(c)(2) and treat a pro rata portion of the dollar basis pool as attributable to distributions of such previously taxed earnings and profits. A taxpayer makes this election by using a dollar basis pool to compute foreign currency gain or loss under section 986(c) with respect to distributions of previously taxed earnings and profits of the foreign corporation, or to compute gain or loss with respect to its stock in the foreign corporation, whichever occurs first. Any subsequent change in the taxpayer's method of assigning dollar basis may be made only with the consent of the Commissioner.

(4) *Examples.* The application of this paragraph (b) is illustrated by the following examples:

Example 1. Distribution. (i) *Facts.* DP, a United States shareholder, owns 100% of the only class of stock in FC, a CFC, which, in turn, owns 100% of the only class of stock in FS, a CFC. DP, FC and FS all use the calendar year as their taxable year. FC and FS both use the u as their functional currency. During year 1, FC earns 100u of non-subpart F income and invests 100u in United States property. DP must include 100u in its gross income for year 1 under section 951(a)(1)(B) with respect to FC. For year 2, FS has no subpart F income or investment of earnings in United States property but FS has 100u of non-previously taxed earnings and profits which it distributes to FC. The distribution of 100u to FC is subpart F income of FC and DP must include the 100u in its gross income for year 2 under section 951(a)(1)(A). Also in year 2, FC has non-subpart F income of 100u. The exchange rates at all times in year 1 and year 2, respectively, are 1u = $1 and 1u = $1.20.

(ii) *Analysis.* With respect to FC, the earnings and profits are classified as follows: 100u of section 959(c)(1) earnings and profits from year 1, 100u of section 959(c)(2) earnings and profits from year 2, and 100u of non-previously taxed earnings and profits from year 2. The dollar basis with respect to the section 959(c)(1) earnings and profits is $100 and the dollar basis with respect to the section 959(c)(2) earnings and profits is $120.

Example 2. Subsequent distribution in a later year. (i) *Facts.* Assume the same facts as in *Example 1*, except that during year 3 neither FC nor FS has any earnings and profits or deficit in earnings and profits or section 956 amount, but FC distributes 100u to DP on December 31, year 3, at which time the spot exchange rate is 1u = $1.30.

(ii) *Analysis.* For purposes of section 959 and 961, the 100u distribution of FC shall be considered attributable to FC's section 959(c)(1) earnings and profits for year 1. The section 959(c)(1) earnings and profits are reduced by 100u and the dollar basis of the account is reduced by $100. Since the spot rate at the time of the 100u distribution to DP is 1u = $1.30, DP recognizes foreign currency gain of $30 ($(100 \times 1.3) - (100 \times 1)$).

Example 3. Dollar basis pooling election. (i) *Facts.* Assume the same facts as in *Example 2*, except that DP elected to maintain the dollar basis of its previously taxed earnings and profits account on a pooled basis for purposes of section 986(c) and section 961 as provided in paragraph (b)(3)(ii) of this section.

(ii) *Analysis.* The section 959(c)(1) earnings and profits are reduced by 100u, but the dollar basis of the account is reduced by $110 ((100u/200u) × $220). In addition, DP recognizes foreign currency gain under section 986(c) of $20 ($130 − ((100u/200u) × $220)).

(c) *Treatment of certain foreign taxes.* (1) For purposes of this section, when previously taxed earnings and profits are distributed by a foreign corporation through a chain of ownership described in section 958(a) such earnings and profits shall be reduced by the functional currency amount of any income, war profits, or excess profits taxes imposed by any foreign country or a possession of the United States on or with respect to such earnings and profits. Any such taxes shall not be included in the foreign corporation's pools of post-1986 foreign income taxes maintained for purposes of sections 902 and 960(a)(1). Such taxes shall be maintained in a separate account and allowed as a credit as provided under section 960(a)(3) when the associated previously taxed earnings and profits are distributed. The taxpayer's dollar basis in the previously taxed earnings and profits account shall be reduced by the dollar amount of such taxes, translated in accordance with section 986(a).

(2) The application of this paragraph (c) is illustrated by the following example:

Example. Imposition of foreign taxes on a CFC. (i) *Facts.* DP, a United States shareholder, owns 100% of the only class of stock in foreign corporation FC, a CFC, which, in turn, owns 100% of the only class of stock in FS, a CFC. DP, FC, and FS all use the calendar year as their taxable year. FC and FS both use the u as their functional currency. During year 1, FS earns 90u of subpart F income, after incurring 10u of foreign income tax allocable to such income under § 1.954–1(c), has earnings and profits in excess of 90u, and makes no distributions. DP must include 90u, translated at the average exchange rate for the year of 1u = $1 as provided in section 989(b)(3), in its gross income for year 1 under section 951(a)(1)(A)(i). As of the end of year 1, FS has section 959(c)(2) earnings and profits of 90u. During year 2, FS has neither earnings and profits nor a deficit in earnings and profits but distributes 90u to FC, and, by reason of section 959(b) and § 1.959–2, such amount is not includible in the gross income of DP for year 2 under section 951(a) with respect to FC. FC incurs a withholding tax of 9u on the 90u distribution from FS (10% of 90u) and an additional foreign income tax of 11u by reason of the inclusion of the distribution in its taxable income for foreign tax purposes in year 2. The average exchange rate for year 2 is 1u = $2.

(ii) *Analysis.* At the end of year 2, FS has section 959(c)(2) earnings and profits of 0 (90u − 90u); and FC has section 959(c)(2) earnings and profits of 70u (90u − 9u − 11u). DP's dollar basis in the 70u section 959(c)(2) earnings and profits account with respect to FC is $50 ($90 inclusion − $18 withholding tax − $22 income tax). The $40 of foreign taxes imposed on FC with respect to the previously taxed earnings and profits are not included in FC's post-1986 foreign income taxes pool. A foreign tax credit with respect to the $40 of foreign tax attributable to the 70u of previously taxed earnings and profits will be allowed under section 960(a)(3) upon distribution of such previously taxed earnings and profits.

(d) *Treatment of other expenses.* Except as provided in paragraph (c) of this section, no expense paid or accrued by a foreign corporation shall be allocated or apportioned to the previously taxed earnings and profits of such corporation.

(e) *Adjustments to previously taxed earnings and profits account*—(1) *In general.* A covered shareholder's previously taxed earnings and profits account (including the dollar basis in such account) is adjusted in the manner provided in paragraphs (e)(2), (f) and (g) of this section, except as otherwise provided in paragraph (e)(3) of this section. For adjustments to a previously taxed earnings and profits account in the case of redemptions, see paragraph (h) of this section.

(2) *Order and amount of adjustments.* As of the close of a foreign corporation's taxable year, and for the taxable year of the covered shareholder in which or with which such taxable year of the foreign corporation ends, the covered shareholder shall make any of the following adjustments that are applicable for that year to the previously taxed earnings and profits account for the stock owned for any portion of such year (within the meaning of section 958(a)) in the foreign corporation in the following order—

(i) *Step 1. Section 951(a)(1)(A) inclusion.* Increase the amount of section 959(c)(2) earnings and profits and the associated dollar basis in the account by the amount of the section 951(a)(1)(A) inclusion with respect to such stock;

(ii) *Step 2. Distributions on such stock.* (A) Decrease the amount of the section 959(c)(1) earnings and profits in the account (but not below zero), and then the amount of section 959(c)(2) earnings and profits in the account (but not below zero) by the amount of earnings and profits distributed to the covered shareholder during the year with respect to such stock, decrease the

dollar basis in the account by the dollar amount attributable to the distributed earnings and profits; and

(B) Increase the amount of the earnings and profits and associated dollar basis, in the account first to the extent provided under paragraph (f)(1) of this section and then to the extent provided under paragraph (g)(1) of this section and then reduce the account to zero;

(iii) *Step 3. Reallocation from other accounts with respect to redemptions.* Increase the amount of the earnings and profits and associated dollar basis in the account to the extent provided under paragraph (h)(3)(ii) of this section.

(iv) *Step 4. Section 956 amount.* Reclassify the section 959(c)(2) earnings and profits and associated dollar basis in such shareholder's previously taxed earnings and profits account with respect to such stock as section 959(c)(1) earnings and profits in an amount equal to the lesser of—

(A) The covered shareholder's section 956 amount for the taxable year with respect to such stock; or

(B) The amount of the section 959(c)(2) earnings and profits attributable to such stock.

(v) *Step 5. Reallocation to other accounts with respect to distributions.* Decrease the amount of section 959(c)(1) earnings and profits and associated dollar basis in the account, and thereafter the amount of section 959(c)(2) earnings and profits and associated dollar basis in the account to the extent provided under paragraph (f)(1) of this section and then under paragraph (g)(1) of this section;

(vi) *Step 6. Reclassification with respect to section 956 amounts.* Reclassify the section 959(c)(2) earnings and profits and the associated dollar basis attributable to such stock as section 959(c)(1) earnings and profits to the extent provided under paragraph (f)(2) of this section and then to the extent provided in paragraph (g)(2) of this section.

(vii) *Step 7. Further adjustment for section 956 amounts.* Increase the amount of section 959(c)(1) earnings and profits and the associated dollar basis in the account by any amount included in the covered shareholder's gross income for the year under section 951(a)(1)(B) with respect to such stock.

(3) *Intercorporate distributions.* If a foreign corporation receives a distribution of earnings and profits from another foreign corporation that is in a chain of ownership described in section 958(a), a covered shareholder's previously taxed earnings and profits accounts with respect to the stock in each foreign corporation in such chain shall be adjusted at the end of the respective corporation's taxable year, and for the taxable year of the covered shareholder in which or with which such taxable year of the foreign corporation ends, as follows:

(i) The covered shareholder's previously taxed earnings and profits account with respect to stock in the distributor shall be decreased (but not below zero), at the same time that the covered shareholder would make adjustments under paragraph (e)(2)(ii) of this section, by the amount of the distribution and the associated dollar basis. Such decrease to the covered shareholder's previously taxed earnings and profits account shall be made first to the section 959(c)(1) earnings and profits and thereafter to the section 959(c)(2) earnings and profits in such account.

(ii) Except as provided in paragraph (c) of this section, the section 959(c)(1) earnings and profits and section 959(c)(2) earnings and profits in the covered shareholder's previously taxed earnings and profits account with respect to the stock in the distributee shall be increased, at the same time that the covered shareholder would make adjustments under paragraph (e)(2)(i) of this section, by an amount equal to the decrease under paragraph (e)(3)(i) of this section and to the extent the distribution is out of non-previously taxed earnings and profits of the distributor, to the extent provided under paragraph (e)(2) of this section. If the receiving corporation uses a non-dollar functional currency that differs from the functional currency used by the distributing corporation, then—

(A) The amount of increase shall be the spot value of the distribution in the receiving corporation's functional currency at the time of the distribution; and

(B) The dollar basis of the amount distributed shall be carried over from the distributing corporation to the receiving corporation.

(4) *Effect on foreign corporation's earnings and profits.* Adjustments to a shareholder's previously taxed earnings and profits account in accordance with this section shall result in corresponding adjustments to the appropriate aggregate category or categories of earnings and profits of the foreign corporation. If an adjustment to a foreign corporation's earnings and profits is required (other than as a result of the previous sentence) the adjustment shall be made only to the non-previously taxed earnings and profits of the corporation except to the extent provided in paragraph (h)(2)(i) of this section. Moreover, if a distribution to a taxpayer exceeds such taxpayer's previously taxed earnings and profits account with respect to stock it owns (within the meaning of section 958(a)) in the foreign corporation making the distribution, the distribution may only be treated as a dividend under section 316 by applying section 316(a)(1) and (2) to the non-previously taxed earnings and profits of the foreign corporation.

(5) *Deficits in earnings and profits.* If a foreign corporation has a deficit in earnings and profits, as determined under section 964(a) and § 1.964–1, for any taxable year, a covered shareholder's previously taxed earnings and profits account with respect to its stock in such foreign corporation shall not be adjusted to take into account the deficit and the deficit shall be applied only to the non-previously taxed earnings and profits of the foreign corporation.

(6) *Examples.* The application of this paragraph (e) is illustrated by the following examples:

Example 1. Distribution to a United States shareholder. (i) *Facts.* DP, a United States shareholder, owns 100% of the only class of stock in FC, a CFC. Both DP and FC use the calendar year as their taxable year. FC uses the ''u'' as its functional currency. During year 1, FC derives 100u of subpart F income, and such amount is included in DP's gross income under section 951(a)(1)(A). The average exchange rate for year 1 is 1u = $1. At the end of year 1, FC's current and accumulated earnings and profits (before taking into account distributions made during year 1) are 500u. Also, on December 31, year 1, when the spot exchange rate is 1u = $1.10, FC distributes 50u of earnings and profits to DP.

(ii) *Analysis.* At the end of year 1, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are first increased from 0 to 100u, pursuant to paragraph (e)(2)(i) of this section as a result of the subpart F inclusion of 100u and then reduced from 100u to 50u, pursuant to paragraph (e)(2)(ii) of this section as a result of the distribution. DP's dollar basis in the 100u of previously taxed earnings and profits is $100 (the dollar amount of the income inclusion under section 951(a)(1)(A)). See section 989(b)(3). The 50u distribution is excluded from DP's gross income pursuant to § 1.959–1(c)(1). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of 50u and non-previously taxed earnings and profits of 400u. DP's dollar basis in the previously taxed earnings and profits account is reduced by a pro rata share of the dollar amount included in income under section 951(a)(1)(A), or by $50 (50u distribution/100u previously taxed earnings and profits x $100 dollar basis). DP recognizes foreign currency gain under section 986(c) of $5 ($55 spot value of 50u distribution − $50 basis).

Example 2. Net deficit in earnings and profits. (i) *Facts.* Assume the same facts as in *Example 1*, except that FC has a net deficit

in earnings and profits of 500u for year 2. At the end of Year 1, FC has 50u of section 959(c)(2) earnings and profits and 400u of non-previously taxed earnings and profits.

(ii) *Analysis.* At the end of year 2, DP's section 959(c)(2) earnings and profits for year 1 remains at 50u, pursuant to paragraph (e)(5) of this paragraph, because a shareholder's previously taxed earnings and profits account is not adjusted to take into account the CFC's deficit in earnings and profits. Pursuant to paragraph (e)(4) of this section, at the end of year 2, FC's non-previously taxed earnings and profits are reduced to (100u), and no adjustment is made to FC's previously taxed earnings and profits, which remains at 50u.

Example 3. Distribution and section 956 inclusion in same year. Assume the same facts as in *Example 1*, except that DP also has a section 956 amount for year 1 with respect to its stock in FC of 200u.

(ii) *Analysis.* At the end of year 1, adjustments are made to DP's previously taxed earnings and profits account in its FC stock in the following order: First, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are increased from 0 to 100u pursuant to paragraph (e)(2)(i) of this section as a result of the subpart F inclusion. Then, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are reduced from 100u to 50u pursuant to paragraph (e)(2)(ii) of this section as a result of the distribution and the 50u distribution is excluded from DP's gross income pursuant to § 1.959–1(c)(1). Then, the remaining 50u of section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are reclassified as section 959(c)(1) earnings and profits pursuant to paragraph (e)(2)(iv) of this section as a result of FC's investment in United States property and 50u of the 200u section 956 amount is excluded from DP's gross income pursuant to § 1.959–1(c)(2). Finally, the remaining 150u section 956 amount equal to $165 (150u × 1.1) is included in DP's gross income pursuant to section 951(a)(1)(B) and the section 959(c)(1) earnings and profits in DP's previously taxed earnings and profits account are increased from 50u to 200u pursuant to paragraph (e)(2)(vii) of this section. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(1) earnings and profits of 200u and non-previously taxed earnings and profits of 250u. DP's dollar basis in the previously taxed earnings and profits account at the end of year 1 is $215 (the $50 attributable to the reclassified 50u of earnings and $165 attributable to the 150u of section 956 inclusion). See section 989(b)(4).

Example 4. Section 956 amount in following year. (i) *Facts.* Assume the same facts as in *Example 3*, except that in year 2, DP has an additional section 956 amount of 200u with respect to its stock in FC and the spot exchange rate on December 31, year 2 is 1u = $1.20.

(ii) *Analysis.* As in *Example 3*, at the end of year 1, DP has a section 959(c)(1) earnings and profits account with respect to its stock in FC of 200u. Although DP has 200u of section 959(c)(1) earnings and profits in its previously taxed earnings and profits account with respect to its stock in FC, section 959(c)(1) earnings and profits are generated by the inclusion of a section 956 amount in a United States shareholder's gross income or the reclassification of section 959(c)(2) earnings and profits to exclude a section 956 amount from a United States shareholder's gross income and cannot be used to exclude any additional section 956 amounts from a United States shareholder's gross income. Consequently, at the end of year 2, the section 959(c)(1) earnings and profits in DP's previously taxed earnings and profits account are increased from 200u to 400u pursuant to paragraph (e)(2)(vii) of this section and the 200u section 956 amount is included in DP's gross income pursuant to section 959(a)(1)(B). Pursuant to paragraph (e)(4) of this section, at the end of year 2, FC has section 959(c)(1) earnings and profits of 400u and non-previously taxed earnings and profits of 50u. DP's dollar basis in its 200u of year 2 section 959(c)(1) earnings and profits is $240.

Example 5. Section 951(a)(1)(A) inclusion and distribution in following year. (i) *Facts.* Assume the same facts as in *Example 4*, except that in year 3, FC derives 250u of subpart F income, which is included in DP's income under section 951(a)(1)(A), makes a 250u distribution to DP, and has 700u of current and accumulated earnings and profits (before taking into account distributions made during year 3). The average exchange rate for year 3 is 1u = $1.10, so DP includes $275 in income (250u × $1.10/1u).

(ii) *Analysis.* As in *Example 4*, at the end of year 2, DP has a previously taxed earnings and profits account with respect to its stock in FC of 400u of section 959(c)(1) earnings and profits. At the end of year 3, adjustments are made in the following order. First, DP's section 959(c)(2) earnings and profits are increased from 0 to 250u pursuant to paragraph (e)(2)(i) of this section as a result of the subpart F inclusion. Then the section 959(c)(1) earnings and profits in DP's previously taxed earnings and profits account are reduced from 400u to 150u and the 250u distribution to DP is excluded from DP's gross income pursuant to § 1.959–1(c)(1). Pursuant to paragraph (e)(4) of this section, at the end of year 3, FC has 150u of section 959(c)(1) earnings and profits, 250u of section 959(c)(2) earnings and profits, and 50u of non-previously taxed earnings and profits. If DP has not made the dollar basis pooling election described in paragraph (b)(3)(ii) of this section, then the 250u distribution out of section 959(c)(1) earnings is assigned a dollar basis of $293.75 ($240 basis in 200u of year 2 earnings and $53.75 basis in 50u of year 1 earnings (50u/200u × $215)). DP's remaining dollar basis in the year 1 section 959(c)(1) earnings is $161.25 ($215 − $53.75). If DP elected to maintain the dollar basis of its previously taxed earnings and profits account on a pooled basis as provided in paragraph (b)(3)(ii) of this section, then the 250u distribution out of section 959(c)(1) earnings is assigned a dollar basis of $280.77 (250u/650u × ($215 + $240 + $275)), and DP's dollar basis in its remaining 400u previously taxed earnings accounts is $449.23 ($730 − $280.77).

Example 6. Distribution to a United States shareholder and a foreign shareholder. (i) *Facts.* DP, a United States shareholder, owns 70% and FP, a nonresident alien, owns 30% of the only class of stock in FC, a CFC that uses the U.S. dollar as its functional currency. Both DP and FC use the calendar year as their taxable year. During year 1, FC derives $100x of subpart F income, $70x of which is included in DP's gross income under section 951(a)(1)(A). FC's current and accumulated earnings and profits (before taking into account distributions made during year 1) are $500x. Also, during year 1, FC distributes $50x of earnings and profits, $35x distribution to DP and $15x distribution to FP.

(ii) *Analysis.* At the end of year 1, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are increased from $0 to $70x, pursuant to paragraph (e)(2)(i) of this section as a result of the subpart F inclusion. The section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account are then reduced from $70x to $35x, pursuant to paragraph (e)(2)(ii) of this section as a result of the distribution. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $35x and non-previously taxed earnings and profits of $415x.

Example 7. Intercorporate Distribution. (i) *Facts.* DP, a United States shareholder, owns 70% and FP, a nonresident alien, owns 30% of the only class of stock in FC, a CFC. FC owns 100% of the only class of stock in FS, a CFC. FC uses the ''u'' as its functional currency and FS uses the ''y'' as its functional currency. DP, FC, and FS all use the calendar year as their taxable year. During year 1, FS derives 100y of subpart F income. The average y:$ exchange rate for year 1 is 1y = $1. On December 31, year 2, FS distributes 100y to FC. The y:u exchange rate on December 31, year 2, is 1y = 0.5u.

(ii) *Analysis.* (A) *Year 1.* At the end of year 1, DP's pro rata share of 70y of subpart F income is included in DP's gross income pursuant to section 951(a)(1)(A)(i) and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to the stock it indirectly owns in FS are correspondingly increased from 0 to 70y pursuant to paragraph (e)(2)(i) of this section as a result of the subpart F income. The dollar basis of the previously taxed earnings and profits in DP's account with respect to its stock in FS is $70. At the end of year 2, FS has section 959(c)(2) earnings and profits of 70y and non-previously taxed earnings and profits of 30y.

(B) *Year 2.* Upon the distribution of 100y = 50u from FS to FC on December 31, year 2, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to the stock it indirectly owns in FS are reduced from 70y to 0 and the section 959(c)(2) earnings and profits in DP's earnings and profits account with respect to its stock in FC are correspondingly increased from 0 to 35u pursuant to paragraph (e)(3) of this section. The entire 100y = 50u distribution is excluded from FC's income for purposes of determining FC's subpart F income under section 951(a) for year 2 with respect to DP pursuant to § 1.959–2(a)(1). Pursuant to paragraph (e)(4)

of this section, at the end of year 2, FS has 0 earnings and profits and FC has section 959(c)(2) earnings and profits of 35u and non-previously taxed earnings and profits of 15u. DP's dollar basis in its 35u of section 959(c)(2) earnings and profits in its earnings and profits account with respect to its stock in FC is $70, carried over from DP's original dollar basis in its 70y of section 959(c)(2) earnings and profits in its previously taxed earnings and profits account with respect to its stock in FS.

Example 8. Sale of CFC stock. (i) *Facts.* DP1, a United States shareholder, owns 100% of the only class of stock in FC, a CFC. At the beginning of year 1, DP1 has a zero basis in its stock in FC. Both DP1 and FC use the calendar year as their taxable year. FC uses the U.S. dollar as its functional currency. During year 1, FC derives $100x of subpart F income and $100x of other income. On December 31 of year 1, DP1 sells all of its stock in FC to DP2, a U.S. person for $200x. Year 1 is a year beginning on or after December 31, 1962.

(ii) *Analysis.* First, DP1 includes the $100x of subpart F income in gross income under section 951(a)(1)(A). The section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to its stock in FC are increased from $0 to $100x pursuant to paragraph (e)(2)(i) of this section and DP1's basis in its FC stock is increased from $0 to $100x pursuant to § 1.961–1(b). FC's section 959(c)(2) earnings and profits are increased from $0 to $100x and its non-previously taxed earnings and profits are correspondingly increased from $0 to $100x pursuant to paragraph (e)(4) of this section. Then pursuant to section 1248(a), because FC has $100x of non-previously taxed earnings and profits attributable to DP1's stock that are attributable to a taxable year beginning on or after December 31, 1962 during which FC was a CFC and DP1 owned its stock in FC, the $100x of gain recognized by DP1 on the sale of its stock ($200x proceeds − $100x basis) is included in DP1's gross income as a dividend. Consequently, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to its stock in FC are increased from $100x to $200x pursuant to paragraph (e)(2)(i) of this section. Upon the sale, DP2 acquires from DP1 a previously taxed earnings and profits account with respect to the FC stock of $200x of section 959(c)(2) earnings and profits and takes a cost basis of $200x in the FC stock pursuant to section 1012.

(f) *Special rule for shareholders with more than one previously taxed earnings and profits account.*—(1) *Adjustments for distributions.* If a covered shareholder owns (within the meaning of section 958(a)) more than one share of stock in a foreign corporation as of the last day of the foreign corporation's taxable year, to the extent that the total amount of any distributions of earnings and profits made with respect to any particular share for the foreign corporation's taxable year would exceed the previously taxed earnings and profits account with respect to such share (an excess distribution amount), the following adjustments shall be made:

(i) *Adjustment of other accounts.* The covered shareholder's previously taxed earnings and profits accounts with respect to the shareholder's other shares of stock in the foreign corporation that are owned by the covered shareholder as of the last day of the CFC's taxable year shall be decreased, in the aggregate, by an amount equal to such excess distribution amount, but not below zero. Such decrease shall be made on a pro rata basis by reference to the amount of the previously taxed earnings and profits in those other accounts and shall be allocated to the section 959(c)(1) and (c)(2) earnings and profits in those accounts in the same manner as a distribution is allocated to such earnings and profits pursuant to the rules of section 959(c) and paragraph (e)(2)(ii)(A) of this section.

(ii) *Adjustment of deficient account.* The covered shareholder's previously taxed earnings and profits account for the first-mentioned share of stock shall correspondingly be increased by the same amount, and then shall be adjusted to zero as provided under paragraph (e)(2)(ii)(B) of this section.

(2) *Adjustments for section 956 amounts.* If a United States shareholder, who owns more than one share of stock in a CFC as of the last day of the CFC's taxable year, has a section 956 amount with respect to its stock in the CFC for a taxable year, to the extent that the section 956 amount with respect to any particular share of stock exceeds the section 959(c)(2) earnings and profits in such shareholder's previously taxed earnings and profits account with respect to such share (an excess section 956 amount), the covered shareholder's section 959(c)(2) earnings and profits in its previously taxed earnings and profits accounts with respect to its other shares of stock that are owned by the United States shareholder on the last day of the CFC's taxable year shall be reclassified as section 959(c)(1) earnings and profits, in the aggregate, by an amount equal to such excess section 956 amount. Such reclassification shall be made on a pro rata basis by reference to the amount of the section 959(c)(2) earnings and profits in each of the United States shareholder's other previously taxed earnings and profits accounts with respect to its stock in the CFC prior to reclassification under this paragraph (f)(2).

(3) *Examples.* The application of this paragraph (f) is illustrated by the following examples:

Example 1. Two blocks of stock. (i) *Facts.* DP, a United States shareholder, owns two blocks, block 1 and block 2, of shares of class A stock in FC, a CFC that uses the U.S. dollar as its functional currency. Both DP and FC use the calendar year as their taxable year. Entering year 1, DP has a previously taxed earnings and profits account with respect to its block 1 shares consisting of $25x of section 959(c)(2) earnings and profits and a previously taxed earnings and profits account with respect to its block 2 shares consisting of $65x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $90x and non-previously taxed earnings and profits of $200x. During year 1, FC makes a distribution of earnings and profits on its Class A stock of $50x on each of block 1 and block 2.

(ii) *Analysis.* First, as a result of the distribution, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are decreased from $25x to $0 and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are decreased from $65x to $15x pursuant to paragraph (e)(2)(ii) of this section. Because there are insufficient previously taxed earnings and profits with respect to block 1, DP may access its excess previously taxed earnings and profits with respect to its block 2 stock, after taking into account any distributions or section 956 amounts with respect to block 2. Accordingly, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are decreased from $15x to $0 pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are increased from $0 to $15x and then decreased from $15x to $0 pursuant to paragraphs (e)(2)(ii)(B) and (f)(1)(ii) of this section. The $40x ($25x + $15x) of the distribution with respect to block 1 and $50x of the distribution with respect to block 2 are excluded from DP's gross income pursuant to § 1.959–1(c)(1). The remaining $10x of the distribution of earnings and profits with respect to block 1 is included in DP's gross income as a dividend. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $0 and non-previously taxed earnings and profits of $190x.

Example 2. Multiple classes of stock. (i) *Facts.* Assume the same facts as in *Example 1,* except that DP also owns a block, block 3, of class B stock in FC. Entering year 1, DP has a previously taxed earnings and profits account with respect to block 3 consisting of $60x of section 959(c)(2) earnings and profits. Entering year 1, FC has $150x of section 959(c)(2) earnings and profits and $200x of non-previously taxed earnings and profits.

(ii) *Analysis.* First, as in *Example 1*, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are decreased from $25x to $0 and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2

are decreased from $65x to $15x pursuant to paragraph (e)(2)(ii) of this section. Because there are insufficient previously taxed earnings and profits with respect to block 1, DP may access its excess previously taxed earnings and profits with respect to block 2 and block 3, after taking into account any distributions or section 956 amounts with respect to those blocks. In addition, the previously taxed earnings and profits from blocks 2 and 3 are decreased pro rata based on the relative previously taxed earnings and profits in the previously taxed earnings and profits accounts with respect to both blocks after taking into account any distributions or section 956 amounts with respect to those blocks. Thus, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are decreased from $15x to $10x ($15x/$75x × $25x) and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 3 are decreased from $60x to $40x ($60x/$75x × $25x) pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section. The section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $25x and then decreased from $25x to $0 pursuant to paragraphs (e)(2)(ii)(B) and (f)(1)(ii) of this section. The entire $50x distribution with respect to block 1 and $50x distribution with respect to block 2 are excluded from DP's gross income pursuant to § 1.959–1(c)(1). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $200x.

Example 3. Distribution in excess of aggregate previously taxed earnings and profits. (i) *Facts.* Assume the same facts as in *Example 2*, except that instead of a total distribution of $100x on Class A shares in year 1, FC makes a total distribution of $200x on its Class A shares in year 1, consisting of a $100x distribution to block 1 and a $100 distribution to block 2.

(ii) *Analysis.* First, as a result of the distribution, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are decreased from $25x to $0 and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are decreased from $65x to $0 pursuant to paragraph (e)(2)(ii) of this section. Because there are insufficient previously taxed earnings and profits in DP's previously taxed earning and profits accounts with respect to blocks 1 and 2, DP may access its excess previously taxed earnings and profits in its previously taxed earnings and profits account with respect to block3 after taking into account any distributions or section 956 amounts with respect to block 3. Consequently, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 3 are decreased from $60x to $0 pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section. Of the total $200x distribution from FC to DP, $150x is excluded from DP's gross income pursuant to § 1.959–1(c)(1). The remaining $50x of the distribution is included in DP's gross income pursuant to section 951(a)(1)(A). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $0 and non-previously taxed earnings and profits of $150x.

Example 4. Sale. (i) *Facts.* Assume the same facts as in *Example 2*, except that DP sells block 3 before the end of year 1.

(ii) *Analysis.* First, as in *Example 2*, the distribution results in a decrease of the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 from $25x to $0 and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 from $65x to $15x pursuant to paragraph (e)(2)(ii) of this section. Because DP does not own block 3 on the last day of year 1, DP cannot use the previously taxed earnings and profits account with respect to block 3 to exclude a distribution in that year to block 1 or 2 from gross income. Therefore, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are decreased from $15x to $0 pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $15x and then decreased from $15x to $0 pursuant to paragraphs (e)(2)(ii)(B) and (f)(1)(ii) of this section. The $40x ($25x + $15x) of the distribution with respect to block 1 and $50x of the distribution with respect to block 2 are excluded from DP's gross income pursuant to § 1.959–1(c)(1). The remaining $10x of the distribution with respect to block 1 is included in DP's gross income as a dividend. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $60x and non-previously taxed earnings and profits of $190x.

Example 5. Section 956 amount. (i) *Facts.* Assume the same facts as in *Example 2*, except that, in addition, during year 1, FC has a section 956 amount of $30x, $5x of which is allocable to each of blocks 1 and 2, and $20x of which is allocable to block 3.

(ii) *Analysis.* Pursuant to paragraph (f)(2) of this section, account adjustments are made for the distribution from FC before any account adjustments are made for the section 956 amount. After account adjustments are made for the distribution from FC as illustrated in E*xample 2*, DP has a previously taxed earnings and profits account with respect each block as follows: Block 1: $0, block 2: $10x of section 959(c)(2) earnings and profits, block 3: $40x of section 959(c)(2) earnings and profits. As a result of the section 956 amount with respect to block 2, pursuant to paragraph (e)(2)(vi) of this section, $5x of DP's section 959(c)(2) earnings and profits in its previously taxed earnings and profits account with respect to block 2 is reclassified as section 959(c)(1) earnings and profits. Consequently, block 2 is left with a previously taxed earnings and profits account consisting of $5x of section 959(c)(1) earnings and profits and $5x of section 959(c)(2) earnings and profits. In addition, pursuant to paragraph (e)(2)(vi) of this section, $20x of DP's section 959(c)(2) earnings and profits in its previously taxed earnings and profits account with respect to block 3 are reclassified as section 959(c)(1) earnings and profits. Consequently, block 3 is left with a previously taxed earnings and profits account consisting of $20x of section 959(c)(1) earnings and profits and $20x of section 959(c)(2) earnings and profits. The total $25x section 956 amount with respect to blocks 2 and 3 is excluded from DP's gross income pursuant to § 1.959–1(c)(2). Because there are insufficient previously taxed earnings and profits in the previously taxed earnings and profits account with respect to block 1, DP may access its excess previously taxed earnings and profits in the previously taxed earnings and profits accounts with respect to blocks 2 and 3 after taking into account any distributions or section 956 amounts with respect to those blocks. In addition, the previously taxed earnings and profits in the previously taxed earnings and profits accounts with respect to blocks 2 and 3 are reclassified pro rata based on the relative previously taxed earnings and profits in those accounts after taking into account any distributions or section 956 amounts with respect to those blocks. Accordingly, pursuant to paragraphs (e)(2)(vi) and (f)(2) of this section, an additional $1x ($5x/$25x × $5x) of the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 2 are reclassified as section 959(c)(1) earnings and profits and an additional $4x ($20x/$25x × $5x) of the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 3 are reclassified as section 959(c)(1) earnings and profits. The $5x section 956 amount with respect to block 1 is also excluded from DP's gross income pursuant to § 1.959–1(c)(2). At the end of year 1, DP's previously taxed earnings and profits accounts with respect to its various blocks of stock are as follows: block 1 has no previously taxed earnings and profits, block 2 has $6x ($5x + $1x) of section 959(c)(1) earnings and profits and $4x ($5x − $1x) of section 959(c)(2) earnings and profits and block 3 has $24x ($20x + $4x) of section 959(c)(1) earnings and profits and $16x ($20x − $4x) of section 959(c)(2) earnings and profits. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has $30x of section 959(c)(1) earnings and profits, $20x of section 959(c)(2) earnings and profits, and $200x of non-previously taxed earnings and profits.

(g) *Special rule for shareholder included in a consolidated group*—(1) *Adjustments for distributions*—(i) *In general.* In the case of a covered shareholder who is a member of a consolidated group, to the extent that the total amount of any distributions of earnings and profits with respect to such covered shareholder's stock in a foreign corporation during such foreign corporation's taxable year would exceed the covered shareholder's previously taxed earnings and profits account with respect to all of the covered shareholder's stock of the foreign

corporation (an excess distribution amount) the previously taxed earnings and profits accounts of the covered shareholder and of the other members of the covered shareholder's consolidated group that own stock in the same foreign corporation and are members of the covered shareholder's consolidated group on the last day of the foreign corporation's taxable year shall be adjusted as follows.

(A) *Adjustment of other members' accounts.* The previously taxed earnings and profits accounts of the other members of the consolidated group that own (within the meaning of section 958(a)) stock in the same foreign corporation and are members of the covered shareholder's consolidated group on the last day of the foreign corporation's taxable year shall be decreased, in the aggregate, by the amount of such excess distribution amount, but not below zero. Such decrease shall be made on a pro rata basis by reference to the amount of such other members' previously taxed earnings and profits accounts and shall be allocated to the section 959(c)(1) and (c)(2) earnings and profits in such accounts in the same manner as a distribution is allocated to such earnings and profits pursuant to section 959(c) and paragraph (e)(2)(ii)(A) of this section.

(B) *Adjustment of the deficient account.* The deficient previously taxed earnings and profits account of such covered shareholder shall correspondingly be increased by the same amount, and then adjusted to zero under paragraph (e)(2)(ii)(B) of this section.

(ii) *Insufficient previously taxed earnings and profits.* If more than one member of the consolidated group is a covered shareholder that has an excess distribution amount with respect to all of its stock in the foreign corporation and there is insufficient previously taxed earnings and profits available in the previously taxed earnings and profits accounts of other consolidated group members to exclude the combined excess distribution amounts of the covered shareholders, the other consolidated group members' previously taxed earnings and profits shall be allocated between the covered shareholders' deficient previously taxed earnings and profits accounts in proportion to each covered shareholder's excess distribution amount.

(2) *Adjustments for section 956 amounts*—(i) *In general.* If a United States shareholder, who is a member of a consolidated group, has a section 956 amount with respect to its stock in a CFC for a taxable year, to the extent that the section 956 amount exceeds the section 959(c)(2) earnings and profits in such United States shareholder's previously taxed earnings and profits accounts with respect to all of its stock in the CFC (an excess section 956 amount), the section 959(c)(2) earnings and profits in the previously taxed earnings and profits accounts of consolidated group members, who are members of the United States shareholder's consolidated group on the last day of the CFC's taxable year, with respect to their stock in the CFC shall be reclassified as section 959(c)(1) earnings and profits, in the aggregate, by an amount equal to such excess section 956 amount. The amount that is reclassified with respect to each such account of such other members shall be proportionate to the amount of section 959(c)(2) earnings and profits in those accounts prior to reclassification under this paragraph (g).

(ii) *Insufficient section 959(c)(2) earnings and profits.* If more than one member of the consolidated group is a United States shareholder that has an excess section 956 amount with respect to its stock in the CFC for the taxable year and there is insufficient aggregate section 959(c)(2) earnings and profits in other consolidated group members' previously taxed earnings and profits accounts to exclude the combined excess section 956 amounts of the Untied States shareholders, the amount of any consolidated group members' section 959(c)(2) earnings and profits that are reclassified on behalf of each United States shareholder shall be proportionate to the excess section 956 amount for each such United States shareholder.

(3) *Stock basis adjustments of members.* See § 1.1502–32 for rules addressing investment adjustments resulting from the application of this paragraph.

(4) *Examples.* The application of this paragraph (g) is illustrated by the following examples:

Example 1. Two consolidated group members. (i) *Facts.* DP1, a United States shareholder, owns one block, block 1, of shares of Class A stock in FC, a CFC that uses the U.S. dollar as its functional currency. DP2, a United States shareholder and a member of DP1's consolidated group, owns one block, block 2, of shares of Class A stock in FC. DP1, DP2 and FC all use the calendar year as their taxable year and FC uses the U.S. dollar as its functional currency. Entering year 1, DP1 has a previously taxed earnings and profits account with respect to block 1 consisting of $50x of section 959(c)(2) earnings and profits and DP2 has a previously taxed earnings and profits account with respect to block 2 consisting of $200x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $250x and non-previously taxed earnings and profits of $100x. In year 1, FC generates no earnings and profits and makes a distribution of earnings and profits on its stock Class A stock, a $100x distribution of earnings and profits to block 1 and a $100x distribution of earnings and profits to block 2.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are decreased from $50x to $0 and the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $200x to $100x. Then, pursuant to paragraphs (e)(2)(v) and (g)(1)(i)(A) of this section, the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $100x to $50x and, pursuant to paragraphs (e)(2)(ii)(B) and (g)(1)(i)(B) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $50x and then decreased from $50x to $0. Pursuant to section 959(a) and § 1.959–1(c), the entire $100x distribution to block 1 and $100x distribution to block 2 are excluded from DP1's and DP2's gross incomes respectively. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $100x.

Example 2. Two consolidated group members; multiple classes of stock. (i) *Facts.* Assume the same facts as in *Example 1*, except that DP1 also owns one block, block 3, of shares of class B stock in FC. DP1 has a previously taxed earnings and profits account with respect to block 3 consisting of $40x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $290x and non-previously taxed earnings and profits of $100x.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are decreased from $50x to $0 and the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $200x to $100x. Then, pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 3 are decreased from $40x to $0 and, pursuant to paragraphs (e)(2)(ii)(B) and (f)(1)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $40x and then decreased from $40x to $0. Finally, pursuant to paragraphs (e)(2)(v) and (g)(1)(i)(A) of this section, the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from

$100x to $90x and, pursuant to paragraphs (e)(2)(ii)(B) and (g)(1)(i)(B) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $10x and then decreased from $10x to $0. Pursuant to section 959(a) and § 1.959–1(c), the entire $100x distribution to block 1 and $100x distribution to block 2 are excluded from DP1's and DP2's gross incomes respectively. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $90x and non-previously taxed earnings and profits of $100x.

Example 3. Three consolidated group members; multiple classes of stock. (i) *Facts.* Assume the same facts as in *Example 2*, except that DP3, a United States shareholder and a member of DP1's consolidated group, owns one block, block 4, of shares of class B stock in FC. DP3 has a previously taxed earnings and profits account with respect to block 4 consisting of $25x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $315x and non-previously taxed earnings and profits of $100x.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are decreased from $50x to $0 and the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $200x to $100x. Then, pursuant to paragraphs (e)(2)(v) and (f)(1)(i) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 3 are decreased from $40x to $0 and, pursuant to paragraphs (e)(2)(ii)(B) and (f)(1)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $40x and then decreased from $40x to $0. Finally, pursuant to paragraphs (e)(2)(v) and (g)(1)(i)(A) of this section, the section 959(c)(2) earnings and profits in DP2's and DP3's previously taxed earnings and profits accounts with respect to blocks 2 and 4 are decreased pro rata from $100x to $92x and from $25x to $23x respectively, and, pursuant to paragraphs (e)(2)(ii)(B) and (g)(1)(i)(B) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are increased from $0 to $10x and then decreased from $10x to $0. Pursuant to section 959(a) and § 1.959–1(c), the entire amounts of the $100x distribution to block 1 and the $100x distribution to block 2 are excluded from DP1's and DP2's gross incomes respectively. Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $115x and non-previously taxed earnings and profits of $100x.

Example 4. Section 956 Amount. (i) *Facts.* Assume the same facts as in *Example 3*, except that instead of a distribution of 200x on its class A stock, FC has a section 956 amount for year 1 of $180x, 45x of which is allocable to each of blocks 1 through 4.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(iv) of this section, the section 959(c)(2) earnings and profits in each shareholder's previously taxed earnings profits account are reclassified as section 959(c)(1) earnings and profits leaving each block of stock with the following account: Block 1: $45x of section 959(c)(1) earnings and profits, $5x of section 959(c)(2) earnings and profits; block 2: $45x of section 959(c)(1) earnings and profits and $155x of section 959(c)(2) earnings and profits; block 3: $40x of section 959(c)(1) earnings and profits and $0 of section 959(c)(2) earnings and profits; block 4: $25x of section 959(c)(1) earnings and profits and $0 of section 959(c)(2) earnings and profits. After the above reclassifications, DP1 has an excess section 956 amount of $5x with respect to block 3. Therefore, pursuant to paragraphs (e)(2)(vi) and (f)(2) of this section, the remaining $5x of section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are reclassified as section 959(c)(1) earnings and profits, leaving DP1 with $50x of section 959(c)(1) earnings and profits and $0 of section 959(c)(2) earnings and profits in its previously taxed earnings and profits account with respect to block 1. The entire $45x section 956 amount with respect to blocks 1 and 3 are excluded from DP1's gross income pursuant to paragraph (c)(2) of this section. After the above reclassifications, DP3 has an excess section 956 amount of $20x with respect to block 4. Therefore, pursuant to paragraphs (e)(2)(vi) and (g)(2)(i) of this section, $20x of the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are reclassified as section 959(c)(1) earnings and profits, leaving DP2 with $65x of section 959(c)(1) earnings and profits and $135x of section 959(c)(2) earnings and profits. The entire $45x section 956 amount with respect to blocks 2 and 4 are excluded from DP2's and DP3's gross incomes, respectively, pursuant to § 1.959–1(c)(2). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(1) earnings and profits of $180x, section 959(c)(2) earnings and profits of $135x, and non-previously taxed earnings and profits of $100x.

Example 5. Ex-member. (i) *Facts.* DP1, a United States shareholder, owns one block, block 1, of shares of Class A stock in FC, a CFC that uses the U.S. dollar as its functional currency. DP2 and DP3, both United States shareholders and members of DP1's consolidated group, own one block each, blocks 2 and 3 respectively, of shares of Class A stock in FC. DP1, DP2, DP3 and FC all use the calendar year as their taxable year. Entering year 1, DP1 has a previously taxed earnings and profits account with respect to block 1 consisting of $50x of section 959(c)(2) earnings and profits, DP2 has a previously taxed earnings and profits account with respect to block 2 consisting of $100x of section 959(c)(2) earnings and profits, and DP3 has a previously taxed earnings and profits account with respect to block 3 consisting of $200x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $350x and non-previously taxed earnings and profits of $100x. On March 15 of year 1, FC makes a distribution of earnings and profits on its stock Class A stock consisting of a $100x distribution of earnings and profits to each of blocks 1, 2 and 3. On July 4 of year 1, DP3 is sold to DP4, a United States person who is not a member of the consolidated group, and DP3 ceases to be a member of the consolidated group.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are decreased from $50x to $0, the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $100x to $0, and the section 959(c)(2) earnings and profits in DP3's previously taxed earnings and profits account with respect to block 3 are decreased from $200x to $100x. Because DP3 was not a member of DP1's consolidated group on the last day of year 1, the remaining $100x of section 959(c)(2) earnings and profits in DP3's previously taxed earnings and profits account with respect to its stock in FC cannot be used to exclude the remaining $50x distribution to DP1 from DP1's gross income. Consequently, pursuant to § 1.959–1(c)(1), $50x of the distribution to block 1, the entire $100x of the distribution to block 2, and the entire $100x of the distribution to block 3 are excluded from DP1's, DP2's, and DP3's gross incomes respectively. The remaining $50x distribution to DP1 is included in DP1's gross income pursuant to section 951(a)(1)(a). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has section 959(c)(2) earnings and profits of $150x and non-previously taxed earnings and profits of $50x.

Example 6. Insufficient excess previously taxed earnings and profits. (i) *Facts.* DP1, a United States shareholder, owns one block, block 1, of shares of Class A stock in FC, a CFC that uses the U.S. dollar as its functional currency. DP2 and DP3, both United States shareholders and members of DP1's consolidated group, own one block each, blocks 2 and 3 respectively, of shares of Class A stock in FC. DP1, DP2, DP3 and FC all use the calendar year as their taxable year. Entering year 1, DP1 has a previously taxed earnings and profits account with respect to block 1 consisting of $40x of section 959(c)(2) earnings and profits, DP2 has a previously taxed earnings and profits account with respect to block 2 consisting of $60x of section 959(c)(2) earnings and profits, and DP3 has a previously taxed earnings and profits account with respect to block 3 consisting of $150x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $250x and non-previously taxed earnings and profits of $100x. On March 15 of year 1, FC makes a distribution of earnings and profits on its Class A stock consisting of a $100x distribution of earnings and profits to each of blocks 1, 2 and 3.

(ii) *Analysis.* First, pursuant to paragraph (e)(2)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's previously taxed earnings and profits account with respect to block 1 are decreased from $40x

to $0, the section 959(c)(2) earnings and profits in DP2's previously taxed earnings and profits account with respect to block 2 are decreased from $60x to $0, and the section 959(c)(2) earnings and profits in DP3's previously taxed earnings and profits account with respect to block 3 are decreased from $150x to $50x. Then, pursuant to paragraph (g)(1)(i)(A) of this section, the section 959(c)(2) earnings and profits in DP3's previously taxed earnings and profits account with respect to its stock in FC are reduced from $50x to $0 and, pursuant to paragraphs (g)(1)(i)(B) and (g)(1)(ii) of this section, the section 959(c)(2) earnings and profits in DP1's and DP2's previously taxed earnings and profits accounts with respect to their stock in FC are increased from $0 to $30x ($60x/$100x × $50x) and $0 to $20x ($40x/$100x × $50x) respectively and then immediately reduce to $0. Pursuant to § 1.959–1(c), $70x ($40x + $30x) of the distribution to DP1, $80x ($60x + $20x) of the distribution to DP2, and $100x of the distribution to DP3 are excluded from gross income. The remaining $30x distributed to DP1 and $20x distributed to DP2 are included in gross income pursuant to section 951(a)(1)(A). Pursuant to paragraph (e)(4) of this section, at the end of year 1, FC has non-previously taxed earnings and profits of $50x.

(h) *Adjustments in the case of redemptions*—(1) *In general.* In the case of a foreign corporation's redemption of stock (a redemption distribution), the effect on the covered shareholder's previously taxed earnings and profits account and on the earnings and profits of the redeeming corporation depends on whether the distribution is treated as a payment in exchange for stock or as a distribution of property to which section 301 applies. For the treatment of deemed redemption distributions in transactions described in section 304(a)(1), see paragraph (h)(4) of this section.

(2) *Exchange treatment*—(i) *Effect on foreign corporation's earnings and profits.* In the case of a redemption distribution that is treated as a payment in exchange for stock under section 302(a) or section 303, the amount of the distribution properly chargeable to the earnings and profits of the redeeming foreign corporation is the amount determined under section 312(a), subject to the limitation in section 312(n)(7) and this paragraph (h)(2)(i). For purposes of section 312(n)(7), the amount properly chargeable to the earnings and profits of the redeeming foreign corporation shall not exceed the sum of—

(A) The amount of the previously taxed earnings and profits account with respect to the redeemed shares of stock (without adjustment for any income inclusion under section 1248 resulting from the redemption); and

(B) A ratable portion of the redeeming corporation's non-previously taxed earnings and profits. Such chargeable amount of earnings and profits shall be allocated to earnings and profits in accordance with section 959(c) and this section.

(ii) *Cessation of previously taxed earnings and profits account.* In the case of a redemption distribution that is treated as a payment in exchange for stock, the redeemed covered shareholder's previously taxed earnings and profits account with respect to the redeemed shares ceases to exist and is not transferred to any other previously taxed earnings and profits account. In such a case, any previously taxed earnings and profits in the redeemed covered shareholder's previously taxed earnings and profits account, after being reduced under paragraph (h)(2)(i) of this section, become non-previously taxed earnings and profits of the foreign corporation.

(iii) *Examples.* The application of this paragraph (h)(2) is illustrated by the following examples:

Example 1. Complete redemption treated as exchange; previously taxed earnings and profits account is depleted. *(i) Facts.* DP, a United States shareholder, owns 70% and FP, a nonresident alien who is unrelated to DP under section 318, owns 30% of the only class of stock in FC, a CFC that uses the U.S. dollar as its functional currency. Both DP and FC use the calendar year as their taxable year and both DP and FC are wholly owned by the same domestic corporation, USP. DP has a previously taxed earnings and profits account consisting of $50x of section 959(c)(2) earnings and profits with respect to its stock in FC and DP has a $50 basis in its FC stock pursuant to section 961(a). FC has $50x of section 959(c)(2) earnings and profits and $50x of non-previously taxed earnings and profits attributable to taxable years of FC beginning on or after December 31, 1962 during which FC was a CFC and during which DP held its shares of stock in FC. FC redeems all of DP's stock for $100x in a redemption that is treated as a payment in exchange for the stock under section 302(a).

(ii) *Analysis.* DP includes $35x ($50x × 70%) in gross income as a dividend pursuant to section 1248(a) as a result of the deemed exchange. FC adjusts its earnings and profits as a result of the exchange under paragraph (h)(2)(i) of this section in the following manner: first, FC's section 959(c)(2) earnings and profits are reduced from $50x to $0; then, FC's non-previously taxed earnings and profits are decreased from $50x to $15x to reflect DP's $35x ratable share of FC's non-previously taxed earnings and profits. DP's previously taxed earnings and profits account ceases to exist and is not transferred to any other previously taxed earnings and profits account.

Example 2. Complete redemption treated as exchange; previously taxed earnings and profits account is not depleted. (i) *Facts.* Assume the same facts as *Example 1,* except that the amount of the redemption distribution by FC to DP is $25x.

(ii) *Analysis.* DP recognizes a $25x loss as a result of the deemed exchange. FC's section 959(c)(2) earnings and profits are decreased from $50x to $25x, pursuant to paragraph (h)(2)(i) of this section. DP's previously taxed earnings and profits account ceases to exist, and the remaining $25x of section 959(c)(2) earnings and profits in such account is not transferred to any other previously taxed earnings and profits account. However, pursuant to paragraph (h)(2)(ii) of this section, the $25x of previously taxed earnings and profits is converted to non-previously taxed earnings and profits of DC.

(3) *Distribution treatment*—(i) *Adjustment of shareholder previously taxed earnings and profits accounts and foreign corporation's earnings and profits.* In the case of a redemption distribution by a foreign corporation that is treated as a distribution of property to which section 301 applies, §§ 1.959–1 and this section shall apply in the same manner as they would apply to any distribution of property to which section 301 applies.

(ii) *Transfer to remaining shares.* To the extent that the previously taxed earnings and profits account with respect to stock redeemed in a transaction described in paragraph (h)(3)(i) of this section exceeds the amount chargeable to the earnings and profits of the corporation under the rules of that paragraph, the excess previously taxed earnings and profits shall be reallocated to the previously taxed earnings and profits accounts with respect to the remaining stock in the foreign corporation in a manner consistent with, and in proportion to, the proper adjustments of the basis in the remaining shares pursuant to § 1.302–2(c).

(iii) *Examples.* The application of this paragraph (h)(3) is illustrated by the following examples:

Example 1. Redemption in exchange for cash that is treated as a distribution. (i) *Facts.* DP, a United States shareholder, owns 100% of the stock in FC, a CFC that uses the U.S. dollar as its functional currency. Both DP and FC use the calendar year as their taxable year. DP owns two blocks of stock in FC, block 1 and block 2. At the beginning of year 1, DP has a previously taxed earnings and profits account with respect to block 1 consisting of $50x of section 959(c)(2) earnings and profits and FC has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $100x. In year 1, FC redeems block 1 for $100x in a redemption that is treated as a distribution of property to which section 301 applies under section 302(d).

(ii) *Analysis.* The section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are reduced from $50x to $0 and FC's section 959(c)(2) earnings and profits are

correspondingly reduced from $50x to $0. The remaining $50x is included in DP's gross income as a dividend under section 301(c)(1) and FC's non-previously taxed earnings and profits are reduced from $100x to $50x.

Example 2. Redemption in exchange for cash that is treated as a distribution. (i) *Facts.* Assume the same facts as *Example 1,* except that DP is redeemed for $25x.

(ii) *Analysis.* The section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are reduced from $50x to $25x and FC's section 959(c)(2) earnings and profits are correspondingly reduced from $50x to $25x. FC's non-previously taxed earnings and profits remain at $100x. Pursuant to paragraph (h)(3)(ii) of this section the remaining $25x of section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to block 1 are reallocated with respect to the remaining stock in FC in a manner consistent with, and in proportion to, the proper adjustments of the basis of the remaining FC shares pursuant to § 1.302–2(c).

(4) *Section 304 transactions*—(i) *Deemed redemption treated as a distribution.* In the case of a stock acquisition described in section 304(a)(1), that is treated as a distribution of property to which section 301 applies, a covered shareholder receiving an amount treated as a distribution of earnings and profits shall have a previously taxed earnings and profits account with respect to stock in each foreign corporation treated as distributing its earnings and profits under section 304(b)(2), even if such person did not otherwise have a previously taxed earnings and profits account with respect to stock in such corporation or corporations. In such a case, §§ 1.959–1 and this section shall apply in the same manner as these regulations would apply to any distribution to which section 301 applies.

(ii) The application of this paragraph (h)(4) is illustrated by the following example:

Example. Cross-chain acquisition of first-tier CFC. (i) *Facts.* DP, a domestic corporation, owns all of the stock in DS, a domestic corporation, and F1, a CFC. DP and DS are members of the same consolidated group. DS owns all of the stock in F2, a CFC. DP, DS, F1 and F2 all use the calendar year as their taxable year and F1 and F2 each use the U.S. dollar as its functional currency. During year 1, F1 purchases all the stock in F2 from DS for $80x in a transaction described in section 304(a)(1). At the end of year 1, before taking into account the purchase of F2's stock, DP has a previously taxed earnings and profits account consisting of $20x of section 959(c)(2) earnings and profits with respect to its stock in F1, and F1 has previously taxed earnings and profits consisting of $20x of section 959(c)(2) earnings and profits and non-previously taxed earnings and profits of $10x. At the end of year1, before taking into account the purchase of F2's stock, DS has a previously taxed earnings and profits account consisting of $50x of section 959(c)(2) earnings and profits with respect to its stock in F2, and F2 has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $0.

(ii) *Analysis.* Under section 304(a)(1), DS is deemed to have transferred the F2 stock to F1 in exchange for F1 stock in a transaction to which section 351(a) applies, and F1 is treated as having redeemed, for $80x, the F1 stock deemed issued to DS. The payment of $80x is treated as a distribution of property to which section 301 applies. Under section 304(b)(2), the determination of the amount which is a dividend is made as if the distribution were made, first, by F1 to the extent of its earnings and profits ($30x), and then by F2 to the extent of its earnings and profits ($50x). Before taking into account the deemed distributions, DS had a previously taxed earnings and profits account consisting of $50x of section 959(c)(2) earnings and profits with respect to its stock in F2, and DP had a previously taxed earnings and profits account consisting of $20x of section 959(c)(2) earnings and profits with respect to its stock in F1. Under paragraph (h)(4)(i) of this section, DS has a previously taxed earnings and profits account with respect to the stock in F1. Under paragraph (g)(1)(i) of this section, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to the F1 stock are reduced from $20x to $0 and the section 959(c)(2) earnings and profits in DS's previously taxed earnings and profits account with respect to the F1 stock are increased from $0 to $20x. The distribution by F1 causes the section 959(c)(2) earnings and profits in DS's previously taxed earnings and profits account with respect to F1 stock to be reduced from $20x to $0, and causes F1's section 959(c)(2) earnings and profits to be reduced from $20x to $0 and its non-previously taxed earnings and profits to be reduced from $10x to $0. The deemed distribution by F2 causes the section 959(c)(2) earnings and profits in DS's previously taxed earnings and profits account with respect to F2 stock to be reduced from $50x to $0, and causes F2's section 959(c)(2) earnings and profits to be reduced from $50x to $0. Of the distribution of $80x, $70x is excluded from DS's gross income pursuant to § 1.959–1(c)(1), and $10x is included in DS's gross income as a dividend.

Par. 5. Section 1.959–4 is revised to read as follows:

§ 1.959–4 Distributions of amounts excluded under section 959(a).

Except as provided in section 960(a)(3) and § 1.960–1, any distribution excluded from gross income of a covered shareholder under section 959(a)(1) and § 1.959–1(c)(1) shall be treated, for purposes of chapter 1 (relating to normal taxes and surtaxes) of subtitle A (relating to income taxes) of the Internal Revenue Code as a distribution which is not a dividend, except such a distribution shall immediately reduce earnings and profits.

Par. 6. Section 1.961–1 is revised to read as follows:

§ 1.961–1 Increase in basis of stock in CFCs and of other property.

(a) *Definitions.* See § 1.959–1(b) for a list of defined terms applicable to § 1.961–1 through § 1.961–4.

(b) *Increase in basis*—(1) *In general.* Except as provided in paragraphs (b)(2) and (b)(3) of this section, the adjusted basis of a United States shareholder's stock in a CFC or property (as defined in paragraph (c)(1) of this section) by reason of the ownership of which such United States shareholder is considered under section 958(a) as owning stock in a CFC shall be increased under section 961(a) each time, and to the extent that, such United States shareholder's previously taxed earnings and profits account with respect to the stock in that CFC is increased pursuant to the steps outlined in § 1.959–3(e)(2).

(2) *Limitation on amount of increase in case of election under section 962.* [Reserved].

(3) *Deemed inclusions under sections 1293(c) and 959(e).* Paragraph (b)(1) of this section shall not apply in the case of a deemed section 951(a) inclusion pursuant to section 1293(c) or 959(e).

(c) *Rules of application*—(1) *Property defined.* The property of a United States shareholder referred to in paragraph (b)(1) of this section shall consist of—

(i) Stock in a foreign corporation;

(ii) An interest in a foreign partnership; or

(iii) A beneficial or ownership interest in a foreign estate or trust (as defined in section 7701(a)(31)).

(2) *Increase with respect to each share or ownership unit.* Any increase under paragraph (b) of this section in the basis of a United States shareholder's stock in a foreign corporation or property (as defined in paragraph (c)(1) of this section) by reason of the ownership of which such United States shareholder is considered under section 958(a) as owning stock in a foreign corporation shall be made on a pro rata basis with respect to each share of such stock or each ownership unit of such property.

(3) *Translation rules.* For purposes of determining an increase in basis under this section, in cases in which the previously taxed earnings and profits account is maintained in a non-United States dollar functional currency, section 951(a) inclusions shall be translated into United States dollars at the appropriate exchange rate as described in section 989(b). Any other increase in basis pursuant to paragraph

(b) of this section (for example, a basis increase resulting from the application of § 1.959–3(f) or (g)) shall be in the amount of the transferor's dollar basis attributable to the previously taxed earnings and profits transferred.

(c) *Examples.* The application of this section is illustrated by the following examples:

Example 1. Basis adjustment for income inclusion. (i) *Facts.* DP, a United States shareholder, owns 800 of the 1,000 shares of the one class of stock in FC and has a basis of $50 in each of its shares. DP and FC use the calendar year as a taxable year and FC is a CFC. FC uses the u as its functional currency. The average exchange rate for year 1 is 1u = $1. In year 1, its first year of operation, FC has 100,000u of subpart F income after the payment of 11,250u of foreign income taxes. DP is required to include in gross income 80,000u (800/1,000 × 100,000u) equal to $80,000 under section 951(a), and 9,000u (80,000u/100,000u × 11,250u) equal to $9,000 under section 78.

(ii) *Analysis.* On December 31, of year 1, DP increases the section 959(c)(2) earnings and profits in its previously taxed earnings and profits account with respect to its stock in FC by 80,000u pursuant to § 1.959–3(e)(2)(i) to reflect the inclusion of 80,000u, or $80,000, in DP's gross income pursuant to section 959(a), and correspondingly increases the basis of each share of its stock in FC by $100 ($80,000/800) from $50 to $150 pursuant to paragraphs (b)(1) and (c)(2) of this section.

Example 2. Sale of CFC stock. (i) *Facts.* Assume the same facts as in *Example 1*, except that in year 2, DP sells all of its stock in FC to DP2, a United States person that is DP's successor in interest (as defined in § 1.959–1(b)(5)), for $200 per share. At the time of sale, the exchange rate is 1u = $1 and DP has a basis of $150 per share in its FC stock and a previously taxed earnings and profits account with respect to its FC stock consisting of 80,000u of section 959(c)(2) earnings and profits with a dollar basis of $80,000. Also, at the time of sale, FC has 50,000u of non-previously taxed earnings and profits, attributable to taxable years of FC beginning on or after December 31, 1962 during which FC was a CFC and DP held its shares of stock in FC.

(ii) *Analysis.* Pursuant to section 1248(a), because FC has 40,000u of non-previously taxed earnings and profits attributable to DP's stock (50,000u × 800/1,000), the $40,000 of gain, equal to 40,000u, recognized by DP on the sale of it stock (($200 − $150) × 800) is included in DP's gross income as a dividend. Consequently, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to its stock in FC are increased from 80,000u to 120,000u pursuant to § 1.959–3(e)(2)(i). DP's basis in each share of its stock in FC is not adjusted, pursuant to paragraph (b)(3) of this section, because the adjustment to DP's previously taxed earnings and profits account results from a deemed section 951(a) inclusion pursuant to section 959(e). Upon the sale, DP2 acquires a previously taxed earnings and profits account with respect to the FC stock of 120,000u pursuant to § 1.959–1(d)(2)(i) and can utilize the account if it qualifies as a successor in interest under § 1.959–1(b)(5). DP2 takes a cost basis of $200 per share in the FC stock pursuant to section 1012.

Par. 7. Section 1.961–2 is revised to read as follows:

§ 1.961–2 Reduction in basis of stock in foreign corporations and of other property.

(a) *Reduction in basis*—(1) *In general.* Except as provided in paragraph (a)(2) of this section, the adjusted basis of a covered shareholder's stock in a foreign corporation or property (as defined in § 1.961–1(c)) by reason of the ownership of which such covered shareholder is considered under section 958(a) as owning stock in a foreign corporation shall be reduced under section 961(b) each time, and to the extent, that such covered shareholder's dollar basis in a previously taxed earnings and profits account with respect to the stock in such foreign corporation is decreased pursuant to the steps outlined in § 1.959–3(e)(2) and shall also be reduced by the dollar amount of any foreign income taxes allowed as a credit under section 960(a)(3) with respect to the earnings and profits accounted for by that decrease.

(2) *Limitation on amount of reduction in case of election under section 962.* [Reserved].

(b) *Rules of application*—(1) *Reduction with respect to each ownership unit.* Any reduction under paragraph (a) of this section in the adjusted basis of a covered shareholder's stock in a foreign corporation or property (as defined in paragraph (b)(1) of this section) by reason of the ownership of which it is considered under section 958(a) as owning stock in a foreign corporation shall be made on a pro rata basis with respect to each share of such stock or each ownership unit of such property.

(2) *Translation rules.* For purposes of determining a decrease in basis under this section, in cases in which the previously taxed earnings and profits account is maintained in a non-United States dollar functional currency, distributions of previously taxed earnings and profits shall be translated using the dollar basis of the earnings distributed. See § 1.959–3(b)(1) and (b)(3)(ii) for rules regarding the dollar basis of previously taxed earnings and profits. If the covered shareholder elects to maintain dollar basis accounts of previously taxed earnings and profits as described in § 1.959–3(b)(3)(ii), the dollar basis of the earnings distributed shall be determined according to the following formula: (functional currency distributed/total functional currency previously taxed earnings and profits) × total dollar basis of previously taxed earnings and profits. See section 989(b)(1) for the appropriate exchange rate applicable to distributions for purposes of section 986(c).

(c) *Amount in excess of basis.* To the extent that the amount of the reduction in the adjusted basis of property provided by paragraph (a) of this section exceeds such adjusted basis, the amount shall be treated as gain from the sale or exchange of property.

(d) *Examples.* The application of this section is illustrated by the following examples:

Example 1. Successor in interest. (i) *Facts.* DP, a United States shareholder, owns all of the 1,000 shares of the one class of stock in FC, which owns all of the 500 shares of the one class of stock in FS. Each share of DP's stock in FC has a basis of $200. DP, FC, and FS use the calendar year as a taxable year and FC and FS are CFCs throughout the period here involved. FC and FS both use the u as their functional currency. In year 1, FS has 100,000u of subpart F income after the payment of 50,000u of foreign income taxes. The average exchange rate for year 1 and year 2 is 1u = $1. For year 1, DP includes 100,000u in gross income under section 951(a) with respect to FS. In accordance with the provisions of § 1.961–1, DP increases the basis of each of its 1,000 shares of stock in FC to $300 ($200 + $100,000/1,000) as of December 31, of year 1. On July 31 of year 2, DP sells 250 of its shares of stock in FC to domestic corporation DT at a price of $350 per share. DT satisfies the requirements of paragraph (d) of § 1.959–1 so as to qualify as DP's successor in interest. On September 30 of year 2, the earnings and profits attributable to the 100,000u included in DP's gross income under section 951(a) for year 1 are distributed to FC which incurs a withholding tax of 10,000u on such distribution (10% of 100,000u) and an additional foreign income tax of 33⅓% or 30,000u by reason of the inclusion of the net distribution of 90,000u (100,000u − 10,000u) in its taxable income for year 2. On June 30 of year 3, FC distributes the remaining 60,000u of such earnings and profits to DP and DT: DP receives 45,000u (750/1,000 × 60,000u) and excludes such amount from gross income under section 959(a) and § 1.959–1(c); DT receives 15,000u (250/1,000 × 60,000u) and, as DP's successor in interest, excludes such amount from gross income under section 959(a) and § 1.959–1(c).

(ii) *Analysis.* As of June 30 of year 3, DP must reduce the adjusted basis of each of its 750 shares of stock in FC to $200 ($300 minus ($45,000/750 + $10,000/1,000 + $30,000/1,000)); and DT must reduce the basis of each of its 250 shares of stock in FC to $250 ($350 minus ($15,000/250 + $10,000/1,000 + $30,000/1,000)).

Example 2. Sale of lower-tier CFC. (i) *Facts.* Assume the same facts as in *Example 1*, except that in addition, on July 31 of year 2, FC sells its 500 shares of stock in FS to domestic corporation DT2 at a price of $600 per share. DT2 satisfies the requirements of

§ 1.959–1(b)(5) so as to qualify as DP's successor in interest. On September 30 of year 2, FS distributes 100,000u of earnings and profits to DT2, which earnings and profits are attributable to the 100,000u included in DP's gross income under section 951(a) for year 1. As DP's successor in interest, DT2 excludes the 100,000u it receives from gross income under section 959(a) and § 1.959–1(c).

(ii) *Analysis.* As of September 30 of year 2, DT2 must reduce the basis of each of its 500 shares of stock in FS to $400 ($600 minus ($100,000/500)).

Example 3. Section 956 amount. (i) *Facts.* DP, a United States shareholder, owns all of the 1,000 shares of the one class of stock in FC, which owns all of the 500 shares of the one class of stock in FS. Each share of DP's stock in FC has a basis of $200. DP, FC, and FS use the calendar year as a taxable year and FC and FS are CFCs throughout the period here involved. FC and FS both use the u as their functional currency. In year 1, FS has 100,000u of subpart F income after the payment of 50,000u of foreign income taxes. The average exchange rate for year 1 and year 2 is 1u = $1. For year 1, DP includes 100,000u in gross income under section 951(a) with respect to FS. In accordance with the provisions of § 1.959–3(e)(2)(i) and § 1.961–1, DP increases the section 959(c)(2) earnings and profits in its earnings and profits account with respect to its FC stock by 100,000u and correspondingly adjusts the basis of each of its 1,000 shares of stock in FC to $300 ($200+$100,000/1,000) as of December 31, of year 1. In year 2, DP has a section 956 amount with respect to its stock in FC of 100,000u.

(ii) *Analysis.* On December 31 of year 2, DP reclassifies 100,000u of section 959(c)(2) earnings and profits as section 959(c)(1) earnings and profits pursuant to § 1.959–3(e)(2)(iv). DP's basis in each of its 1,000 shares of stock in FC remains unchanged at $300 per share.

Par. 8. Section 1.961–3 is added to read as follows:

§ 1.961–3 Basis adjustments in stock held by foreign corporation.

(a) *Where the upper-tier entity is 100% owned by a single United States shareholder*—(1) *In general.* If a United States shareholder is treated under section 958(a) as owning stock in a CFC (lower-tier CFC) by reason of owning, either directly or pursuant to the application of section 958(a), stock in one or more other CFCs (each an ''upper-tier CFC''), any increase to such United States shareholder's basis in stock or other property under § 1.961–1 of this section resulting from an adjustment to such United States shareholder's previously taxed earnings and profits account with respect to its stock in the lower-tier CFC shall also be made to each upper-tier CFC's basis in either the stock in the lower-tier CFC or the property by reason of which it is considered to own stock in the lower-tier CFC under section 958(a), but only for purposes of determining the amount included under section 951 in the gross income of such United States shareholder or its successor in interest. In addition, any downward adjustment to such United States shareholder's (or its successor in interest's) previously taxed earnings and profits account with respect to its stock in a distributor under § 1.959–3(e)(3) shall result in a corresponding reduction of the basis of the distributee's stock in the distributor for purposes of determining the amount included in such United States shareholders gross income under section 951(a).

(2) *Examples.* The application of this paragraph (a) is illustrated by the following examples:

Example 1. Intercorporate dividend from lower-tier CFC to upper-tier CFC. (i) *Facts.* DP, a United States shareholder, owns all of the stock in FC, a CFC, and FC owns all of the stock in FS, a CFC. DP, FC and FS all use the calendar year as their taxable year and FC and FS both use the U.S. dollar as their functional currency. In year 1, FS has $100x of subpart F income that is included in DP's gross income under section 951(a)(1). In year 2, FS pays a dividend of $100x to FC.

(ii) *Analysis.* On December 31 of year 1, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to its stock in FS are increased by $100x pursuant to § 1.959–3(e)(2)(i) to reflect the inclusion of $100x in DP's gross income under section 951(a)(1)(A). DP's basis in its stock in FC is correspondingly increased by $100x pursuant to § 1.961–1(b). FC's basis in its stock in FS is also increased by $100x pursuant to paragraph (a) of this section, but only for purposes of determining the amount included in DP's gross income under section 951. At the end of year 2, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to its stock in FS are decreased by $100x and its previously taxed earnings and profits account with respect to its stock in FC are increased by $100x pursuant to § 1.959–3(e)(3) to reflect the transfer of the previously taxed earnings and profits from FS to FC. The $100x distribution is excluded from FC's income for purposes of determining the amount included in DP's gross income pursuant to § 1.959–2(a). FC's basis in its stock in FS, for purposes of determining the amount included in DP's gross income under section 951, is decreased by $100x pursuant to paragraph (a) of this section.

Example 2. Sale of upper-tier CFC stock. (i) *Facts.* DP, a United States shareholder, owns all of the stock in FC, a CFC. FC owns all of the stock in FS1, a CFC, and FS1 owns all of the stock in FS2, a CFC. DP, FC, FS1, and FS2 all use the calendar year as their taxable year and FC, FS1 and FS2 all use the U.S. dollar as their functional currency. In year 1, FS2 has $100x of subpart F income which is included in DP's gross income under section 951(a)(1)(A). In year 2, FC sells FS1 to FT, a nonresident alien, and recognizes $100x of gain on the sale.

(ii) *Analysis.* On December 31 of year 1, the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to its stock in FS2 are increased by $100x pursuant to § 1.959–3(e)(2)(i) to reflect the inclusion of $100x in DP's gross income under section 951(a)(1). DP's basis in its stock in FC is correspondingly increased by $100x under § 1.961–1(b). FC's basis in its stock in FS1 and FS1's basis in its stock in FS2 are also each increased by $100x under paragraph (a) of this section, but only for purposes of determining the amount included in the gross income of DP under section 951. In year 2, the $100x of gain on FC's sale of FS1 stock would be subpart F income that would be includible in DP gross income under section 951(a)(1)(A). However, since FC has an additional $100x of basis in its stock in FS1 for purposes of determining the amount included in DP's gross income under section 951, the sale of FS1 by FC does not generate any subpart F income to DP.

(b) *Exception where the upper-tier entity is less than 100 percent owned by a single United States shareholder*—(1) *In general.* If United States shareholders are treated, under section 958(a), as owning stock in a CFC (lower-tier CFC) by reason of owning, either directly or pursuant to the application of section 958(a), stock in one or more other CFCs (each an ''upper-tier CFC''), and if, in the aggregate, the lower-tier CFC is less than wholly owned by a single United States shareholder, any increase to any United States shareholder's basis in stock or other property under § 1.961–1(b) of this section resulting from an increase to such United States shareholder's previously taxed earnings and profits account with respect to its stock in such lower-tier CFC shall result in an increase to each upper-tier CFC's basis in either the stock in the lower-tier CFC or the property by reason of which such upper-tier CFC is considered to own stock in the lower-tier CFC under section 958(a), but only for purposes of determining the amount included under section 951 in the gross income of such United States shareholder or its successor in interest. The amount of the increase to each upper-tier CFC's basis in either the stock in the lower-tier CFC or the property by reason of which such upper-tier CFC is considered to own stock in the lower-tier CFC under section 958(a) shall be equal to the amount that would be excluded from the gross income of such upper-tier CFC pursuant to section 959(b) and § 1.959–2(a) if the amount that gave rise to the adjustment to the United States shareholder's previously taxed earnings and profits account with respect to its stock in the lower-tier CFC were actually distributed through a chain of ownership to such upper-tier CFC. In

addition, any decrease to such United States shareholder's (or successor in interest's) previously taxed earnings and profits account with respect to its stock in a distributor under § 1.959–3(e)(3) shall result in a corresponding reduction of the basis of the distributee's stock in the distributor. The reduction of the basis of the distributee's stock in the distributor shall be equal to the amount that would be excluded from the gross income of the distributee pursuant to section 959(b) and § 1.959–2(a).

(2) *Example.* The application of this paragraph (b) is illustrated by the following example:

Example. Less than wholly owned CFC. (i) *Facts.* DP, a United States shareholder, owns 70%, and FP, a nonresident alien, owns 30% of the stock in FC, a CFC. FC in turn owns 100% of the stock in FS, a CFC. Each of DP, FC, FN and FS use the calendar year as their taxable year and both FC and FS use the U.S. dollar as their functional currency. Entering year 1, DP has a basis of $50x in FC and FC has a basis of $50x in FS. In year 1, FS earns $100x of subpart F income. In year 2, FC sells FS for $150x.

(ii) *Analysis.* On December 31 of year 1, DP includes $70x of the $100x of subpart F income earned by FS in gross income under section 951(a)(1)(A). DP increases its section 959(c)(2) earnings and profits in its earnings and profits account with respect to its stock in FS by $70x pursuant to § 1.959–3(e)(2)(i). DP increases its basis in FC from $50x to $120x pursuant to § 1.961–1(b). FC increases its basis in FS from $50× to $150× pursuant to paragraph (b)(1) of this section (but only for purposes of determining FC's subpart F income with respect to DP) because if the $100x amount of subpart F income of FS that caused the $70x increase to DP's previously taxed earnings and profits account with respect to its stock in FS had been distributed to FC, the entire $100x would be excluded from FC's gross income pursuant to section 959(b) and § 1.959–2(a) for purposes of determining DP's inclusion under section 951(a)(1)(A). In year 2, when FC sells FS, for purposes of determining DP's subpart F inclusion, FC is treated as recognizing $0 on the sale ($150x sale proceeds − $150x basis). Therefore, DP includes $0 in income under section 951(a)(1)(A) as a result of the sale. Although the sale does not generate gain for purposes of determining DP's subpart F inclusion, it does cause FC's non-previously taxed earnings and profits to be increased by $100x ($150x sale proceeds − $50x basis).

(c) *Translation rules.* Rules similar to those provided in § 1.961–1(c)(3) and § 1.961–2(b)(3) shall apply for purposes of determining the exchange rates used to reflect any change to the basis of stock or other property under this section.

Par. 9. Section 1.961–4 is added to read as follows:

§ 1.961–4 Section 304 transactions.

(a) *Deemed redemption treated as a distribution*—(1) *In general.* In the case of a stock acquisition described in section 304(a)(1) that is treated as a distribution of earnings and profits of a foreign acquiring corporation or a foreign issuing corporation or both, basis adjustments shall be made in accordance with the rules of §§ 1.961–1, 1.961–2, and 1.961–3.

(2) *Examples.* The application of this section is illustrated by the following examples:

Example 1. Cross-chain acquisition of first-tier CFC. (i) *Facts.* DP, a domestic corporation, owns all of the stock in DS, a domestic corporation, and F1, a CFC. DS owns all of the stock in F2, a CFC. DP, DS, F1 and F2 all use the calendar year as their taxable year and F1 and F2 use the U.S. dollar as their functional currency. During year 1, F1 purchases all of the stock in F2 from DS for $80x in a transaction described in section 304(a)(1). At the end of year 1, before taking into account the purchase of F2's stock, DP has a previously taxed earnings and profits account consisting of $20x of section 959(c)(2) earnings and profits with respect to its stock in F1, and F1 has section 959(c)(2) earnings and profits of $20x and non-previously taxed earnings and profits of $10x. At the end of year 1, before taking into account the purchase of F2's stock, DS has a previously taxed earnings and profits account consisting of $50x of section 959(c)(2) earnings and profits with respect to its stock in F2 and F2 has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $0. Before taking into account the purchase of F2's stock, DP's basis in F1's stock is $30x and DS's basis in F2's stock is $60x.

(ii) *Analysis.* Under section 304(a)(1), DS is deemed to have transferred the F2 stock to F1 in exchange for F1 stock in a transaction to which section 351(a) applies, and F1 is treated as having redeemed, for $80x, the F1 stock hypothetically issued to DS. The payment of $80x is treated as a distribution to which section 301 applies. Under section 304(b)(2), the determination of the amount which is a dividend is made as if the distribution were made, first, by F1 to the extent of its earnings and profits ($30x), and then by F2 to the extent of its earnings and profits ($50x). Before taking into account the deemed distributions, DS had a previously taxed earnings and profits account of $50x with respect to its stock in F2, and DP had a previously taxed earnings and profits account of $20x with respect to its stock in F1. Under § 1.959–3(h)(4)(i), DS is deemed to have a previously taxed earnings and profits account with respect to stock in F1. Under § 1.959–3(g)(1), the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account with respect to F1 stock are reduced from $20x to $0. As a result, DP's basis in F1's stock is reduced from $30x to $10x under § 1.961–2(a). The deemed distribution of earnings and profits by F2 causes the section 959(c)(2) earnings and profits in DS's previously taxed earnings and profits account with respect to F2 stock to be reduced from $50x to $0. Under § 1.961–2(a) and § 1.961–3(a), F1's basis in its newly acquired F2's stock is reduced from $60x to $10x. F1 has a transferred basis of $10x in F2's stock.

Example 2. Cross-chain acquisition of lower-tier CFC. (i) *Facts.* DP, a domestic corporation, owns all of the stock in two CFCs, FX and FY. FX owns all of the stock in FZ, a CFC. FX, FY and FZ use the U.S. dollar as their functional currency. During year 1, FY purchases all of the stock in FZ from FX for $80x in a transaction described in section 304(a)(1). On December 31 of year 1, before taking into account the purchase of FZ's stock, FY has section 959(c)(2) earnings and profits of $20x and non-previously taxed earnings and profits of $10x, and FZ has section 959(c)(2) earnings and profits of $50x and non-previously taxed earnings and profits of $0. Before taking into account FX's purchase of FZ's stock, DP's basis in FX's stock is $60×; DP's basis in FY's stock is $30x; and FX's basis in FZ's stock, for purposes of determining the amount includible in DP's gross income under section 951(a), is $60x.

(ii) *Analysis.* Under section 304(a)(1), FX is deemed to have transferred the FZ stock to FY in exchange for FY stock in a transaction to which section 351(a) applies, and FY is treated as having redeemed, for $80x, the FY stock hypothetically issued to FX. The payment of $80x is treated as a distribution of property to which section 301 applies. Under section 304(b)(2), the determination of the amount which is a dividend is made as if the distribution were made, first, by FY to the extent of its earnings and profits, $30x, and then by FX to the extent of its earnings and profits, $50x. Under § 1.959–2(b), FX is deemed to receive the distributions from FY and FZ through a chain of ownership described in section 958(a), and $70x is excluded from FX's gross income under section 959(b) and § 1.959–2(a). Under § 1.959–3(e)(3), the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account for the stock in FY are reduced from $20x to $0; the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account for the stock in FZ are reduced from $50x to $0; and the section 959(c)(2) earnings and profits in DP's previously taxed earnings and profits account for the stock in FX are increased from $0 to $70x (and such account is further increased to $80x due to the inclusion of $10x of subpart F income in DP's gross income under section 951(a)). Under § 1.961–2(a), DP's basis in the stock in FY is reduced from $30x to $10x. DP's basis in the stock in FX is first reduced by $50x under § 1.961–2(a), and then increased by $80x under § 1.961–1(b), for a net increase of $30x, to $90x. Under § 1.961–3(a), FY's basis in the stock in FZ, for purposes of determining the amount includible in DP's gross income under section 951(a), is reduced by $50× to $10x.

Par. 10. Section 1.1502–12 as amended by adding paragraph (s) to read as follows:

§ 1.1502–12 Separate taxable income.

* * * * *

(s) The exclusion from gross income of previously taxed earnings and profits shall be determined by the rules of § 1.959–3(g).

Par. 11. In § 1.1502–32, add a sentence after the second sentence in paragraph (b)(3)(ii)(D), add a sentence after the fourth sentence in paragraph (b)(3)(iii)(B), and add *Example 11* in paragraph (b)(5)(ii) to read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(D) * * * Further, an increase to a member's previously taxed earnings and profits account under § 1.959–3(g)(1)(i)(B) that pursuant to section 961(a) and § 1.961–1(b) results in an increase to a member's basis in the stock in a CFC shall be treated as the receipt of tax exempt income. * * *

(iii) * * *

(B) * * * Also included as a noncapital, nondeductible expense is a decrease to a member's previously taxed earnings and profits account under § 1.959–3(g)(1)(i)(A) that results in a decrease to a member's basis in the stock in a CFC pursuant to section 961(b) and § 1.961–2(a). * * *

* * * * *

(5) * * *

(ii) * * *

Example 11. (a) *Facts.* P owns all of the stock of S and S1. S, a United States shareholder, owns 50 percent of the stock in FC, a CFC that uses the U.S. dollar as its functional currency. S1, a United States shareholder owns the remaining 50 percent of the stock in FC. Entering year 1, S has a previously taxed earnings and profits account with respect to its stock in FC consisting of $50x of section 959(c)(2) earnings and profits and S1 has a previously taxed earnings and profits account with respect to its stock in FC consisting of $200x of section 959(c)(2) earnings and profits. Entering year 1, FC has section 959(c)(2) earnings and profits of $250x and non-previously taxed earnings and profits of $100x. In year 1, FC generates no earnings and profits and makes a $100x distribution of earnings and profits on FC stock held by S and a $100x distribution of earnings and profits on the FC stock held by S1.

(b) *Analysis.* First, pursuant to § 1.959–3(e)(2)(ii), the section 959(c)(2) earnings and profits in S's previously taxed earnings and profits account with respect to its FC stock are decreased from $50x to $0 and the section 959(c)(2) earnings and profits in S1's previously taxed earnings and profits account with respect to its FC stock are decreased from $200x to $100x. Then, pursuant to § 1.959–2(e)(2)(v) and (g)(1)(i)(A), the section 959(c)(2) earnings and profits in S1's previously taxed earnings and profits account with respect to its FC stock are decreased from $100x to $50x and, pursuant to § 1.959–3(e)(2)(ii)(B) and (g)(1)(i)(B), the section 959(c)(2) earnings and profits in S's previously taxed earnings and profits account with respect to its FC stock are increased from $0 to $50x and then decreased from $50x to $0. Pursuant to § 1.959–1(c) of this section, the entire $100x distribution to S and $100x distribution to S1 are excluded from S's and S1's gross incomes. Pursuant to paragraph (b)(3)(ii)(D) of this section, the $50x increase to the section 959(c)(2) earnings and profits in S's previously taxed earnings and profits account with respect to its FC stock pursuant to § 1.959–3(g)(1)(i)(B) is treated as the receipt of $50x of tax-exempt income by S. Pursuant to paragraph (b)(2)(ii) of this section, P's basis in S's stock is increased by $50x. Pursuant to paragraph (b)(3)(iii)(B) of this section, the $50x decrease to the section 959(c)(2) earnings and profits in S1's previously taxed earnings and profits account with respect to its FC stock pursuant to § 1.959–3(g)(1)(i)(A) is treated as a noncapital nondeductible expense to S1. Pursuant to paragraph (b)(2)(iii) of this section, P's basis in S1's stock is decreased by $50x.

* * * * *

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 06–7195 Filed 8–28–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–145154–05]

RIN 1545–BF68

User Fees Relating to Enrollment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed amendments to the regulations relating to user fees for the special enrollment examination to become an enrolled agent, the application for enrollment of enrolled agents, and the renewal of this enrollment. The charging of user fees is authorized by the Independent Offices Appropriations Act (IOAA) of 1952. This document also contains a notice of public hearing on these proposed regulations.

DATES: Written or electronically-generated comments must be received by September 28, 2006. Outlines of topics to be discussed at the public hearing scheduled for September 29, 2006, must be received by September 28, 2006.

ADDRESSES: Comments are encouraged to be submitted to: CC:PA:LPD:PR (REG–145154–05), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be sent electronically via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–145154–05).

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments and/or to be placed on the building access list to attend the hearing, Richard Hurst at *Richard.A.Hurst@irscounsel.treas.gov* or at (202) 622–7180; concerning cost methodology, Eva Williams at (202) 622–6400; concerning the proposed regulations, Matthew Cooper at (202) 622–4940 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 330 of Title 31 of the United States Code authorizes the Secretary of the Treasury to regulate practice before the Treasury Department. Pursuant to section 330 of Title 31, the Secretary has published regulations governing practice before the IRS in 31 CFR part 10 and reprinted them as Treasury Department Circular No. 230 (Circular 230). These regulations are administered by the IRS Office of Professional Responsibility (OPR).

Section 10.3 of Circular 230 generally authorizes attorneys, certified public accountants, enrolled agents and enrolled actuaries to practice before the IRS. An enrolled agent is defined as an individual enrolled as an agent pursuant to the provisions of Circular 230. The provisions of Circular 230 provide that an individual desiring to become an enrolled agent is eligible for enrollment through either the successful passing of a written examination or through demonstration of sufficient expertise in tax administration based on former employment with the IRS. Specifically, section 10.4(a) authorizes the Director of OPR to grant enrollment to an applicant who demonstrates special competence in tax matters by passing a written examination administered by, or administered under the oversight of, the Director of OPR and who has not engaged in any conduct that would justify the censure, suspension, or disbarment of any practitioner under the provisions of Circular 230. Accordingly, every year OPR develops and administers a Special Enrollment

Examination (SEE) that is given to all applicants desiring to become enrolled agents so that they can practice before the IRS. The IRS charged applicants a user fee of $55 ($45 if taking the examination in part) in order to take the 2005 SEE.

Section 10.4(b) authorizes the Director of OPR to grant enrollment for former IRS employees if the former employee meets certain requirements, including length of employment with the IRS and substantive tax expertise. Application for enrollment based on former employment with the IRS must be made within three years from the date of separation from such employment.

Once eligible for enrollment, by either passing the examination or because of former employment with the IRS, an applicant must file an application for enrollment on Form 23, ''Application for Enrollment to Practice before the Internal Revenue Service,'' with the Director of OPR. As part of the application for enrollment process, the applicant must enclose a check or money order payable to the IRS in the amount set forth on Form 23, which constitutes a fee charged to each applicant for enrollment. The fee is nonrefundable regardless of whether the applicant is granted enrollment. The current user fee for enrollment on the Form 23 (Rev. February 2005) is $80. The Director of OPR will act upon an application for enrollment and issue an enrollment card to each individual whose application for enrollment to practice before the IRS is approved.

Pursuant to section 10.6(d), each individual, once enrolled, is required to renew the enrollment every three years to maintain an active enrollment to practice before the IRS. In order to qualify for renewal, an applicant must certify the completion of the continuing professional education requirements set forth in section 10.6(e) of Circular 230. A nonrefundable user fee of $80 is currently charged for each application for renewal of enrollment filed with the Director of OPR on Form 8554, ''Application for Renewal of Enrollment to Practice Before the Internal Revenue Service.''

Contracting Out of Special Enrollment Examination

OPR has recently contracted out certain functions pertaining to the SEE to a private contractor. The contractor will furnish the resources, facilities, and services necessary to administer the entire SEE program, which includes examination development, administration of SEE, notification to IRS of candidates who took the examination, and the results of the examination. The contractor will receive payment for its services by charging a fee to exam applicants. OPR will, nonetheless, still maintain an oversight role with respect to the SEE. The contractor will collect a user fee on behalf of the IRS based on the full costs incurred by the IRS. These proposed regulations only establish a user fee with respect to the government costs for overseeing the SEE and do not include any fee that the contractor may charge for its services. Accordingly, while the user fee imposed pursuant to these regulations is less than the user fee that applicants were charged in 2005, the total fee that applicants will be charged is greater. The IRS estimates that by using a contractor, however, the total fees incurred will be less than the total fees that would otherwise be charged by the IRS in order to recover the full cost of the IRS administering all aspects of the SEE.

User Fees for Special Enrollment Examination, Enrollment, and Renewal of Enrollment

The user fee that the IRS currently charges applicants in order to take the SEE is being modified to reflect the change in IRS costs of administering the exam program as a result of the contracting out of the exam. The user fees that the IRS currently charge applicants for the enrollment and renewal of enrollment process are less than the actual cost of overseeing the enrollment process. The IRS is proposing new user fees to take the SEE to become an enrolled agent, the application for enrollment and the renewal of such enrollment.

Proposed section 300.4 establishes an $11 per part user fee for the SEE. Proposed sections 300.5 and 300.6 establish separate $125 user fees for the enrollment and renewal of enrollment process.

Authority

The IOAA of 1952 (31 U.S.C. 9701) authorizes agencies to prescribe regulations that establish charges for services provided by the agency. The charges must be fair and be based on the costs to the Government, the value of the service to the recipient, the public policy or interest served, and other relevant facts. The IOAA of 1952 provides that regulations implementing user fees are subject to policies prescribed by the President, which are currently set forth in OMB Circular A–25, 58 FR 38142 (July 15, 1993) (the OMB Circular).

The OMB Circular encourages user fees for Government-provided services that confer benefits on identifiable recipients over and above those benefits received by the general public. Under the OMB Circular, an agency that seeks to impose a user fee for Government-provided services must calculate its full cost of providing those services. In general, a user fee should be set at an amount in order for the agency to recover the cost of providing the special service, unless the Office of Management and Budget grants an exception. Pursuant to the guidelines in the OMB Circular, the IRS has calculated its cost of providing services under the enrolled agents program. The IRS has determined that the full cost to the IRS of overseeing the SEE is $11 per part per applicant. The IRS has determined that the full cost of administering the enrollment and renenrollment process is $125 per enrolled agent.

The proposed user fees will be implemented under the authority of the IOAA of 1952 and the OMB Circular.

Proposed Effective Date

These regulations are proposed to apply thirty days after the date of publication in the **Federal Register** of the final regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the information that follows. The economic impact of these regulations on any small entity would result from a small entity, including a sole proprietor, being required to pay a fee prescribed by these regulations in order to obtain a particular service. The dollar amount of the fee is not, however, substantial enough to have a significant economic impact on any entity subject to the fee. Moreover, payment of the fee is voluntary. The only persons subject to the fee are those who elect to take the special enrollment exam. Persons who elect to take the exam will have determined that it is in their economic interest to do so. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the substance of the proposed regulations, as well as on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for September 29, 2006, at 10 a.m. in the 11th floor conference room at 1901 S. Bell Street, Crystal City, VA. Due to building security procedures, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments and an outline of the comments to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by September 28, 2006. A period of ten (10) minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Matthew S. Cooper of the Office of the Associate Chief Counsel (Procedure & Administration), Administrative Provisions & Judicial Practice Division.

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 300 is proposed to be amended as follows:

PART 300—USER FEES

Paragraph 1. The authority citation for part 300 continues to read as follows:

Authority: 31 U.S.C. 9701.

Par. 2. Section 300.0 is amended as follows:

1. Paragraphs (b)(4), (5), and (6) are added.

2. Paragraph (c) is revised.

The additions and revision read as follows:

§ 300.0 User fees, in general.

* * * * *

(b) * * *

(4) Taking the special enrollment examination to become an enrolled agent.

(5) Enrolling an enrolled agent.

(6) Renewing the enrollment of an enrolled agent.

(c) *Effective Date.* This part 300 is applicable March 16, 1995, except that the user fee for processing offers in compromise is applicable November 1, 2003, and the user fee for the special enrollment examination, enrollment, and renewal of enrollment for enrolled agents is applicable thirty days after the date of publication in the **Federal Register** of the final regulations.

Par. 3. Section 300.4 is added to read as follows:

§ 300.4 Special enrollment examination fee.

(a) *Applicability.* This section applies to the special enrollment examination to become an enrolled agent pursuant to 31 CFR 10.4(a).

(b) *Fee.* The fee for taking the special enrollment examination is $11.00 per part.

(c) *Person liable for the fee.* The person liable for the special enrollment examination fee is the applicant taking the examination.

Par. 4. Section 300.5 is added to read as follows:

§ 300.5 Enrollment of enrolled agent fee.

(a) *Applicability.* This section applies to the initial enrollment of enrolled agents with the IRS Office of Professional Responsibility pursuant to 31 CFR 10.5(b).

(b) *Fee.* The fee for initially enrolling as an enrolled agent with the IRS Office of Professional Responsibility is $125.00.

(c) *Person liable for the fee.* The person liable for the enrollment fee is the applicant filing for enrollment as an enrolled agent with the IRS Office of Professional Responsibility.

Par. 5. Section 300.6 is added to read as follows:

§ 300.5 Renewal of enrollment of enrolled agent fee.

(a) *Applicability.* This section applies to the renewal of enrollment of enrolled agents with the IRS Office of Professional Responsibility pursuant to 31 CFR 10.6(d)(6).

(b) *Fee.* The fee for renewal of enrollment as an enrolled agent with the IRS Office of Professional Responsibility is $125.00.

(c) *Person liable for the fee.* The person liable for the renewal of enrollment fee is the person renewing their enrollment as an enrolled agent with the IRS Office of Professional Responsibility.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 06–7246 Filed 8–25–06; 12:09 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2006–0484; FRL–8213–8]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the state of Iowa for the purpose of establishing exemptions for indoor sources of air pollution that are not directly vented to the outside but have emissions that leave the building through doors, vents or other means. This revision also clarifies that the permitting exemptions do not relieve the owner or operator of any source from any obligation to comply with any other applicable requirements. The state has demonstrated that air pollution emissions from this equipment are negligible and these exemptions are likely to result in no significant impact on human health or the environment. We have reviewed the state's justification for the revisions and agree with its conclusions.

DATES: Comments on this proposed action must be received in writing by September 28, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2006–0484 by one of the following methods:

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

2. *E-mail: Hamilton.heather@epa.gov.*

3. *Mail:* Heather Hamilton, Environmental Protection Agency, Air

Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. *Hand Delivery or Courier.* Deliver your comments to: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. 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 to 4:30, excluding legal holidays.

Please see the direct final rule that is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Heather Hamilton at (913) 551–7039, or by e-mail at *Hamilton.heather@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule that is located in the rules section of this **Federal Register**.

Dated: August 15, 2006.

William Rice,

Acting Regional Administrator, Region 7.

[FR Doc. E6–14312 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 71, No. 167
Tuesday, August 29, 2006

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

Forest Service

Tehama County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Tehama County Resource Advisory Committee (RAC) will meet in Red Bluff, California. Agenda items to be covered include: (1) Introductions, (2) Approval of Minutes, (3) Public Comment, (4) Revising a Meeting Schedule, (5) Status of the Final Expenditures, (6) Chairman's Perspective, (7) General Discussion, (8) Next Agenda.

DATES: The meeting will be held on September 14, 2006 from 9 a.m. and end at approximately 12 p.m.

ADDRESSES: The meeting will be held at the Lincoln Street School, Conference Room A, 1135 Lincoln Street, Red Bluff, CA. Individuals wishing to speak or propose agenda items must send their names and proposals to Tricia Christofferson, Acting 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) 968–5329; 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 12, 2006 will have the opportunity to address the committee at those sessions.

Dated: August 23, 2006.

Tricia Christofferson,

Acting Designated Federal Official.

[FR Doc. 06–7212 Filed 8–28–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 37–2006]

Foreign–Trade Zone 98 Birmingham, Alabama, Application for Subzone Status, NACCO Materials Handling Group, Inc., Plant (Forklift Truck Components), Sulligent, Alabama

An application has been submitted to the Foreign–Trade Zones Board (the Board) by the City of Birmingham, grantee of FTZ 98, requesting special–purpose subzone status for the forklift truck components manufacturing facility of NACCO Materials Handling Group, Inc. (NMHG), located in Sulligent, Alabama. The application was submitted pursuant to the provisions of the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on August 22, 2006.

The NMHG plant (68 acres/301,000 sq.ft.) is located in Lamar County on U.S. Highway 278 East, in Sulligent, Alabama, about 100 miles west of Birmingham. The facility (550 employees) is used to produce component parts, transmissions and drive axles for forklift trucks (Class I through Class V) powered by gasoline, propane, or electric motors. The manufacturing process at the facility involves machining, cutting, sawing, shearing, milling, welding, bending, and assembly with a total annual production value of approximately $150 million at full capacity. Components purchased from abroad (up to 20% of finished forklift truck value) used in manufacturing include: parts of forklift trucks, engines, parts of engines, control panels, control centers, switchgear assemblies, distribution boards, printed circuits, torque converters, parts of transmissions, gears, bearing housings, electric motors, hydraulic pumps, crankshafts, camshafts, transmission shafts, relays, flywheels, pulleys, tubes/pipes, ignition parts, harnesses, catalytic converters, filters, heat exchangers, hydraulic cylinders and related fluid power components, parts of valves and check appliances, fuel injection pumps, electromagnetic couplings/clutches/brakes, wire, electric conductors/converters, steering components, caps/lids, parts of pumps/compressors, starters, bearings, floor coverings, electrical connectors and related assemblies, wiring harnesses, fasteners, couplings/u–joints, chains, gaskets, generators, carbon brushes, transformers, rotors, stators, power supplies, converters, spark plugs, ignition coils and distributors, starter motors, relays, switches, horns, capacitors, resistors, fuses, controllers, circuit breakers and protectors, conductors, lamps/lighting equipment, wheel hubs, and parts of seats (duty rate range: free - 9.0%).

FTZ procedures would exempt NMHG from Customs duty payments on the foreign components used in export production. On its domestic sales and exports to NAFTA markets, the company would be able to choose the duty rate that applies to forklift truck components (duty free) for the foreign–sourced inputs noted above. The forklift truck duty rate (free) would apply if the finished components are shipped via zone–to-zone transfer to U.S. forklift truck assembly plants with subzone status. Duties would be deferred or reduced on foreign production equipment admitted to the proposed subzone until such time as it becomes operational. The application indicates that subzone status would help improve the facility's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is October 30, 2006. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to November 13, 2006.

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations: U.S. Department of

Commerce Export Assistance Center, Suite 707, 950 22nd Street North, Birmingham, Alabama 35203–5309; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 1115, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, District of Columbia 20230–0002; Tel: (202) 482–2862.

Dated: August 22, 2006.

Andrew McGilvray,

Acting Executive Secretary.

[FR Doc. E6–14338 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1475]

Grant of Authority for Subzone Status, Nissan Forklift Corporation North America (Forklift Trucks), Marengo, Illinois

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, an application from the Greater Rockford Airport Authority, grantee of Foreign–Trade Zone 176 (Rockford, Illinois), for authority to establish special–purpose subzone status for the forklift truck manufacturing facilities of Nissan Forklift Corporation North America, in Marengo, Illinois, was filed by the Board on June 8, 2005, and notice inviting public comment was given in the **Federal Register** (FTZ Docket 28–2005, 70 FR 34742, 6–15–2005); 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 would be satisfied, and that approval of the application would be in the public interest if approval were subject to restriction;

Now, therefore, the Board hereby grants authority for subzone status for activity related to industrial forklift trucks at the manufacturing and warehousing facilities of Nissan Forklift Corporation North America located in Marengo, Illinois (Subzone 176E), as described in the application and **Federal Register** notice, and subject to the FTZ Act and the Board's regulations, including Section 400.28, and further subject to a restriction requiring that all articles of textile materials classified under HTSUSι 6307.90.3010, 6307.90.3020, 6307.90.8940, 6307.90.8995, 6307.90.9882, and 6307.90.9884 must be admitted under privileged foreign status (19 CFR 146.41).

Signed at Washington, DC, this 21st day of August 2006.

David M. Spooner,

Assistant Secretary of Commercefor Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Andrew McGilvray,

Acting Executive Secretary.

[FR Doc. E6–14336 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1474]

Expansion of Foreign–Trade Zone 22, Chicago, Illinois, Area

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 Illinois International Port District, grantee of Foreign–Trade Zone 22, submitted an application to the Board for authority to expand FTZ 22 to: include a site (142 acres) at the ProLogis Park 80 (Site 8) in Morris, a site (12 acres) at the Eagle Global Logisitcs facility (Site 9) in Elk Grove Village, a site (43 acres) at the Bolingbrook Distribution Center (Site 10) in Bolingbrook, and a site (157 acres) at the Heartland Corporate Center (Site 11) in Shorewood; restore zone status to 41 acres removed from Site 5 (CenterPoint Intermodal Center); and, grant zone status to Temporary Site 7 (O'Hare Express North Business Park) on a permanent basis in the Chicago, Illinois, area, within the Chicago Customs port of entry (FTZ Docket 49–2005; filed 10/14/05);

Whereas, notice inviting public comment was given in the **Federal Register** (70 FR 61429, 10/24/05), 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 22 is approved, subject to the FTZ Act and the Board's regulations, including Section 400.28, and further subject to the Board's standard 2,000–acre activation limit for the overall zone project and a sunset provision for Sites 8 through 11 that would terminate authority for the sites on September 30, 2011, for any of the sites that have not been activated under FTZ procedures prior to that date.

Signed at Washington, DC, this 21st day of August 2006.

David M. Spooner,

Assistant Secretary of Commerce,for Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Andrew McGilvray,

Acting Executive Secretary.

[FR Doc. E6–14337 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1476]

Approval of Requests for Manufacturing Authority, Within Four FTZ Distribution Facilities - Michelin North America, Inc., (Wheel Assemblies)

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, applications to the Board were submitted by four grantees (FTZ Docket 53–2005; filed 10/20/2005) requesting FTZ manufacturing authority on behalf of Michelin North America, Inc., to conduct wheel assembly at its FTZ tire–distribution facilities listed below:

Grantee: FTZ 84, Port of Houston Authority

Site: SZ 84R, Houston, Texas

Grantee: FTZ 38, South Carolina State Ports Authority

Site: FTZ 38 - Site 5, Laurens, South Carolina
Grantee: FTZ 126, Economic Development Authority of Western Nevada
Site: FTZ 126 - Site 7, Reno, Nevada
Grantee: FTZ 70, Greater Detroit Foreign Trade Zone, Inc.
Site: FTZ 70 - Site 18, Temperance, Michigan

Whereas, notice inviting public comment has been given in the **Federal Register** (70 FR 62295, 10/31/2005) and the applications have 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 the Board's regulations are satisfied, and that the proposals are in the public interest;

Now, therefore, the Board hereby orders:

The applications for manufacturing authority for wheel assemblies on behalf of Michelin North America, Inc., at the FTZ facilities listed above, and as described in the applications and in the **Federal Register** notice, are approved, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 21st day of August 2006.

David M. Spooner,

Assistant Secretary of Commercefor Import Administration, Alternate Chairman, Foreign–Trade Zones Board.

Attest:

Andrew McGilvray,

Acting Executive Secretary.

[FR Doc. E6–14334 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–838]

Notice of Final Results of Antidumping Duty Changed Circumstances Review: Certain Softwood Lumber Products from Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) has determined, pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), that Ivis Partners Ltd. (IVIS) is the successor–in-interest to Ivis Wood Products Ltd. (Ivis Wood) and, as a result, should be accorded the same treatment previously accorded to Ivis Wood in regard to the antidumping order on certain softwood lumber products from Canada as of the date of publication of this notice in the **Federal Register**.

EFFECTIVE DATE: August 29, 2006.

FOR FURTHER INFORMATION CONTACT: Constance Handley or David Layton, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0631 or (202) 482–0371, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 16, 2006, in accordance with section 751(b)(1) of the Act and 19 CFR 351.216(b) (2004), IVIS, a Canadian producer of softwood lumber products and interested party in this proceeding, filed a request for a changed circumstances review. In response to this request, the Department initiated a changed circumstances review of the antidumping duty order on certain softwood lumber from Canada. *See Initiation of Antidumping Duty Changed Circumstances Review: Certain Softwood Products from Canada*, 71 FR 18072 (April 10, 2006) (*Initiation Notice*). On April 4, 2006, the Department issued a questionnaire to IVIS requesting further details on its purchase of Ivis Woods. IVIS' response was received by the Department on April 13, 2006. On May 10, 2006, the Department issued an additional supplemental questionnaire to IVIS. IVIS' response was received on May 17, 2006. On June 22, 2006, the Department preliminarily determined that IVIS was the successor–in-interest to Ivis Wood. *See Notice of Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Softwood Lumber Products from Canada*, 71 FR 35867 (June 22, 2006) (*Preliminary Results*). We invited parties to comment on the *Preliminary Results*. We received no comments.

Scope of the Order

The products covered by this order are softwood lumber, flooring and siding (softwood lumber products). Softwood lumber products include all products classified under subheadings 4407.1000, 4409.1010, 4409.1090, and 4409.1020, respectively, of the Harmonized Tariff Schedule of the United States (HTSUS), and any softwood lumber, flooring and siding described below. These softwood lumber products include:

(1) Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or finger–jointed, of a thickness exceeding six millimeters;
(2) Coniferous wood siding (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v–jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded or finger–jointed;
(3) Other coniferous wood (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v–jointed, beaded, molded, rounded or the like) along any of its edges or faces (other than wood mouldings and wood dowel rods) whether or not planed, sanded or finger–jointed; and
(4) Coniferous wood flooring (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbeted, chamfered, v–jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded or finger–jointed.

Although the HTSUS subheadings are provided for convenience and U.S. Customs purposes, the written description of the merchandise subject to this order is dispositive.

As specifically stated in the Issues and Decision Memorandum accompanying the *Notice of Final Determination of Sales at Less Than Fair Value: Certain Softwood Lumber Products from Canada*, 67 FR 15539 (April 2, 2002) (*see* comment 53, item D, page 116, and comment 57, item B–7, page 126), available at www.ia.ita.doc.gov/frn, drilled and notched lumber and angle cut lumber are covered by the scope of this order.

The following softwood lumber products are excluded from the scope of this order provided they meet the specified requirements detailed below:

(1) *Stringers* (pallet components used for runners): if they have at least two notches on the side, positioned at equal distance from the center, to properly accommodate forklift blades, properly classified under HTSUS 4421.90.97.40.
(2) *Box–spring frame kits*: if they contain the following wooden pieces - two side rails, two end (or top) rails and varying numbers of slats. The side rails and the end rails should be radius–cut at both ends. The kits should be individually packaged, they should

contain the exact number of wooden components needed to make a particular box spring frame, with no further processing required. None of the components exceeds 1'' in actual thickness or 83'' in length.

(3) *Radius–cut box–spring-frame components*, not exceeding 1'' in actual thickness or 83'' in length, ready for assembly without further processing. The radius cuts must be present on both ends of the boards and must be substantial cuts so as to completely round one corner.

(4) *Fence pickets* requiring no further processing and properly classified under HTSUS 4421.90.70, 1'' or less in actual thickness, up to 8'' wide, 6' or less in length, and have finials or decorative cuttings that clearly identify them as fence pickets. In the case of dog–eared fence pickets, the corners of the boards should be cut off so as to remove pieces of wood in the shape of isosceles right angle triangles with sides measuring 3/4 inch or more.

(5) *U.S. origin lumber* shipped to Canada for minor processing and imported into the United States, is excluded from the scope of this order if the following conditions are met: 1) the processing occurring in Canada is limited to kiln–drying, planing to create smooth–to-size board, and sanding, and 2) if the importer establishes to the satisfaction of CBP that the lumber is of U.S. origin.

(6) *Softwood lumber products contained in single family home packages or kits*,[1] regardless of tariff classification, are excluded from the scope of this order if the importer certifies to items 6 A, B, C, D, and requirement 6 E is met:

A. The imported home package or kit constitutes a full package of the number of wooden pieces specified in the plan, design or blueprint necessary to produce a home of at least 700 square feet produced to a specified plan, design or blueprint;

B. The package or kit must contain all necessary internal and external doors and windows, nails, screws, glue, sub floor, sheathing, beams, posts, connectors, and if included in the purchase contract, decking, trim, drywall and roof shingles specified in the plan, design or blueprint;

C. Prior to importation, the package or kit must be sold to a retailer of complete home packages or kits pursuant to a valid purchase contract referencing the particular home design plan or blueprint, and signed by a customer not affiliated with the importer;

D. Softwood lumber products entered as part of a single family home package or kit, whether in a single entry or multiple entries on multiple days, will be used solely for the construction of the single family home specified by the home design matching the entry.

E. For each entry, the following documentation must be retained by the importer and made available to CBP upon request:

i. A copy of the appropriate home design, plan, or blueprint matching the entry;

ii. A purchase contract from a retailer of home kits or packages signed by a customer not affiliated with the importer;

iii. A listing of inventory of all parts of the package or kit being entered that conforms to the home design package being entered;

iv. In the case of multiple shipments on the same contract, all items listed in E(iii) which are included in the present shipment shall be identified as well.

Lumber products that CBP may classify as stringers, radius cut box–spring-frame components, and fence pickets, not conforming to the above requirements, as well as truss components, pallet components, and door and window frame parts, are covered under the scope of this order and may be classified under HTSUS subheadings 4418.90.45.90, 4421.90.70.40, and 4421.90.97.40.

Finally, as clarified throughout the course of the investigation, the following products, previously identified as Group A, remain outside the scope of this order. They are:

1. Trusses and truss kits, properly classified under HTSUS 4418.90;
2. I–joist beams;
3. Assembled box spring frames;
4. Pallets and pallet kits, properly classified under HTSUS 4415.20;
5. Garage doors;
6. Edge–glued wood, properly classified under HTSUS 4421.90.97.40;
7. Properly classified complete door frames;
8. Properly classified complete window frames; and
9. Properly classified furniture.

In addition, this scope language was further clarified to specify that all softwood lumber products entered from Canada claiming non–subject status based on U.S. country of origin will be treated as non–subject U.S.-origin merchandise under the countervailing duty order, provided that these softwood lumber products meet the following condition: upon entry, the importer, exporter, Canadian processor and/or original U.S. producer establish to CBP's satisfaction that the softwood lumber entered and documented as U.S.-origin softwood lumber was first produced in the United States as a lumber product satisfying the physical parameters of the softwood lumber scope.[2] The presumption of non–subject status can, however, be rebutted by evidence demonstrating that the merchandise was substantially transformed in Canada.

On March 3, 2006, the Department issued a scope ruling that any product entering under HTSUS 4409.10.05 which is continually shaped along its end and/or side edges which otherwise conforms to the written definition of the scope is within the scope of the order.[3]

Final Results of Changed Circumstances Review

Based on the information provided by IVIS, and the fact that the Department did not receive any comments during the comment period following the preliminary results of this review, the Department hereby determines that IVIS is the successor–in-interest to Ivis Wood for antidumping duty cash deposit purposes.

Instructions to U.S. Customs and Border Protection

The Department will instruct CBP to suspend liquidation of all shipments of the subject merchandise produced and exported by IVIS entered, or withdrawn from warehouse, for consumption, on or after the publication date of this notice at 3.78 percent (*i.e.*, Ivis Wood's cash deposit rate). This deposit rate shall remain in effect until publication of the final results of the next administrative review in which Ivis Wood participates.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance

[1] To ensure administrability, we clarified the language of exclusion number 6 to require an importer certification and to permit single or multiple entries on multiple days as well as instructing importers to retain and make available for inspection specific documentation in support of each entry.

[2] *See* the scope clarification message (ι 3034202), dated February 3, 2003, to CBP, regarding treatment of U.S. origin lumber on file in Room B-099 of the Central Records Unit (CRU) of the Main Commerce Building.

[3] *See* Memorandum from Constance Handley, Program Manager, to Stephen J. Claeys, Deputy Assistant Secretary regarding Scope Request by the Petitioner Regarding Entries Made Under HTSUS 4409.10.05, dated March 3, 2006.

with 19 CFR 351.306. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is in accordance with sections 751(b) and 777(i)(1) of the Act, and section 351.216(e) of the Department's regulations.

Dated: August 23, 2006.

David M. Spooner,

Assistant Secretaryfor Import Administration.

[FR Doc. E6–14339 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Solicitation of Applications for Allocation of Tariff Rate Quotas on the Import of Certain Worsted Wool Fabrics to Persons Who Cut and Sew Men's and Boys Worsted Wool Suits, Suit-Type Jackets and Trousers in the United States

AGENCY: Department of Commerce, International Trade Administration.

ACTION: The Department of Commerce (Department) is soliciting applications for an allocation of the 2007 tariff rate quotas on certain worsted wool fabric to persons who cut and sew men's and boys worsted wool suits, suit-type jackets and trousers in the United States.

SUMMARY: The Department hereby solicits applications from persons (including firms, corporations, or other legal entities) who cut and sew men's and boys' worsted wool suits and suit-like jackets and trousers in the United States for an allocation of the 2007 tariff rate quotas on certain worsted wool fabric. Interested persons must submit an application on the form provided to the address listed below by September 28, 2006. The Department will cause to be published in the **Federal Register** its determination to allocate the 2007 tariff rate quotas and will notify applicants of their respective allocation as soon as possible after that date. Promptly thereafter, the Department will issue licenses to eligible applicants.

DATES: To be considered, applications must be received or postmarked by 5 p.m. on September 28, 2006.

ADDRESSES: Applications must be submitted to the Industry Assessment Division, Office of Textiles and Apparel, Room 3001, United States Department of Commerce, Washington, D.C. 20230 (telephone: (202) 482-4058). Application forms may be obtained from that office (via facsimile or mail) or from the following Internet address: *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp*.

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4058.

SUPPLEMENTARY INFORMATION:

Background

Title V of the Trade and Development Act of 2000 (the Act) created two tariff rate quotas (TRQs), providing for temporary reductions in the import duties on limited quantities of two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers: (1) for worsted wool fabric with average fiber diameters greater than 18.5 microns (Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11); and (2) for worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS heading 9902.51.12). On August 6, 2002, President Bush signed into law the Trade Act of 2002, which includes several amendments to Title V of the Act. On December 3, 2004, the Act was further amended pursuant to the Miscellaneous Trade Act of 2004, Public Law 108-429, by increasing the TRQ for worsted wool fabric with average fiber diameters greater than 18.5 microns, HTS 9902.51.11, to an annual total level of 5.5 million square meters, and extending it through 2007, and increasing the TRQ for average fiber diameters of 18.5 microns or less, HTS 9902.51.15 (previously 9902.51.12), to an annual total level of 5 million square meters and extending it through 2006. On August 17, 2006 the Act was further amended pursuant to the Pension Protection Act of 2006, Public Law 109-280, which extended both TRQs, 9902.51.11 and 9902.51.15, through 2009.

The Act requires that the TRQs be allocated to persons who cut and sew men's and boys' worsted wool suits, suit-type jackets and trousers in the United States. On May 16, 2005, the Department published regulations establishing procedures for allocating the TRQ. 70 FR 25774, 15 CFR 335. In order to be eligible for an allocation, an applicant must submit an application on the form provided at *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp* to the address listed above by 5 p.m. on September 28, 2006 in compliance with the requirements of 15 CFR 335. Any business confidential information that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law.

Dated: August 23, 2006.

Philip J. Martello,

Acting Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. E6–14332 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Solicitation of Applications for Allocation of Tariff Rate Quotas on the Import of Certain Worsted Wool Fabrics to Persons Who Weave Such Fabrics in the United States

AGENCY: Department of Commerce, International Trade Administration.

ACTION: The Department of Commerce (Department) is soliciting applications for an allocation of the 2007 tariff rate quotas on certain worsted wool fabric to persons who weave such fabrics in the United States.

SUMMARY: The Department hereby solicits applications from persons (including firms, corporations, or other legal entities) who weave worsted wool fabrics in the United States for an allocation of the 2007 tariff rate quotas on certain worsted wool fabric. Interested persons must submit an application on the form provided to the address listed below by September 28, 2006. The Department will cause to be published in the **Federal Register** its determination to allocate the 2007 tariff rate quotas and will notify applicants of their respective allocation as soon as possible after that date. Promptly thereafter, the Department will issue licenses to eligible applicants.

DATES: To be considered, applications must be received or postmarked by 5 p.m. on September 28, 2006.

ADDRESSES: Applications must be submitted to the Industry Assessment Division, Office of Textiles and Apparel, Room 3001, United States Department of Commerce, Washington, DC 20230 (telephone: (202) 482-4058). Application forms may be obtained from that office (via facsimile or mail) or from the following Internet address: *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp/fabric.*

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4058.

SUPPLEMENTARY INFORMATION:

Background

Title V of the Trade and Development Act of 2000 (the Act) created two tariff rate quotas (TRQs), providing for temporary reductions in the import duties on limited quantities of two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers: (1) for worsted wool fabric with average fiber diameters greater than 18.5 microns (Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11); and (2) for worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS heading 9902.51.12). On August 6, 2002, President Bush signed into law the Trade Act of 2002, which includes several amendments to Title V of the Act. On December 3, 2004, the Act was further amended pursuant to the Miscellaneous Trade Act of 2004, Public Law 108-429. The 2004 amendment included authority for the Department to allocate a TRQ for new HTS category, HTS 9902.51.16. This HTS category refers to worsted wool fabric with average fiber diameter of 18.5 microns or less. The amendment provided that HTS 9902.51.16 is for the benefit of persons (including firms, corporations, or other legal entities) who weave such worsted wool fabric in the United States that is suitable for making men's and boys' suits. The TRQ for HTS 9902.51.16 provided for temporary reductions in the import duties on 2,000,000 square meters annually for 2005 and 2006. The amendment requires that the TRQ be allocated to persons who weave worsted wool fabric with average fiber diameter of 18.5 microns or less, which is suitable for use in making men's and boys' suits, in the United States. On August 17, 2006, the Act was further amended pursuant to the Pension Protection Act of 2006, Public Law 109-280, which extended the TRQ for HTS 9902.51.16 through 2009.

On May 16, 2005, the Department published regulations establishing procedures for allocating the TRQ. 70 FR 25774, 15 CFR 335. In order to be eligible for an allocation, an applicant must submit an application on the form provided at *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp/fabric* to the address listed above by 5 p.m. on September 28, 2006 in compliance with the requirements of 15 CFR 335. Any business confidential information that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law.

Dated: August 23, 2006.

Philip J. Martello,

Acting Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. E6–14333 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 082306E]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public committee meeting.

SUMMARY: The North Pacific Fishery Management Council's (Council) Steller Sea Lion Mitigation Committee (SSLMC) will meet in Seattle, WA.

DATES: The meeting will be held on September 12–14, 2006, from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center, 7600 Sand Point Way NE, Building 4, Seattle, WA.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Bill Wilson, North Pacific Fishery Management Council; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The main issues to be discussed by the SSLMC are the proposal ranking tool and the first chapters of the draft Biological Opinion. The Committee will complete work on development of the ranking tool and prepare a report for the Scientific and Statistical Committee (SSC).

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

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: August 24, 2006.

James P. Burgess,

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

[FR Doc. E6–14311 Filed 8–28–06; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare an Environmental Impact Statement (EIS)/Overseas Environmental Impact Statement (OEIS) for a Proposal To Enhance Training, Testing, and Operational Capability Within the Hawaii Range Complex and To Announce Public Scoping Meetings

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality regulations (40 CFR parts 1500–1508), and Executive Order 12114 (Environmental Effects Abroad of Major Federal Actions), the Department of the Navy (DoN) announces its intent to prepare an EIS/OEIS. This EIS/OEIS will evaluate the potential environmental effects of increasing usage and enhancing the capability of the Hawaii Range Complex to achieve and maintain Fleet readiness and to conduct current, emerging, and future training and research, development, test, and evaluation (RDT&E) operations. The EIS/OEIS will consider two action Alternatives to accomplish these objectives, in addition to the No Action Alternative.

The following will be invited to be cooperating agencies: Department of Energy, Missile Defense Agency, U.S. Army, U.S. Fish and Wildlife Service, and National Marine Fisheries Service.

DATES: Public scoping meetings will be held in Hawaii to receive oral and/or written comments on environmental concerns that should be addressed in the EIS/OEIS. The public scoping meetings will be held on:

1. Wednesday, September 13, 2006, 4 p.m.–8 p.m., Maui Arts and Cultural Center, One Cameron Way, Kahului, Maui, Hawaii.

2. Thursday, September 14, 2006, 4 p.m.–8 p.m., Disabled American

Veterans Hall, 2685 North Nimitz Highway, Honolulu, Oahu, Hawaii.

3. Saturday, September 16, 2006, 4 p.m.–8 p.m., Hilo Hawaiian Hotel, 71 Banyan Drive, Hilo, Hawaii, Hawaii.

4. Monday, September 18, 2006, 4 p.m.–8 p.m., Kauai Civil Defense Agency, Suite 100, 3990 Kaana Street, Kauai, Lihue, Hawaii.

Each of the four scoping meetings will consist of an informal, open house session with information stations staffed by DoN representatives. Additional information concerning the meetings will be available on the EIS/OEIS Web page located at: *http://www.govsupport.us/navynepahawaii*.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Clements, Pacific Missile Range Facility, P.O. Box 128, Kekaha, Kauai, Hawaii 96752–0128, telephone 1–866–767–3347.

SUPPLEMENTARY INFORMATION: The Hawaii Range Complex geographically encompasses offshore, nearshore, and onshore areas located on or around the major islands of the Hawaiian Island chain. The geographic scope of this EIS/OEIS (Study Area) includes the Hawaii Offshore Operation Areas, consisting of 170,000 square nautical miles of ocean, generally from 17 to 26 degrees north latitude and from 154 to 162 degrees west longitude, land areas used by the DoN within these Operation Areas, and the Pacific Missile Range Facility (PMRF) Temporary Operating Area, consisting of 2.1 million square nautical miles to the north and west of Kauai. These ranges and Operation Areas are used to conduct operations and training involving military hardware, personnel, tactics, munitions, explosives, and electronic combat systems. Several of the areas are also used for RDT&E, including missile defense testing.

The purpose of the Proposed Action is to: (1) Provide the Hawaii Range Complex with sufficient capabilities to support Fleet and DoD training, major exercises based on training requirements identified to support the U.S. Unified Commanders, and the development, testing, and evaluation of existing, upgraded, and newly developed DoD and other federal agency systems; (2) provide additional range capabilities and support facilities at the Hawaii Range Complex, to include the PMRF, to fully integrate range services in a modern, multi-threat, multi-dimensional environment, ensuring safe conduct and evaluation of training and RDT&E missions; and (3) fulfill DoN commitment to update analyses on marine mammal exposures to noise in the water.

The need for the Proposed Action is to: (1) Ensure a robust training, testing, and operational capability within the Hawaii Range Complex operating areas and to take advantage of Hawaii's location to not only provide training for local assets, but also provide capability for short notice and surge deployments from the West Coast; (2) support the acquisition and integration into the Fleet of advanced military technology and accommodate future increases in operational training tempo; and (3) maintain the long-term viability of the range complex while protecting human health and the environment.

The No Action Alternative is the continuation of training operations, RDT&E activities, ongoing base operations, and maintenance of the technical and logistical facilities that support these operations and activities, and the monitoring of marine mammals. The No Action Alternative includes the current level of training and test activities, including the biennial Rim of the Pacific exercises. Alternative 1 includes the activities described in the No Action Alternative with the addition of increased training necessary to support the Fleet Response Training Plan, Hawaii Range Complex improvements and modernizations, planned RDT&E activities, and necessary force structure changes. Alternative 2 would include all of the activities described in Alternative 1 with the addition of major events, such as supporting three carrier strike groups training at the same time, increasing the tempo of training exercises, and additional RDT&E programs at PMRF. Future RDT&E programs proposed as part of Alternative 2 would include directed energy programs involving lasers.

Key environmental issues that will be addressed in the EIS/OEIS, as applicable, include: biological resources (marine mammals and threatened and endangered species), cultural resources, environmental justice, health and safety, and noise. The DoN has been involved in long-term research plans studying the quantification of exposure of marine mammal species to acoustic emissions with differing experimental approaches and detailed observations of effects. Now that initial findings are available, this EIS/OEIS will include acoustic exposure modeling and effects-analysis for marine mammals within the defined study area.

The DoN is initiating the scoping process to identify community concerns and local issues that will be addressed in the EIS/OEIS. Federal, state, and local agencies, the public, and interested persons are encouraged to provide oral and/or written comments to the DoN to identify specific environmental issues or topics of environmental concern that the commenter believes the DoN should consider. All comments, written or provided orally at the scoping meetings, will receive the same consideration during EIS/OEIS preparation.

Written comments on the scope of the EIS/OEIS should be postmarked no later than October 13, 2006. Comments may be mailed to Mr. Tom Clements, Pacific Missile Range Facility, P.O. Box 128, Kekaha, Kauai, Hawaii 96752–0128.

Dated: August 24, 2006.

Saundra K. Melancon,

Paralegal Specialist, Alternate Federal Register Liaison Officer.

[FR Doc. E6–14324 Filed 8–28–06; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, 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 October 30, 2006.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6)

Reporting and/or Recordkeeping burden. OMB invites public comment.

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: August 23, 2006.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Revision.

Title: Annual State Application Under Part C of the IDEA as Amended in 2004.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 56.

Burden Hours: 560.

Abstract: The Individuals with Disabilities Education Improvement Act of 2004, signed on December 3, 2004, became PL 108–446. In order to be eligible for a grant under 20 U.S.C. 1433, a State shall provide assurance to the Secretary that the State has adopted a policy that appropriate early intervention services are available to all infants and toddlers with disabilities in the State and their families, including Indian infants and toddlers with disabilities and their families residing on a reservation geographically located in the State, infants and toddlers with disabilities who are homeless children and their families, and has in effect a statewide system that meets the requirements of 20 U.S.C. 1435. Information Collection 1820–0550 is being revised so that a State can provide assurances that it either has or does not have in effect policies, procedures, methods, descriptions, and assurances that meet the application requirements of part C of the Act as found in Pub. L. 108–446.

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 3172. 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 *ICDocketMgr@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 electronically mailed to *ICDocketMgr@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. E6–14303 Filed 8–28–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 28, 2006.

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 IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: August 23, 2006.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Postsecondary Education

Type of Review: New.

Title: Annual Performance Report for the Student Support Services Program.

Frequency: Annually.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 960.

Burden Hours: 5,760.

Abstract: Student Support Services Program grantees must submit the report annually. The reports are used to evaluate grantees' performance, and to award prior experience points at the end of each project (budget) period. The Department also aggregates the data to provide descriptive information on the projects and to analyze the impact of the Student Support Services Program on the academic progress of participating students.

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 3001. 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 *ICDocketMgr@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 electronically mailed to *ICDocketMgr@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. E6–14305 Filed 8–28–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.938H]

Correction; Notice Announcing Availability of Funds and Application Deadline for Hurricane Education Recovery Awards; Correction

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUPPLEMENTARY INFORMATION: On August 18, 2006, we published a notice in the **Federal Register** (71 FR 47785) announcing the availability of funds and application deadline for Hurricane Education Recovery Awards under Title II of the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror and Hurricane Recovery, 2006 (Pub. L. 109–234). On page 47786 of that notice, under the *Pre-Application Requirements* section, the last sentence of that section indicates that after submission of the pre-application, ''Institutions will then have until September 12, 2006 to submit their application and budget through the e-Application system.'' This date is corrected to read ''September 19, 2006''.

FOR FURTHER INFORMATION CONTACT: David Johnson, Hurricane Education Recovery Awards, U.S. Department of Education, 1990 K Street, NW., room 6155, Washington, DC 20006–8544. Telephone: (202) 502–7516.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: You may view this document, as well as other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Program Authority: Division B, Title IV of Public Law 109–148; Title II of Public Law 109–234.

Dated: August 23, 2006.

James F. Manning,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. E6–14340 Filed 8–28–06; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8213–7]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree, to address a lawsuit filed by Kentuckians for the Commonwealth, Friends of the Chattahoochee and Sierra Club (collectively, ''plaintiffs''): *Kentuckians for the Commonwealth, et al.* v. *Johnson,* No. 06CV00184 (RMU) (D. D.C.). Plaintiffs filed a complaint on February 2, 2006 and their First Amended Complaint on April 14, 2006, claiming that EPA had failed to perform non-discretionary duties under CAA section 111(b)(1)(B) to review and, if appropriate, revise the new source performance standards (''NSPS'') for nonmetallic mineral processing plants (Subpart OOO) and for coal preparation plants (Subpart Y). Under the proposed consent decree, within18 months from when the Court enters the consent decree, EPA would be required to sign, and promptly forward to the Office of Federal Register, one or a combination of the following for each NSPS: (a) A proposed or final determination that review of the NSPS is not appropriate in light of readily available information on the efficacy of such standard; (b) a proposed determination that based on a complete review of the NSPS, revision is not appropriate; or (c) a proposed rule containing revisions to the NSPS. Within 30 months from when the Court enters the consent decree, EPA would be required to sign and promptly forward to the Office of Federal Register one or a combination of the following for each NSPS: (a) A final determination that review of the NSPS is not appropriate in light of readily available information on the efficacy of such standard; (b) a final determination that based on a complete review of the NSPS, revision is not appropriate; or (c) a final rule containing revisions to the NSPS.

DATES: Written comments on the proposed consent decree must be received by September 28, 2006.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2006–0727, online at *http://www.regulations.gov* (EPA's preferred method); by e-mail to *oei.docket@epa.gov*; mailed to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Wordperfect or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Susan Stahle, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: (202) 564–1272; fax number (202) 564–5603; e-mail address: *stahle.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

Under the terms of the proposed consent decree, once the Court enters the decree EPA will begin its efforts involving NSPS Subparts OOO and Y to determine what is needed for each NSPS. Within eighteen (18) months of entry of the consent decree, the appropriate EPA official will sign and promptly forward to the Office of Federal Register one or a combination of the following for each NSPS: (a) A proposed or final determination that review of the NSPS is not appropriate in light of readily available information on the efficacy of such standard; (b) a proposed determination that based on a complete review of the NSPS, revision is not appropriate; or (c) a proposed rule containing revisions to the NSPS.

Within thirty (30) months of entry of the consent decree, the appropriate EPA official will sign and promptly forward to the Office of Federal Register one or a combination of the following for each NSPS: (a) A final determination that review of the NSPS is not appropriate in light of readily available information on the efficacy of such standard; (b) a final determination that based on a complete review of the NSPS, revision is not appropriate; or (c) a final rule containing revisions to the NSPS.

For a period of thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the proposed consent decree from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines, based on any comments which may be submitted, that consent to the consent decree should be withdrawn, the terms of the decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How Can I Get A Copy of the Consent Decree?

Direct your comments to the official public docket for this action under Docket ID No. EPA–HQ–OGC–2006–0727 which contains a copy of the consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, 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 Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *http://www.regulations.gov.* You may use the *http://www.regulations.gov* 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 in the system, select ''search,'' then key in the appropriate docket identification number.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *http://www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to Whom Do I Submit Comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (e-mail) system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through *http://www.regulations.gov,* your e-mail address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: August 21, 2006.

Richard B. Ossias,

Associate General Counsel.

[FR Doc. E6–14316 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8213–5]

FY 2006 and 2007 Targeted Watersheds Grant Program: Availability of Funds and Request for Proposals for Implementation Projects (CFDA 66.439—Funding Opportunity Number EPA–OW–OWOW–06–3)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice, extension of the submission date for proposals for watershed projects.

SUMMARY: On August 15, 2006, EPA published a notice announcing the availability of funds for grants and cooperative agreements under EPA's Targeted Watersheds Grant Program. The announcement solicits proposals for watershed restoration and/or protection projects throughout the country. This notice is to extend the submission date for proposals to November 15, 2006. EPA is extending the submission date for proposals to be consistent with Agency communications.

DATES: Proposals are now due by November 15, 2006.

ADDRESSES: Erin Collard; USEPA; Office of Wetlands, Oceans, and Watersheds; Room 7136G; Mail Code 4501T; 1301 Constitution Avenue, NW.; Washington, DC 20004; telephone: 202–566–2655.

FOR FURTHER INFORMATION CONTACT: For questions regarding this extension, please contact Carol Peterson at 202–566–1304 or by e-mail at *peterson.carol@epa.gov.* A copy of the Targeted Watersheds Grant Program Request for Proposals, this notice extending the date for submitting proposals, and additional information on the program can be found on the

Targeted Watersheds Grant Web site at *http://www.epa.gov/twg.*

Dated: August 22, 2006.

Bonnie Thie,

Acting Director, Office of Wetlands, Oceans and Watersheds.

[FR Doc. 06–7216 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2006–0748; FRL–8213–1]

Notice of Intent To Provide Internet Publication of Proposed Penalties under the Clean Water Act and Safe Drinking Water Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) intends to issue notices of proposed penalty orders issued under the Clean Water Act and the Safe Drinking Water Act via the Internet. EPA is encouraging the Regions to use the Internet as a more effective and efficient means to provide such notice.

FOR FURTHER INFORMATION CONTACT: Kelly Kaczka Brantner, Office of Enforcement and Compliance Assurance, Office of Civil Enforcement, Water Enforcement Division, Mail Code 2243A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 202–564–9933; fax number: 202–564–0018; e-mail address: *Brantner.Kelly@epa.gov*.

SUPPLEMENTARY INFORMATION: Both the Clean Water Act and the Safe Drinking Water Act authorize the U.S. Environmental Protection Agency (EPA) to assess administrative penalties for specified violations of the Act. See sections 309(g) and 311(b)(6) of the Clean Water Act (CWA), 33 U.S.C. 1319(g) and 33 U.S.C. 1321(b)(6) and section 1423(c) of the Safe Drinking Water Act (SDWA), 42 U.S.C. 300h–2(c). These provisions require EPA to provide public notice of any civil penalty order before issuing any such order.

For such administrative actions, EPA's *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties*, 40 CFR Part 22, require notice to the public ''by a method reasonably calculated to provide notice.'' 40 CFR 22.45(b)(2). Typically, notice is provided through publication in newspapers of general circulation.

The Part 22 rules and the Clean Water Act do not define what methods of notice are reasonable. Courts have recognized that the Internet may be one method reasonably calculated to provide public notice. Thus, for example in discussing service of process by e-mail, the United States Court of Appeals for the Ninth Circuit has recently described in broad language a court's authority to adapt its procedures to meet technological advances as follows:

> ''In proper circumstances, this broad constitutional principle [*i.e.*, that the selected method of service must be reasonably calculated to provide notice and an opportunity to respond] unshackles the federal courts from anachronistic methods of service and permits them entry into the technological renaissance.'' *Rio Properties, Inc.* v. *Rio International Interlink*. 284 F.3d 1007, 1017 (9th Cir. 2002)

Given the wide accessibility of the Internet among the population, the Office of Enforcement and Compliance Assurance has concluded, in consultation with the Office of General Counsel, that publication through such means is reasonably calculated to apprise the public of such proposed orders. Thus, Internet notice would meet the requirements of the CWA, SDWA, and EPA regulations.

Using the Agency's Internet site to provide notice of proposed actions makes the notice available to the public during the entirety of the comment period rather than on the one day that the notice is published in the local newspaper. The Internet provides a cost effective means of providing access to a larger number of notices, in one place, for a longer period of time.

Additionally, while the Agency tries to provide notice to those most likely to be affected by an action by publishing notice in local newspapers, in using the Internet, the Agency can reach a broader audience. This will enable those interested persons beyond the finite distribution areas of local newspapers to be made aware of pending agency actions.

EPA Headquarters is encouraging the Regions to use the Agency's Internet site to provide notice of proposed CWA and SDWA actions. To ensure wide public acceptance of public notice provided through the Internet, the Office of Enforcement and Compliance Assurance is recommending procedures designed with two objectives in mind: Making the public aware that notices will be available on the website for the Region issuing the order, and providing easy access to the notices. We suggest consideration of the following practices for Web based notices:

—The Region's homepage should include a link entitled ''Public Notices Under Sections 309(g)and 311(b)(6) of the Clean Water Act and Section 1423(c) of the Safe Drinking Water Act.'' (Public Notice).

—The Public Notice Web page should provide a link to the actual notices as well as the docket number, the date the notice is posted, the Respondent's name, the state where they are located, and the proposed penalty.

—The notice should be accessible from the Public Notice Web page in html format or as a PDF file which includes all the information required under 40 CFR 22.45(b)(2).

—The Public Notice Web page should list the actions that are being noticed in chronological order.

—The Public Notice Web page may list notices for which the agency is currently accepting comment more prominently than those which have expired. However, public notices should remain on the Web site for a reasonable time once the comment period has expired.

—The Web page should also include a link to download Adobe Acrobat with easily understood instructions for doing so.

We recognize that not all members of the public may have ready access to the Internet, however due to the general availability of the Internet through schools, offices and libraries, we believe that Internet notice will likely reach a larger audience than has the past practice of publishing a notice in a newspaper provided that the above practices are followed. Because there may be circumstances in which the lack of access to computers in low-income communities may raise environmental justice issues, Regions may consider providing supplemental notice.

In particular instances where the Regions find that additional notice may be helpful, newspaper notice, press release or other forms of communication may supplement the Internet notice.

Mark Pollins,

Director, Water Enforcement Division, Office of Civil Enforcement, Office of Enforcement & Compliance Assurance.

[FR Doc. E6–14315 Filed 8–28–06; 8:45 am]

BILLING CODE 6560–50–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Meeting of the President's Council of Advisors on Science and Technology

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (FACA).

Dates and Place: September 12, 2006, Washington, DC. The meeting will be held in the Continental Ballroom of the George Washington University Marvin Center Building, 800 21st St. NW., Washington DC 20052.

Type of Meeting: Open. Further details on the meeting agenda will be posted on the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.*

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology is scheduled to meet in open session on Tuesday September 12, 2006, at approximately 9 a.m. The PCAST is tentatively scheduled to discuss its report and recommendations related to energy technology. The co-chairs of the PCAST subcommittee on networking and information technology are tentatively scheduled to provide an update on subcommittee activities and lead a discussion on the PCAST review of the Federal Networking and Information Technology Research and Development (NITRD) Program. A presentation on ethical and societal issues related to emerging technology capabilities is also tentatively scheduled to occur. This session will end at approximately 5 p.m. Additional information and the final agenda will be posted at the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.*

Public Comments: There will be time allocated for the public to speak on the above agenda items. This public comment time is designed for substantive commentary on PCAST's work topics, not for business marketing purposes. Please submit a request for the opportunity to make a public comment five (5) days in advance of the meeting. The time for public comments will be limited to no more than 5 minutes per person. Written comments are also welcome at any time following the meeting. Please notify Celia Merzbacher, PCAST Executive Director, at (202) 456–7116, or fax your request/comments to (202) 456–6021.

FOR FURTHER INFORMATION CONTACT: For information regarding time, place and agenda, please call Celia Merzbacher at (202) 456–7116, prior to 3 p.m. on Friday, September 8, 2006. Information will also be available at the PCAST Web site at: *http://www.ostp.gov/PCAST/pcast.html.* Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology was established by Executive Order 13226, on September 30, 2001. The purpose of PCAST is to advise the President on matters of science and technology policy, and to assist the President's National Science and Technology Council in securing private sector participation in its activities. The Council members are distinguished individuals appointed by the President from non-Federal sectors. The PCAST is co-chaired by Dr. John H. Marburger, III, the Director of the Office of Science and Technology Policy, and by E. Floyd Kvamme, a Partner at Kleiner Perkins Caufield & Byers.

Celia Merzbacher,

PCAST Executive Director, Office of Science and Technology Policy.

[FR Doc. E6–14451 Filed 8–28–06; 8:45 am]

BILLING CODE 3170–W4–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://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 September 25, 2006.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Southcrest Financial Group, Inc., Fayetteville, Georgia; to merge with Maplesville Bancorp, and thereby indirectly acquire Peachtree Bank, both of Maplesville, Alabama.

B. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

2. Baldwin Bancshares, Inc., Baldwin, Wisconsin; to acquire 100 percent of the voting shares of Gavic Services, Inc., Spring Valley, Wisconsin, and thereby indirectly acquire voting shares of The Bank of Spring Valley, Spring Valley, Wisconsin.

Board of Governors of the Federal Reserve System, August 24, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–14310 Filed 8–28–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:30 a.m., Tuesday, September 5, 2006.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications

scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, August 25, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 06–7253 Filed 8–25–06; 1:17 pm]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0203]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 28, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to FDA for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2005, there are an estimated 243 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions, and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2005. CDER estimates 3,085 annual responses that include the following submissions: 101 new drug applications; 3 biologics license applications; 1,915 manufacturing supplements; 921 labeling supplements; and 145 efficacy supplements. CBER estimates 676 annual responses that include the following submissions: 6 biologics license applications, 614 manufacturing supplements, 46 labeling supplements, and 10 efficacy supplements. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of May 25, 2006 (71 FR 30144), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
FDA 3397	243	15.48	3,761	0.30	1,128

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

Dated: August 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14266 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0327]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information that will permit an applicant to certify that it qualifies as a ''small business'' within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA).

DATES: Submit written or electronic comments on the collection of information by October 30, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MDUFMA Small Business Qualification Certification (Form FDA 3602)—(OMB Control Number 0910–0508)—Extension

MDUFMA amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 2, 2006 (71 FR 43784), announcing fees for fiscal year (FY) 2007. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

For FY 2006, you can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million (including all of your affiliates, partners, and parent firms), you will also qualify for a waiver of the fee for your first (ever) premarket application (PMA, product development protocol (PDP), biologics licensing application (BLA), or Premarket Report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

Form FDA 3602 is available in guidance document, ''Guidance for Industry and FDA: FY 2006 MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2006 and subsequent fiscal years.

Description of Respondents: Respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	2,000	1	2,000	1	2,000
Total Hours					2,000

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

The burden is based on the number of applications received in the last 3 years.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14267 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 13, 2006 from 12 noon to approximately 3:45 p.m.

Location: National Institutes of Health, Bldg. 29B, Conference Rooms A and B, Bethesda, MD.

Contact Person: Gail Dapolito or Jane Brown, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 13, 2006, the committee will discuss a proposed strategy for the reclassification of Category IIIA allergenic products. The committee will also receive an update of the research program of the Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic and Allergenic Products, Center for Biologics Evaluation and Research.

Procedure: On September 13, 2006, from 12 noon to approximately 3:15 pm, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 6, 2006. Oral presentations from the public will be scheduled between approximately 1:45 pm and 2:45 pm. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 6, 2006.

Closed Committee Deliberations: On September 13, 2006 from approximately 3:15 pm to 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss individual research programs in the Office of Vaccines Research and Review.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14295 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was originally announced in the **Federal Register** of August 1, 2006 (71 FR 43487). The amendment is being made to reflect changes in the *Agenda* portion of the document. The word ''TRASYOL'' should read ''TRASYLOL''. In the same paragraph, the word ''apportioning'' should read ''aprotinin''. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cathy Groupe, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6778, e-mail: *Cathy.Groupe@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the information line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 2006, FDA announced that the Cardiovascular and Renal Drugs Advisory Committee would meet on September 21, 2006, from 8 a.m. to 5 p.m., and the committee would discuss clinical data for aprotinin injection (trade name, TRASYLOL), an approved product, new drug application (NDA) 020–304, Bayer Pharmaceuticals). On page 43487, in the third column, the *Agenda* portion of the document is amended to read as follows:

Agenda: The committee will discuss clinical data for aprotinin injection (trade name, TRASYLOL), an approved product, new drug application (NDA) 020–304, Bayer Pharmaceuticals) with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. This discussion follows a February 8, 2006, FDA Public Health Advisory for the use of aprotinin injection (*www.fda.gov/cder/drug/advisory/aprotinin.htm*).

The background material for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Cardiovascular and Renal Drugs Advisory Committee'' (Click on the year 2006 and scroll down to the above named committee meeting.)

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14294 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Subcommittee: To provide advice and recommendations to the Committee for Pharmaceutical Science on FDA's regulatory issues.

Date and Time: The meeting will be held on October 18, 2006, from 8:30 a.m. to 5:30 p.m. and on October 19, 2006, from 8:30 a.m. to 1 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi Phan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD. 20857, 301–827–7001, FAX: 301–827–6801, e-mail: *mimi.phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Advisory Committee for Pharmaceutical Science (ACPS).'' (Click on the year 2006 and scroll down to ACPS meetings.)

Agenda: On October 18, 2006, the subcommittee will: (1) Receive an update on previous Clinical Pharmacology Subcommittee meeting recommendations and an introduction to three new topics of this meeting; (2) discuss and provide comments on the first new topic: The scope and strength of evidence to support the inclusion of pharmacogenetic information on Cytochrome P2D6 polymorphisms in a revision of the label for tamoxifen to improve the benefit/risk of the drug; and (3) discuss and provide comments on the second new topic: evaluation of transporter-based drug interactions. On October 19, 2006, the subcommittee will consider the third new topic: The impact of using prior knowledge on drug development and regulatory decisions. Prior knowledge of disease change over time and covariates, placebo variation and drug effects can be used to make better decisions and design more informative clinical trials. Examples will be used to demonstrate these principles.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before October 3, 2006. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 3, 2006.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mimi Phan at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14296 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Psychopharmacologic Drugs Advisory Committee scheduled for September 7, 2006, is cancelled. This amended meeting was announced in the **Federal Register** of August 17, 2006 (71 FR 47502).

FOR FURTHER INFORMATION CONTACT: Cicely Reese, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cicely.reese@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14293 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0331]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research.'' This draft guidance, when finalized, is intended to assist Institutional Review Boards (IRBs), clinical investigators, and sponsors in the development and conduct of emergency research.The draft guidance

also describes the additional specific human subject protection requirements for emergency research. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing on emergency research conducted without informed consent under FDA regulations.

DATES: Submit written or electronic comments on the draft guidance by October 30, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, 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 phone requests to 800–835–4709 or 301–827–1800. 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 document.

FOR FURTHER INFORMATION CONTACT: Carolyn Hommel, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research.'' This draft guidance was developed to assist IRBs, clinical investigators, and sponsors in the development and conduct of emergency research, that is, research in emergency settings when an exception from the informed consent requirements is requested under FDA's emergency research regulation. Further, the draft guidance describes the additional specific human subject protection requirements for emergency research, such as community consultation and public disclosure activities, the need for the concurrence of a licensed physician, use of data monitoring committees, use of independent IRBs, and the documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study.

In addition to the draft guidance, FDA is holding a public hearing on emergency research conducted without informed consent under FDA regulations. The public hearing is designed to solicit the views of individuals and groups affected by challenges encountered in the conduct of emergency research in the absence of informed consent, including patient advocacy groups, individuals who have participated in clinical trials, IRB members, sponsors, clinical investigators, medical societies, ethicists, and other interested parties. FDA will consider comments and suggestions received at the hearing together with any comments received on the draft guidance to determine whether the current framework is adequate for the ethical conduct of emergency research, or whether modifications would be appropriate.

Under the regulations in 21 CFR 50.24, and the conforming amendments contained in 21 CFR parts 56, 312, 314, 601, 812, and 814, an exception may be requested from the requirement to obtain informed consent from each subject, or the subject's legally authorized representative, prior to enrollment in a clinical investigation. The narrow exception applies to emergency research for which, among other things, the following conditions exist: (1) An investigational new drug application (IND) or investigational device exemption application (IDE) is required; (2) that involves human subjects who have a life-threatening medical condition (for which available treatments are unproven or unsatisfactory); (3) that involves subjects who because of their medical condition (e.g., unconsciousness) cannot give informed consent; and (4) where, to be effective, the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible. Studies involving an exception from the general requirement of informed consent may proceed only after a sponsor has received prior written permission from FDA, and the IRB has found and documented that specific conditions have been met.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the exception from informed consent requirements for emergency research. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 56 (21 CFR part 56) have been approved under OMB control number 0910–0130, the collections of information in part 312 (21 CFR part 312) have been approved under OMB control number 0910–0014, and the collections of information in part 812 (21 CFR part 812) have been approved under OMB control number 0910–0078. Modifications to these approved information collection requirements are underway or will be made at the time that each information collection is renewed. The agency believes that this is appropriate because this guidance has only a minor impact on these existing collections of information.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14262 Filed 8–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: September 28, 2006, 8:30 a.m.–5 p.m. and September 29, 2006, 8 a.m.–3 p.m.

Place: Hilton Hotel, 620 Perry Parkway, Gaithersburg, Maryland 20877.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will work on its sixth report which will be submitted to Congress and to the Secretary of the Department of Health and Human Services. The report will focus on the role of Title VII, section 747 grant programs in preparing primary care practitioners to care for underserved high-risk groups and vulnerable populations.

Agenda: The meeting on Thursday, September 28, will begin with opening comments from the Chair of the Advisory Committee and introductory remarks from senior management of the Health Resources and Services Administration. A plenary session will follow in which there will be a brief review of six papers commissioned for the Advisory Committee's sixth report. The Advisory Committee will develop a definition of ''vulnerability'' for the report. In both small groups and in the plenary session, the Advisory Committee will determine recommendations for the report. There will be an annual election for chair and two vice chairs. An opportunity will be provided for public comment.

On Friday, September 29, the Advisory Committee will discuss in the plenary session how the commissioned papers will be used in the sixth report, determine an initial outline for the report, and discuss how grantee data will be incorporated. Small groups will draft a report abstract, expand the report's outline, and determine commentary to accompany grantee data. Grantee anecdotal information will also be considered for the report. The Advisory Committee will plan next steps in the report preparation process. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., Ph.D., Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6785. The Web address for information on the Advisory Committee is *http://bhpr.hrsa.gov/medicine-dentistry/actpcmd.*

Dated: August 21, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–14271 Filed 8–28–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability and solicitation of comments.

SUMMARY: This is a Notice of Availability and request for comments on certain draft policy documents prepared by HRSA's Bureau of Primary Health Care (BPHC). HRSA plans to periodically make some draft policy documents (including draft Program Information Notices (PINs)) available for public comment on the Internet at *http://bphc.hrsa.gov*. Comments will be reviewed and analyzed, and a summary and general response will be published as soon as possible after the deadline for receipt of comments.

DATES: We must receive comments on or before the due date specified for each document.

ADDRESSES: Addresses to which comments should be sent will be provided on the HRSA Web site along with each draft document.

Background:

HRSA administers the Consolidated Health Center Program, which supports more than 3,700 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve clients that are primarily low income and minorities, and deliver preventive and primary care services to patients regardless of their ability to pay. Charges for health care services are set according to income.

HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Consolidated Health Center Program. Therefore, HRSA will periodically, as appropriate, solicit comments on some policies and policy documents via the HRSA Web site. This will provide all interested parties with equal access to the proposed document and an opportunity to comment. In some cases, HRSA may solicit comments on new, proposed policies. In other cases, HRSA may seek comments on documents that represent a written statement of an already-existing policy. In these situations, although the policy is being actively applied during the comment period, the written document may be adjusted after the comments are reviewed and analyzed.

FOR FURTHER INFORMATION CONTACT: For questions regarding the process described above, please contact Shannon Dunne Faltens, Senior Public Health Analyst, Division of Policy and Development, Bureau of Primary Health Care, at *sdunne-faltens@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Note that HRSA will not publish an individual **Federal Register** notice for each document made available for public comment. The applicability of this notice to BPHC policy documents expires 2 years from the date of publication of this notice. Within one year after the publication of this notice, HRSA will publish a second notice to ensure that the public remains aware of this process.

Federal Register notices will continue to be published inviting public comment on all information collection activities that fall under the purview of the Paperwork Reduction Act of 1995.

Dated: August 17, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E6–14272 Filed 8–28–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2006–0045]

Data Privacy and Integrity Advisory Committee

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: This notice announces the date, time, location, and agenda for the next meeting of the Department of Homeland Security Data Privacy and Integrity Advisory Committee. This meeting will be open to the public, with the exception of a one-hour administrative session.

DATES: The meeting will be held from 8 a.m. to 11:30 a.m. and 2 p.m. to 5 p.m. on Wednesday, September 20, 2006, in Arlington, Virginia.

ADDRESSES: The Department of Homeland Security Data Privacy and Integrity Advisory Committee meeting will be held in the Town Hall at the Transportation Security Administration, 601 South 12th Street, Arlington, Virginia 22202. Persons wishing to make comments or who are unable to attend or speak at the meeting may submit comments at any time. Comments must be identified by DHS–2006–0045 and may be submitted by any one of the following methods:

- Federal Rulemaking Portal: *http://www.regulations.gov.* Follow instructions for submitting comments on the Web site.
- E-mail: *PrivacyCommittee@dhs.gov.* Include docket number in the subject line of the message.
- Fax: 571–227–4171.
- Mail: Ms. Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Mail Stop D–3, Arlington, Virginia 22202.

Instructions: All submissions received must include the Department of Homeland Security and DHS–2006–0045, the docket number for this action. Comments received will also be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Committee, go to *http://www.regulations.gov.* Comments received will be posted without alteration at *www.dhs.gov/privacy,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Hugo Teufel III, Chief Privacy Officer, or Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Arlington, Virginia 22202, by telephone (571) 227–3813, by facsimile (571) 227–4171, or by e-mail *PrivacyCommittee@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Data Privacy and Integrity Advisory Committee (''Privacy Advisory Committee'') will be meeting on Wednesday, September 20, 2006, in the Town Hall at the Transportation Security Administration, 601 South 12th Street, Arlington, Virginia 22202. The meeting will be held from 8 a.m. to 11:30 a.m. and 2 p.m. to 5 p.m.

At the meeting, the Chief Privacy Officer will provide an update on the activities of the Privacy Office. The subcommittees will update the Committee on the work currently being conducted. In the morning and afternoon sessions, invited speakers will discuss screening, redress, and data integrity. A tentative agenda has been posted on the Privacy Advisory Committee Web site at *www.dhs.gov/privacy.*

Public comments will be accepted during the meeting between 4:30 p.m. and 5 p.m. All those who wish to testify during this time may register in advance or sign-up on the day of the meeting. In order to allow as many people as possible to testify, witnesses should limit their remarks to three minutes. For those wishing to make written comments, please follow the procedure noted above.

Public attendance is encouraged. Any member of the public who wishes to attend the public session is requested to provide his or her name and affiliation no later than 2 p.m. EST, Tuesday, September 19, 2006, to Rebecca J. Richards via e-mail at *PrivacyCommittee@dhs.gov,* or via telephone at (571) 227–3813. This will assist with the preparation of name badges, meeting materials and seating arrangements. Everyone who plans to attend is respectfully requested to be present and seated by 7:45 a.m. for the morning session and by 1:45 p.m. for the afternoon session.

All attendees are required to enter the Transportation Security Administration building through the Visitors' Center located to the left of the main entrance. Identification is required for all visitors to enter the building. Name badges will be issued to identify meeting attendees.

Persons with disabilities who require special assistance should indicate this in their admittance request and are encouraged to identify anticipated special needs as early as possible.

Although every effort will be made to accommodate all members of the public, seating is limited and will be allocated on a first-come, first-served basis.

Hugo Teufel III,

Chief Privacy Officer.

[FR Doc. E6–14321 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5041–N–31]

Notice of Proposed Information Collection: Comment Request; Submission Requirements for the Section 202 Supportive Housing for the Elderly and the Section 811 Supportive Housing for Persons With Disabilities Capital Advance Programs

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* October 30, 2006.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Deitzer, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or *Lillian_Deitzer@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Director, Office of Housing Assistance and Grants Administration, U.S. Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–3000 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Submission Requirements for the Section 202 Supportive Housing for the Elderly and the Section 811 Supportive Housing for Persons with Disabilities Capital Advance Programs.

OMB Control Number, if applicable: 2502–0470.

Description of the need for the information and proposed use: This submission, for which the Department is requesting clearance, is to permit the continued processing of all Sections 202 and 811 capital advance projects that have not yet been finally closed. The submission includes processing of the application for firm commitment to final closing of the capital advance. The information collection is needed to assist HUD in determining the Owner's eligibility and capacity to finalize the development of a housing project under the Section 202 and Section 811 Capital Advance Programs. A thorough evaluation of an Owner's capabilities is critical to protect the Government's financial interest, and to mitigate any possibility of fraud, waste and mismanagement of public funds.

Agency form numbers, if applicable: HUD–: 2453.1–CA, 2554, 90163–CA, 90164–CA, 90165–CA, 90166A–CA, 90166–CA, 90167–CA, 90169–CA, 90169.1–CA, 90170–CA, 90171–CA, 90172A–CA, 90172B–CA, 90173–A–CA, 90173–B–CA, 90173–C–CA, 90174–CA, 90175–CA, 90175.1–CA, 90176–CA, 90177–CA, 90178–CA, 90179–CA, 91732A–CA, 92434–CA, 92435–CA, 92466.1–CA, 92452, 92452–A, 92452–CA, 92476–A–CA, 92004–F, 92433–CA, 92443–CA, 92450–CA, 92466–CA, 92476–A, 93432–CA, 93566–CA, and 93566.1–CA.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of burden hours needed to prepare the information collection is 8,413. The number of respondents is 260 generating approximately 2,500 annual responses; the frequency of response is monthly, annually, and on occasion; and the estimated time needed to prepare the response varies from 30 minutes to 6 hours.

Status of the proposed information collection: Revision of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: August 24, 2006.

Frank L. Davis,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. E6–14350 Filed 8–28–06; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket Nos. FR–4723–FA–09, FR–4800–FA–19, FR–4900–FA–17, and FR–4950–FA–14]

Announcement of Funding Awards for the Housing Opportunities for Persons with AIDS (HOPWA) Program, Fiscal Years 2002, 2003, 2004, and 2005

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of past funding decisions made by the Department in a competition for funding under the 2002, 2003, 2004 and 2005 Notices of Funding Availability (NOFAs) for the Housing Opportunities for Persons with AIDS (HOPWA) program. This announcement contains the names of the awardees and the amounts of the awards made available by HUD in 2002, 2003, 2004 and 2005. **Federal Register** notices on these actions were not published at the time; however, the public was advised of these grant selections since they were posted on HUD's Web site. The postings contained listings of the selected applicants including descriptions of the projects.

FOR FURTHER INFORMATION CONTACT: David Vos, Director, Office of HIV/AIDS Housing, Office of Community Planning and Development, 451 Seventh Street, SW., Room 7212, Washington, DC 20410–7000; telephone (202) 708–1934 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at (800) 877–8339. For general information on this and other HUD programs, call Community Connections at (800) 998–9999 or visit the HUD Web site at *http://www.hud.gov.*

SUPPLEMENTARY INFORMATION: The HOPWA program competition was designed to award grants for the renewal of continuing permanent supportive housing activities and for new projects, referred to as Special Projects of National Significance, that provide housing assistance and supportive services to persons and their families living with HIV/AIDS. Funds were made available for a three-year operating period starting the year following the respective competition.

New project grants were made under two categories of assistance: (1) Special Projects of National Significance which, due to their innovative nature or their potential for replication, are likely to serve as effective models in addressing the needs of low-income persons living with HIV/AIDS and their families; and (2) projects which are part of Long-Term Comprehensive Strategies (Long-Term) for providing housing and related services for low-income persons living with HIV/AIDS and their families in areas that do not receive HOPWA formula allocations.

For the Fiscal Year 2002 competition, a total of $28,755,493 was provided to 28 grant recipients nationwide. For the Fiscal Year 2003 competition, a total of $25,935,009 was provided to 25 grant recipients nationwide. For the Fiscal Year 2004 competition, a total of $20,175,475 was provided to 22 grant recipients nationwide. For the Fiscal Year 2005 competition, a total of $37,501,089 was provided to 35 grant recipients nationwide. Project information for all years was made available on the Department's Web site. Notices on these grant selections were inadvertently not published at the time in the **Federal Register**.

The HOPWA assistance made available in this announcement was authorized by the AIDS Housing Opportunity Act (42 U.S.C. 12901), as amended by the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992) and was appropriated by the HUD Appropriations Act for 2001. The grants competitions were included within the SuperNOFA (Notice of Funding Availability) announcements for HUD's Discretionary Programs published in the

Federal Register on March 26, 2002 (67 FR 14457) for the Fiscal Year 2002 competition; April 25, 2003 (68 FR 21741) for the Fiscal Year 2003 competition; May 14, 2004 (69 FR 27633) for the Fiscal Year 2004 competition; and March 21, 2005 (70 FR 14110) for the Fiscal Year 2005 competition. Applications were reviewed and rated on the basis of selection criteria contained in each corresponding NOFA. This notice fulfills a required grants management action.

Dated: August 3, 2006.

Pamela H. Patenaude,

Assistant Secretary for Community Planning and Development.

FISCAL YEAR 2002 FUNDING AWARDS FOR THE HOPWA PROGRAM

Recipient	State	Amount
Alaska Housing Finance Corporation	AK	$740,800.00
AIDS Alabama, Inc	AL	480,580.00
Tenderloin AIDS Resource Center	CA	1,302,645.00
Alameda Co. Housing and Community Development Corporation	CA	1,370,000.00
Maui AIDS Foundation	HI	1,324,743.00
Gregory House Programs	HI	50,000.00
Travelers and Immigrants Aid/Chicago Connections	IL	1,151,382.00
AIDS Foundation of Chicago	IL	1,293,331.00
Pioneer Civic Services	IL	440,166.00
Kansas Department of Health and Environment	KS	1,370,000.00
Kentucky Housing Corporation	KY	50,000.00
Desire Community Housing Corp	LA	1,279,890.00
Action, Inc	MA	1,292,869.00
Baltimore City Dept. of Housing & Community Development	MD	1,370,000.00
Maryland Dept. of Health & Mental Hygiene, AIDS Foundation	MD	1,139,977.00
AIDS Project	ME	895,913.00
Clare Housing	MN	1,150,583.00
Interfaith Residence dba Doorways	MO	1,322,930.00
New Hampshire, Division of Behavioral Health, Office of Homeless and Housing Services	NH	908,000.00
New Jersey Department of Health and Human Services	NJ	925,653.00
United Bronx Parents, Inc	NY	1,227,143.00
Bailey House Inc	NY	1,286,000.00
Greyston Health Services, Inc	NY	1,141,814.00
Oregon Housing and Community Services	OR	706,965.00
Tarrant Co	TX	813,346.00
Vermont Housing and Conservation Board	VT	1,073,048.00
Downtown Emergency Service Center	WA	1,307,305.00
Spokane Co. Community Services Dept	WA	1,340,410.00
Total		28,755,493.00

FISCAL YEAR 2003 FUNDING AWARDS FOR THE HOPWA PROGRAM

Recipient	State	Amount
Alaska Housing Finance Corporation	AK	$731,120.00
Cochise County	AZ	677,377.00
San Jose City	CA	1,323,800.00
San Francisco Redevelopment Agency	CA	1,286,000.00
The Salvation Army Alegria Program	CA	1,010,991.00
I.M. Sulzbacher Center for the Homeless	FL	1,186,841.00
City of Savannah, Georgia	GA	299,278.00
Gregory House Programs	HI	1,080,000.00
Idaho Housing And Finance Assn	ID	1,314,000.00
Interfaith Residence, dba Doorways	IL	342,238.00
AIDS Foundation of Chicago	IL	1,280,742.00
Commonwealth of Kentucky	KY	496,608.00
Community Healthlink, Inc	MA	1,286,000.00
Cambridge Cares about AIDS, Inc	MA	1,335,524.00
Health Care for the Homeless, Inc	MD	1,083,657.00
Frannie Peabody Center	ME	1,327,675.00
City of Detroit Health Department	MI	1,370,000.00
Nebraska Dept. Health and Human Services	NE	1,357,192.00
State of New Hampshire	NH	607,545.00
The Fortune Society, Inc	NY	1,132,788.00
Our House of Portland	OR	1,306,963.00
Asociacion de Puertorriquenos en Marcha, Inc	PA	1,286,000.00
Virgin Islands Community AIDS Resource and Education	VI	1,158,225.00
Burlington Housing Authority	VT	368,445.00
AIDS Resource Center of Wisconsin	WI	1,286,000.00
Total		25,935,009.00

FISCAL YEAR 2004 FUNDING AWARDS FOR THE HOPWA PROGRAM

Recipient	State	Amount
AIDS Alabama, Inc	AL	$616,405.00
Pima County, Arizona, Community Development and Neighborhood Conservation Department	AZ	945,443.00
Housing Services Affiliate of the Bernal Heights Neighborhood Ctr	CA	537,270.00
Del Norte Neighbor Development Corporation	CO	489,036.00
Delaware HIV Consortium	DE	734,000.00
City of Key West, Community Development Office	FL	1,422,000.00
City of Savannah, Community Planning and Development Division	GA	710,696.00
Cornerstone Services, Inc	IL	773,628.00
Lexington-Fayette Urban County Government, Division of Community Development	KY	1,426,690.00
UNITY for the Homeless, Inc	LA	540,139.00
Justice Resource Institute	MA	1,137,716.00
Salvation Army	MN	368,731.00
State of Montana, Department of Public Health and Human Services	MT, ND & SD.	1,450,800.00
Harbor Homes, Inc	NH	525,457.00
Santa Fe Community Housing Trust	NM	1,215,680.00
Church Avenue Merchants Block Association, Inc (CAMBA)	NY	822,154.00
State of Oregon Department of Human Services	OR	1,455,000.00
Rhode Island Housing and Mortgage Finance Corp (Sunrise Project)	RI	1,265,606.00
Rhode Island Housing and Mortgage Finance Corp. (New Transitions Project)	RI	766,355.00
AIDS Resource Center of Wisconsin	WI	1,364,000.00
State of West Virginia Office of Economic Opportunity	WV	1,001,581.00
State of Wyoming Department of Health	WY	607,088.00
Total		20,175,475.00

FISCAL YEAR 2005 FUNDING AWARDS FOR THE HOPWA PROGRAM

Recipient	State	Amount
AIDS Alabama	AL	$502,679.00
Health Services Center, Inc	AL	572,331.00
Alaska Housing Finance Corporation	AK	757,675.00
County of Alameda	CA	1,425,362.00
The Salvation Army, a California Corporation	CA	281,326.00
Stanislaus Community Assistance Project	CA	1,244,488.00
East Oakland Community Project	CA	1,287,500.00
Colorado Health Network DBA Colorado AIDS Project	CO	730,643.00
Connections Community Support Programs, Inc	DE	1,339,000.00
Gulf Coast Jewish Services, Inc	FL	1,339,000.00
Maui AIDS Foundation	HI	1,381,120.00
AIDS Foundation of Chicago	IL	1,132,016.00
Cornerstone Services, Inc	IL	1,192,264.00
Heartland Human Care Services, Inc	IL	1,020,510.00
Heartland Human Care Services, Inc	IL	1,339,000.00
Pioneer Civic Services	IL	406,443.00
Kentucky Housing Corporation	KY	1,027,915.00
Odyssey House Louisiana, Inc	LA	1,388,000.00
Frannie Peabody Center	ME	990,976.00
City of Baltimore Heath Department	MD	1,300,974.00
AIDS Interfaith Residential Services, Inc	MD	1,018,355.00
State of Montana, Department of Public Health and Human Services	MT	1,429,307.00
State of New Hampshire	NH	824,120.00
City of Nashua, NH, Division of Public Health & Community Services	NH	1,360,232.00
Bailey House, Inc	NY	991,478.00
United Bronx Parents, Inc	NY	1,338,999.00
Greyston Health Services	NY	1,239,639.00
Regional HIV/AIDS Consortium	NC	1,190,276.00
Calcutta House, Inc	PA	741,268.00
Tarrant County	TX	916,010.00
Alamo Area Resource Center	TX	1,209,281.00
City of Dallas	TX	773,839.00
State of Vermont	VT	1,227,657.00
Spokane County	WA	1,151,406.00
State of West Virginia, Office of Economic Opportunities	WV	1,430,000.00
Total		37,501,089.00

[FR Doc. E6–14250 Filed 8–28–06; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4800–FA–17]

Announcement of Funding Awards for the Self-Help Homeownership Opportunity Program; Fiscal Year 2003

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for the Self-Help Homeownership Opportunity Program (SHOP). This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Deputy Director, Office of Affordable Housing Programs, Office of Community Planning and Development, 451 Seventh Street, SW., Room 7162, Washington, DC 20410–7000; telephone (202) 708–2684 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, call Community Connections at 1–800–998–9999 or visit the HUD Web site at *http://www.hud.gov.*

SUPPLEMENTARY INFORMATION: The Fiscal Year 2003 Self-Help Homeownership Opportunity Program competition is designed to facilitate and encourage innovative homeownership opportunities through self-help housing where the homebuyer contributes a significant amount of sweat-equity toward the construction of the new dwelling. Applicants must be a national or regional nonprofit organization or consortium.

The competition was announced in the SuperNOFA published April 25, 2003 (68 FR 21447). The NOFA allowed for approximately $25,085,875 for SHOP. Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

For the Fiscal Year 2003 competition, a total of $25,085,875 was awarded to three projects nationwide.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the grantees and amounts of the awards in Appendix A to this document.

Dated: August 3, 2006.

Nelson R. Bregon,

General Deputy Assistant Secretary for Community Planning and Development.

FISCAL YEAR 2003 FUNDING AWARDS FOR SELF-HELP HOMEOWNERSHIP OPPORTUNITY PROGRAMS

Recipient	State	Amount
Habitat for Humanity International	GA	$13,233,636.00
Housing Assistance Council	DC	7,998,213.00
Community Frameworks	WA	3,854,026.00
Total		$25,085,875.00

[FR Doc. E6–14251 Filed 8–28–06; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4723–FA–08]

Announcement of Funding Awards for the Self-Help Homeownership Opportunity Program; Fiscal Year 2002

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for the Self-Help Homeownership Opportunity Program (SHOP). This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Deputy Director, Office of Affordable Housing Programs, Office of Community Planning and Development, 451 Seventh Street, SW., Room 7162, Washington, DC 20410–7000; telephone (202) 708–2684 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, call Community Connections at 1–800–998–9999 or visit the HUD Web site at *http://www.hud.gov.*

SUPPLEMENTARY INFORMATION: The Fiscal Year 2002 Self-Help Homeownership Opportunity Program competition is designed to facilitate and encourage innovative homeownership opportunities through self-help housing where the homebuyer contributes a significant amount of sweat-equity toward the construction of the new dwelling. Applicants must be a national or regional nonprofit organization or consortium.

The competition was announced in the SuperNOFA published March 26, 2002 (67 FR 14157). The NOFA allowed for approximately $22,000,000 for SHOP. Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

For the Fiscal Year 2002 competition, a total of $22,000,000 was awarded to five projects nationwide.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the grantees and amounts of the awards in Appendix A to this document.

Dated: August 3, 2006.

Nelson R. Bregon,

General Deputy Assistant Secretary for Community Planning and Development.

FISCAL YEAR 2002 FUNDING AWARDS FOR SELF-HELP HOMEOWNERSHIP OPPORTUNITY PROGRAMS

Recipient	State	Amount
Habitat for Humanity International	GA	$10,809,000.00
Housing Assistance Council	DC	6,861,000.00
PPEP Microbusiness and Housing Development Corporation	AZ	2,356,000.00
Community Frameworks	WA	1,623,000.00
ACORN Housing Corporation	IL	351,000.00
Total		22,000,000.00

[FR Doc. E6–14348 Filed 8–28–06; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5086–N–01]

Robert L. Woodson, Jr., Award: Changes to the Award Program

AGENCY: Office of General Counsel, HUD.

ACTION: Notice.

SUMMARY: In 2004, HUD established the Robert L. Woodson, Jr., Award (Woodson Award) as an annual award program of America's Affordable Communities Initiative. The award program was established to recognize state and local governments for excellence in providing affordable housing through regulatory reduction. Through this notice, HUD announces its intention to alter the award process in order to provide more flexibility in the nomination and selection of award recipients. HUD intends to eliminate time restrictions for submitting applications that nominate jurisdictions for exhibiting outstanding leadership in reducing regulatory burden. This notice would eliminate the current time restrictions for submitting applications for the Woodson Award. This notice would allow applications to be submitted at any time during the calendar year, and allow HUD to announce Woodson Award winners at any time during the year. This added flexibility should help encourage creativity in reducing regulatory barriers to affordable housing.

FOR FURTHER INFORMATION CONTACT: Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10282, Washington, DC 20410–0500, telephone (202) 708–1793 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: In 2003, HUD established America's Affordable Communities Initiative (AACI) as a departmentwide effort designed to help communities across America identify and overcome regulatory barriers that impede the availability of affordable housing, as well as help HUD identify its own regulations that present barriers to the development of affordable housing. The Robert L. Woodson, Jr., Award, named in memory and in honor of HUD's late Chief of Staff, is designed to recognize state and local governments that aggressively work toward and have had success in the reduction of regulatory barriers to affordable housing.

The award program currently provides for nominations of jurisdictions to be submitted on an annual basis in March, with nominations reviewed and jurisdictions selected for awards generally by June of each year. In the first 2 years of the award program, one state agency and 17 communities from across the country received the Woodson Award.

As HUD reaches out to communities throughout the year, through AACI or other HUD initiatives, it strives to encourage efforts and activities to bring affordable housing within reach of all Americans. HUD has decided that it would be better to honor communities for being successful in regulatory reform at various times of the year, rather than only annually. HUD believes that a more frequent focus on states and communities that have successfully increased the supply of affordable housing through regulatory reform will better promote awareness of the effectiveness of this policy priority in creating affordable housing opportunities. The change may also help maintain an active national discussion of this important subject. In addition, the more immediate dissemination of the successful steps taken by the honorees to expand affordable housing may also be of immediate assistance to other communities exploring similar ideas.

This notice announces that, commencing with Fiscal Year 2007 (which begins October 1, 2006), state and local governments can be nominated for and receive a Woodson Award at any point during the year. In addition to the benefits that HUD sees through this change in the award program, HUD also believes that it will reduce the burden on those who desire to nominate state and local governments by eliminating the time constraints imposed by a set application date. This change will enable jurisdictions to apply for an award when they are best prepared to do so.

Additional information about the Robert L. Woodson, Jr., Award program, and the recipients honored to date, and America's Affordable Communities Initiative can be found at *http://www.hud.gov/affordablecommunities.*

Dated: August 21, 2006.

A. Bryant Applegate,

Senior Counsel and Director of America's Affordable Communities Initiative.

[FR Doc. E6–14249 Filed 8–28–06; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4950–FA–33]

Announcement of Funding Awards for the Housing Opportunities for People Who Are Homeless and Addicted to Alcohol Program; Fiscal Year 2005

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for the Housing Opportunities for People who are Homeless and Addicted to Alcohol Program. This announcement contains the names of the awardees and

the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Robyn Raysor, Deputy Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410–7000; telephone (202) 708–4300 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at (800) 877–8339. For general information on this and other HUD programs, call Community Connections at (800) 998–9999 or visit the HUD Web site at *http://www.hud.gov.*

SUPPLEMENTARY INFORMATION: The Fiscal Year 2005 Housing Opportunities for People who are Homeless and Addicted to Alcohol Program was designed to provide supportive housing assistance to chronically homeless persons who have been living on the streets for at least three-hundred sixty-five (365) days over the last five (5) years and have a long term addiction to alcohol, otherwise known as serial inebriates. Clients served by these funds will have been living on the streets at the time of initial contact and will have no history of living in transitional or permanent housing over the last five years.

The competition was announced in the SuperNOFA published March 21, 2005 (70 FR 14135). The NOFA allowed for approximately $10,000,000 to award approximately ten two-year grants that averaged approximately $1,000,000 per award. Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

For the Fiscal Year 2005 competition, a total of $10,000,000 was awarded to 12 program providers nationwide.

Public Law 108–7, approved February 20, 2003 (111 Stat. 494) authorizes this two-year demonstration program. The Supportive Housing Program is authorized by Title IV, Subtitle C, of the Stewart B. McKinney-Vento Homeless Assistance Act (McKinney-Vento Act), 42 U.S.C. 11381.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the names of grantees and amounts of awards in Appendix A to this document.

Dated: August 3, 2006.

Nelson R. Bregon,

General Deputy Assistant Secretary for Community Planning and Development.

APPENDIX A—FISCAL YEAR 2005 FUNDING AWARDS FOR THE HOUSING OPPORTUNITIES FOR PEOPLE WHO ARE HOMELESS AND ADDICTED TO ALCOHOL PROGRAM

Recipient	State	Amount
South East Tennessee Human Resource Agency	TN	$993,436.00
Community Mental Health Council, Inc	IL	248,595.00
Contra Costa Health Services	CA	990,307.00
Colorado Coalition for the Homeless	CO	990,495.00
Emergency Services and Homeless Coalition of Jacksonville	FL	894,150.00
Common Ground Community, Inc	NY	803,628.00
Project Renewal, Inc	NY	633,416.00
San Francisco Department of Public Health	CA	982,033.00
ECH Lifebuilders	CA	992,339.00
Santa Cruz County Health Services Agency	CA	701,840.00
City of Santa Monica	CA	712,489.00
Pathways to Housing DC	DC	991,933.00
Total		9,934,661.00

[FR Doc. E6–14344 Filed 8–28–06; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket Nos. FR–4900–FA–15 and FR–4951–FA–03]

Announcement of Funding Awards for the Self-Help Homeownership Opportunity Program; Fiscal Years 2004 and 2005

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for the Self-Help Homeownership Opportunity Program (SHOP). This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Deputy Director, Office of Affordable Housing Programs, Office of Community Planning and Development, 451 Seventh Street, SW., Room 7162, Washington, DC 20410–7000; telephone (202) 708–2684 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, call Community Connections at 1–800–998–9999 or visit the HUD Web site at *http://www.hud.gov*.

SUPPLEMENTARY INFORMATION: The Fiscal Years 2004 and 2005 Self-Help Homeownership Opportunity Program competitions were designed to facilitate and encourage innovative homeownership opportunities through self-help housing where the homebuyer would contribute a significant amount of sweat-equity toward the construction of the new dwelling. Applicants were required to be a national or regional nonprofit organization or consortium.

The competitions were announced in the SuperNOFAs published May 14, 2004 (69 FR 27359) for the Fiscal Year 2004 competition and September 8, 2005 (70 FR 53490) for the Fiscal Year 2005 competition. The NOFA allowed for approximately $26,840,700 for SHOP for the Fiscal Year 2004 competition and approximately $24,800,000 for SHOP for the Fiscal Year 2005 competition. Applications were rated and selected for funding on the basis of

selection criteria contained in that Notice.

For the Fiscal Year 2004 competition, a total of $26,840,700 was awarded to three projects nationwide. For the Fiscal Year 2005 competition, a total of $24,800,000 was awarded to four projects nationwide.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the grantees and amounts of the awards in Appendix A to this document.

Dated: August 3, 2006.

Nelson R. Bregon,

General Deputy Assistant Secretary for Community Planning and Development.

Appendix A

FISCAL YEAR 2004 FUNDING AWARDS FOR SELF-HELP HOMEOWNERSHIP OPPORTUNITY PROGRAMS

Recipient	State	Amount
Habitat for Humanity International	GA	$14,000,000
Housing Assistance Council	DC	10,000,000
PPEP Microbusiness and Housing Development Corporation	AZ	2,840,700
Total		26,840,700

FISCAL YEAR 2005 FUNDING AWARDS FOR SELF-HELP HOMEOWNERSHIP OPPORTUNITY PROGRAMS

Recipient	State	Amount
ACORN Housing Corporation	IL	$527,000
Community Frameworks	WA	4,500,000
Housing Assistance Council	DC	9,000,000
Habitat for Humanity International	GA	10,773,000
Total		24,800,000

[FR Doc. E6–14345 Filed 8–28–06; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Industrial Minerals Surveys.

Current OMB approval number: 1028–0062.

Abstract: Respondents supply the U.S. Geological Survey with domestic production and consumption data on nonfuel mineral commodities. This information will be published as monthly, quarterly, semiannual, and annual reports for use by Government agencies, industry, and the general public.

Bureau form number: Various (38 forms).

Frequency: Monthly, Quarterly Semiannual, and Annual.

Description of respondents: Producers and Consumers of Industrial Materials.

Annual Responses: 16,758.

Annual burden hours: 12,100.

Bureau clearance officer: Alfred Travnicek, 703–648–7231.

W. David Menzie,

Acting Chief Scientist, Minerals Information Team.

[FR Doc. 06–7209 Filed 8–28–06; 8:45 am]
BILLING CODE 4311–AM–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Mine Development and Minerals Information Supplement.

Current OMB approval number: 1028–0060.

Abstract: Respondents supply the U.S. Geological Survey with domestic production, exploration, and mine development data on nonfuel mineral commodities. This information will be published as an Annual Report for use by Government agencies, industry, education programs, and the general public.

Bureau form number: 9–4000–A.

Frequency: Annual.

Description of respondents: Nonfuel Mineral Producers and Exploration Operations.

Annual Responses: 617.

Annual burden hours: 463.

Bureau clearance officer: Alfred Travnicek, 703–648–7231.

W. David Menzie,

Acting Chief Scientist, Minerals Information Team.

[FR Doc. 06–7217 Filed 8–28–06; 8:45 am]

BILLING CODE 4311–AM–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Comprehensive Test Ban Treaty.

Current OMB approval number: 1028–0059.

Abstract: The information, required by the Comprehensive Test Ban Treaty (CTBT), will provide the CTBT Technical Secretariat with geographic locations of sites where chemical explosions greater than 300 tons TNT-equivalent have occurred. Respondents to the information collection request are U.S. nonfuel minerals producers.

Bureau form number: 9–4040–A.

Frequency: Annual.

Description of respondents: Companies that have conducted in the last calendar year, or that will conduct in the next calendar year, explosions with a total charge size of 300 tons of TNT–equivalent or greater.

Annual Responses: 3,000.

Annual burden hours: 750.

Bureau clearance officer: Alfred Travnicek, 703–648–7231.

W. David Menzie,

Acting Chief Scientist, Minerals Information Team.

[FR Doc. 06–7218 Filed 8–28–06; 8:45 am]

BILLING CODE 4311–AM–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–01–134–1220–AL–241A]

Notice of Public Meetings, McInnis Canyons National Conservation Area Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meetings.

SUMMARY: The McInnis Canyons National Conservation Area (MCNCA) Advisory Council will hold two additional meetings, scheduled on September 21, 2006 and December 14, 2006. The meetings will begin at 4 p.m. and will be held at the Mesa County Administration Building; 544 Rood Avenue, Grand Junction, CO.

DATES: The meetings will be held on September 21 and December 14, 2006.

ADDRESSES: For further information or to provide written comments, please contact the Bureau of Land Management (BLM), 2815 H Road, Grand Junction, Colorado 81506; (970) 244–3000.

SUPPLEMENTARY INFORMATION: The Colorado Canyons National Conservation Area was established on October 24, 2000 when the Colorado Canyons National Conservation Area and Black Ridge Wilderness Act of 2000 (the Act) was signed by the President. The Act required that the Advisory Council be established to provide advice in the preparation and implementation of the CCNCA Resource Management Plan. The name was congressionally changed at the end of 2004 from Colorado Canyons National Conservation Area to McInnis Canyons National Conservation Area (MCNCA).

The MCNCA Advisory Council will meet on Thursday, September 21, 2006 and Thursday, December 14, 2006 at the Mesa County Administration Building; 544 Rood Avenue, Grand Junction, CO, beginning at 4 p.m. The agenda topics for the September meeting are:

(1) MCNCA accomplishments for 2006.

(2) MCNCA proposed priorities for 2007.

(3) Camping Needs in Rabbit Valley.

(4) Advisory Council field trip schedules.

(5) Public Comment period.

(6) Set tentative Agenda for next meeting.

All meetings will be open to the public and will include a time set aside for public comment. Interested persons may make oral statements at the meetings or submit written statements at any meeting. Per-person time limits for oral statements may be set to allow all interested persons an opportunity to speak.

Summary minutes of all Council meetings will be maintained at the Bureau of Land Management Office in Grand Junction, Colorado. They are available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting. In addition, minutes and other information concerning the MCNCA Advisory Council, can be

obtained from the MCNCA Web site at: *http://www.co.blm.gov/mcnca/index.htm.,* which will be updated following each Advisory Council meeting.

Dated: August 21, 2006.

Paul H. Peck,

Manager, McInnis Canyons National Conservation Area.

[FR Doc. E6–14292 Filed 8–28–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–038–1220–AL; HAG 06–0179]

Meeting Notice for National Historic Oregon Trail Interpretive Center Advisory Board

AGENCY: Bureau of Land Management (BLM), Vale District, DOI.

ACTION: Notice of meetings.

SUMMARY: The National Historic Oregon Trail Interpretive Center Advisory Board will meet September 19, 2006, from 8 a.m. to 12 p.m. (PDT) at the National Historic Oregon Trail Interpretive Center, 22267 Highway 86, Baker City, OR 97914.

Meeting topics will include a Center update, education and outreach, and other topics as may come before the board. The meeting is open to the public. Public comment is scheduled for 10 to 10:15 a.m.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the National Historic Oregon Trail Interpretive Center Advisory Board may be obtained from Debbie Lyons, Public Affairs Officer, Vale District Office, 100 Oregon Street, Vale, Oregon 97918, (541) 473–6218 or e-mail *Debra_Lyons@or.blm.gov.*

Dated: August 23, 2006.

David R. Henderson,

District Manager.

[FR Doc. E6–14290 Filed 8–28–06; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

[MT–922–06–1310-FI-P; MTM 90699, MTM 90700, MTM 90749, MTM 90750, MTM 90751]

Notice of Proposed Reinstatement of Terminated Oil and Gas leases MTM 90699, MTM 90700, MTM 90749, MTM 90750, and MTM 90751

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Per 30 U.S.C. 188(d), Richard A. Horn timely filed a petition for reinstatement of oil and gas leases MTM 90699, MTM 90700, MTM 90749, MTM 90750, and MTM 90751, Carter County, Montana. The lessee paid the required rentals accruing from the date of termination.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals and royalties of $5 per acre and 16½percent or 4 percentages above the existing competitive royalty rate. The lessee paid the $500 administration fee for the reinstatement of each lease and $163 cost for publishing this Notice.

The lessee met the requirements for reinstatement of the leases per Sec. 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). We are proposing to reinstate the leases, effective the date of termination subject to:

- The original terms and conditions of the leases;
- The increased rental of $5 per acre for each lease;
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate for each lease; and
- The $163 cost of publishing this Notice.

FOR FURTHER INFORMATION CONTACT: Karen L. Johnson, Chief, Fluids Adjudication Section, BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101–4669, 406–896–5098.

Dated: August 22, 2006.

Karen L. Johnson,

Chief, Fluids Adjudication Section.

[FR Doc. E6–14331 Filed 8–28–06; 8:45 am]

BILLING CODE 4310–$$–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–563]

In the Matter of Certain Portable Power Stations and Packaging Therefor; Notice of Request for Written Submissions on Remedy, the Public Interest, and Bonding With Respect to the Respondent Found in Default

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission is requesting briefing on remedy, the public interest, and bonding with respect to a respondent previously found in default.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at http://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation by notice on March 9, 2006, based on a complaint filed by Roadmaster (USA) Corporation (''Roadmaster'') of Eatontown, New Jersey. 71 FR 13,166 (March 14, 2006). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain portable power stations and packaging therefor by reason of infringement of United States Design Patent No. D469,739; U.S. Trademark Registration No. 2,594,538; and Copyright Registration No. VA–1–261–495. The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation names Sinochem Ningbo, Ltd., of Ningbo, China (''Sinochem''), as the only respondent.

On May 9, 2006, complainant Xerox Roadmaster moved pursuant to 19 U.S.C. 1337(g)(1) and Commission Rule 210.16 for an order (1) directing Sinochem to show cause why it should not be found in default for failing to respond to the complaint and notice of investigation, and (2) upon failure of the respondent to show such cause, for an initial determination (''ID'') finding the respondent in default. The administrative law judge (''ALJ'') issued an ID on July 12, 2006, finding Sinochem in default, because respondent did not reply to the complaint nor notice of investigation, and respondent did not reply to the show cause order issued by the ALJ on November 5, 2005. The Commission

declined to review the ALJ's determination that respondent Sinochem, the only respondent named in the investigation, defaulted.

On August 9, 2006, Roadmaster filed a declaration requesting immediate relief in the form of a limited exclusion order against the defaulting respondent. Section 337(g)(1) (19 U.S.C. 1337(g)(1)) and Commission Rule 210.16(c) (19 CFR 210.16(c)) authorize the Commission to order limited relief against a respondent found in default, unless after consideration of the public interest factors, it finds that such relief should not issue. The Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry are either adversely affecting it or likely to do so. For background, see In the Matter of Certain Devices for Connecting Computers via Telephone Lines, Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainant and the investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is requested to state the dates that the intellectual property rights at issue expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on September 6, 2006. Reply submissions must be filed no later than the close of business on September 13, 2006. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 210.5. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in §§ 210.16 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.16 and 210.50).

Issued: August 23, 2006.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–14269 Filed 8–28–06; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–579]

In the Matter of Certain Nickel Metal Hydride Consumer Batteries, Components Thereof, and Consumer Electronic Products Containing Same; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 26, 2006, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Ovonic Battery Company, Inc. of Rochester Hills, Michigan. A supplement was filed on August 17, 2006. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain nickel metal hydride consumer batteries, components thereof, and consumer electronic products containing same by reason of infringement of one or more of claims 11–13, 18, and 19 of U.S. Patent No. 5,536,591. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Thomas S. Fusco, *Esq.*, Office of Unfair

Import Investigations, U.S. International Trade Commission, telephone (202) 205–2571.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in § 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2006).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 22, 2006, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain nickel metal hydride consumer batteries, components thereof, and consumer electronic products containing same by reason of infringement of one or more of claims 11–13, 18, and 19 of U.S. Patent No. 5,536,591, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

Ovonic Battery Company, Inc., 2968 Waterview Drive, Rochester Hills, MI 48309.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Varta Aktiengesellschaft, Am Leineufer 51, 30419 Hanover, Germany.

Varta Microbattery GmbH, Daimlerstr. 1, Ellwangen Germany 73479.

Varta Microbattery, Inc., 1311 Mamaroneck Avenue, Suite 120, White Plains, New York 10605.

(c) The Commission investigative attorney, party to this investigation, is Thomas S. Fusco, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 24, 2006.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–14306 Filed 8–28–06; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–477]

Sub-Saharan Africa: Factors Affecting Trade Patterns of Selected Industries

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on July 27, 2006 of a request from the United States Trade Representative (USTR) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (''the Commission'') instituted investigation No. 332–477, *Sub-Saharan Africa: Factors Affecting Trade Patterns of Selected Industries.*

EFFECTIVE DATE: August 18, 2006.

Background: As requested by the USTR, the Commission will conduct an investigation under section 332(g) and prepare three annual reports providing certain information on the competitive factors affecting industries within Sub-Saharan Africa (SSA) that have experienced significant shifts in exports.

In each of the reports, the Commission will provide an overview of the trends in SSA exports in the (1) Agriculture, (2) mining and manufacturing, and (3) services sectors, as well as profiles of SSA industries within those sectors that produce products (as identified by the USTR) that have shown significant export shifts in recent years. The reports will be based on the most recent 5-year period for which data are available.

Each industry profile will provide the following information, to the extent data are available:

- A description of the leading industries within SSA that export the subject products, including their position relative to global competitors;
- Identification of the leading SSA exporting countries and their key markets; and
- Analysis of the competitive factors, by country, that have contributed to the shift in exports. (Such factors may include access to inputs, labor, technology, investment, trade policies-*e.g.,* tariffs and trade preference programs such as the African Growth and Opportunity Act (AGOA), privatization, and liberalization.)

As specified in the USTR's letter, the first annual report will cover industries producing the following products: (1) Agriculture—cut flowers, cocoa butter and paste, nuts (coconuts, Brazil nuts, and cashews), and prepared and preserved fish; (2) mining and manufacturing—acyclic alcohol, unwrought aluminum, textiles and apparel, petroleum gas (liquified natural gas), flat-rolled steel, and wood veneer sheets; and (3) services—financial services and tourism.

The Commission expects to deliver the first annual report to the USTR by April 3, 2007. The second and third reports will be delivered 12 and 24 months, respectively, after delivery of the first annual report.

The Commission anticipates that industry coverage for the subsequent reports will be determined in consultation with the USTR no later than 2 months after delivery of the previous year's report.

FOR FURTHER INFORMATION CONTACT: Project Leader: Brad C. Gehrke (202–3329 or *brad.gehrke@usitc.gov*). Deputy Project Leader: Joanne E. Guth (202–205–3264 or *joanne.guth@usitc.gov*).

Industry-specific information may be obtained from the above persons. For more information on legal aspects of the investigation, contact William Gearhart of the Commission's Office of the General Counsel at 202–205–3091 or *william.gearhart@usitc.gov.* The media should contact Margaret O'Laughlin, Office of External Relations at 202–205–1819 or *margaret.olaughlin@usitc.gov.*

Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ONLINE) at *http://www.usitc.gov/secretary/edis.htm.*

Public Hearing: A public hearing in connection with the first report in this investigation will be held beginning at 9:30 a.m. on December 6, 2006, at the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All persons have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file a letter to such effect with the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436, not later than the close of business (5:15 p.m. EST) on November 13, 2006, in accordance with the requirements in the ''Written Submissions'' section below.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements or briefs concerning the first report in this investigation. All written submissions, including requests to appear at the hearing, statements, and briefs, should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. Any prehearing statements or briefs should be filed not later than close of business, November 15, 2006; the deadline for filing posthearing statements or briefs is close of business, December 15, 2006. All written submissions must conform with the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the rules requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see *Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf;* persons with questions regarding electronic filing should contact the Office of the Secretary at 202–205–2000 or *edis@usitc.gov*).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6. Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties.

In her request letter, the USTR stated that she intended to make the Commission's report available to the public in its entirety, and asked that the Commission not include any confidential business or national security information in the report it sends to her office. Consequently, the Commission's report will not contain any such information. Any confidential business information received by the Commission in this investigation and used in preparing the report will not be published in a manner that would reveal the operations of the firm supplying the information.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Secretary at 202–205–2000.

By order of the Commission.

Issued: August 23, 2006.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–14302 Filed 8–28–06; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number: 1103–NEW]

Office of Community Oriented Policing Services; Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Monitoring Information Collections.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS), 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. This proposed information collection was previously published in the **Federal Register** Volume 71, Number 119, page 35701 on June 21, 2006, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment September 28, 2006. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Monitoring Information Collections.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office

of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* COPS Office hiring grantees that are selected for in-depth monitoring of their grant implementation and equipment grantees that report using COPS funds to implement a criminal intelligence system will be required to respond. The Monitoring Information Collections include two types of information collections: the Monitoring Request for Documentation and the 28 CFR Part 23 Monitoring Kit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 140 respondents annually will complete the collections: 40 respondents to the Monitoring Request for Documentation at 3 hours per respondent; 100 respondents to the 28 CFR Part 23 Monitoring Kit at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 320 total annual burden hours associated with this collection.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: August 23, 2006.

Lynn Bryant,

Department Clearance Officer, PRA, Department of Justice.

[FR Doc. E6–14280 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0034]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: Collection of Laboratory Analysis Data on Drug Samples Tested by Non-Federal (State and Local Government) Crime Laboratories.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), 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 October 30, 2006. 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 Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

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:* Collection of Laboratory Analysis Data on Drug Samples Tested by Non-Federal (State and Local Government) Crime Laboratories.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* none. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, Local or tribal government. *Other:* None. *Abstract:* Information is needed from state and local laboratories to provide DEA with additional analyzed drug information for the National Forensic Laboratory Information System.

(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 there are one hundred fifty (150) total respondents for this information collection. One hundred twenty (120) respond monthly at .16 hour (10 minutes) for each response and thirty (30) respond quarterly at .16 hour (10 minutes) for each response, for a total number of 1560 respondents.

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that there are 259 annual burden hours associated with this collection.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: August 23, 2006.

Lynn Bryant,

Department Clearance Officer, U.S. Department of Justice.

[FR Doc. E6–14278 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–290P]

Controlled Substances: Proposed Aggregate Production Quotas for 2007

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed year 2007 aggregate production quotas.

SUMMARY: This notice proposes initial year 2007 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

DATES: Comments or objections must be received on or before September 19, 2006.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–290P'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537,

Attention: DEA **Federal Register** Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations.

The proposed year 2007 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2007 to provide adequate supplies of each substance for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed year 2007 aggregate production quotas, the Deputy Administrator considered the following factors: total actual 2005 and estimated 2006 and 2007 net disposals of each substance by all manufacturers; estimates of 2006 year-end inventories of each substance and of any substance manufactured from it and trends in accumulation of such inventories; product development requirements of both bulk and finished dosage form manufacturers; projected demand as indicated by procurement quota applications filed pursuant to Section 1303.12 of Title 21 of the Code of Federal Regulations; and other pertinent information.

Pursuant to Section 1303 of Title 21 of the Code of Federal Regulations, the Deputy Administrator of the DEA will, in early 2007, adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2006 year-end inventory and actual 2006 disposition data supplied by quota recipients for each basic class of Schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA of 1970 (21 U.S.C. 826), and delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations, and redelegated to the Deputy Administrator pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations, the Deputy Administrator hereby proposes that the year 2007 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—schedule I	Proposed year 2007 quotas
2,5–Dimethoxyamphetamine	2,001,000 g
2,5–Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5–Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7)	10 g
3–Methylfentanyl	2 g
3–Methylthiofentanyl	2 g
3,4–Methylenedioxyamphetamine (MDA)	20 g
3,4–Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4–Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5–Trimethoxyamphetamine	2 g
4–Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4–Bromo-2,5-dimethoxyphenethylamine (2–CB)	7 g
4–Methoxyamphetamine	77 g
4–Methylaminorex	2 g
4–Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
5–Methoxy-3,4-methylenedioxyamphetamine	2 g
5–Methoxy-N,N-diisopropyltryptamine	5 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	3 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine	5 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g

Basic class—schedule I	Proposed year 2007 quotas
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	8 g
Cathinone	3 g
Codeine-N-oxide	302 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	2,549,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	8,000,000 g
Heroin	5 g
Hydromorphinol	3,000 g
Hydroxypethidine	2 g
Lysergic acid diethylamide (LSD)	61 g
Marihuana	4,500,000 g
Mescaline	2 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	310 g
N,N-Dimethylamphetamine	7 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	7 g
Psilocyn	7 g
Tetrahydrocannabinols	312,500 g
Thiofentanyl	2 g
Trimeperidine	2 g

Basic class—schedule II	Proposed year 2007 quotas
1–Phenylcyclohexylamine	2 g
Alfentanil	5,000 g
Alphaprodine	2 g
Amobarbital	2 g
Amphetamine	17,000,000 g
Cocaine	286,000 g
Codeine (for sale)	39,605,000 g
Codeine (for conversion)	55,000,000 g
Dextropropoxyphene	167,365,000 g
Dihydrocodeine	2,200,000 g
Diphenoxylate	828,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	41,252,000 g
Hydrocodone (for conversion)	1,500,000 g
Hydromorphone	3,300,000 g
Isomethadone	2 g
Levo-alphacetylmethadol (LAAM)	6 g
Levomethorphan	5 g
Levorphanol	6,000 g
Meperidine	9,753,000 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[680,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2405,000 grams for methamphetamine mostly for conversion to a Schedule III product; and 45,000 grams for methamphetamine (for sale)]	
Methylphenidate	35,000,000 g
Morphine (for sale)	35,000,000 g
Morphine (for conversion)	110,774,000 g

Basic class—schedule II	Proposed year 2007 quotas
Nabilone	2 g
Noroxymorphone (for sale)	1,002 g
Noroxymorphone (for conversion)	6,600,000 g
Opium	1,400,000 g
Oxycodone (for sale)	49,200,000 g
Oxycodone (for conversion)	2,600,000 g
Oxymorphone	1,500,000 g
Pentobarbital	28,000,000 g
Phencyclidine	2,021 g
Phenmetrazine	2 g
Racemethorphan	2 g
Remifentanil	2,700 g
Secobarbital	2 g
Sufentanil	6,500 g
Thebaine	72,453,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other Schedules I and II controlled substances included in Sections 1308.11 and 1308.12 of Title 21 of the Code of Federal Regulations be established at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the **ADDRESSES** section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for Schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14284 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,772]

E.I. Dupont, Dupont Automotive Systems Division, Troy, MI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on July 25, 2006 in response to a petition filed by a company official on behalf of workers at E.I. DuPont, DuPont Automotive Systems Division, Troy, Michigan. The workers at the subject facility produced automotive paints.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC, this 18th day of August, 2006.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–14329 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–56,672A]

Golden Northwest Aluminum, Inc., Northwest Aluminum Specialties Company, Currently Known as Northwest Aluminum Specialties, Inc., The Dalles, OR; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26

U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment assistance on March 18, 2005, applicable to workers of Golden Northwest Aluminum, The Dalles, Oregon. The notice was published in the **Federal Register** on May 2, 2005 (70 FR 27711).

At the request of the United Steelworkers, District 12, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of aluminum.

New information shows that in June 2006, Golden Northwest Aluminum, Inc., and its division, Northwest Aluminum Specialties Company formed Northwest Aluminum Specialties, Inc. Currently, Northwest Aluminum Specialties Company is now known as Northwest Aluminum Specialties, Inc.

Information also shows that some workers separated from employment at the subject firm had their wages reported under two separate unemployment insurance (UI) tax accounts for Golden Northwest Aluminum, Inc. and Northwest Aluminum Specialties, Inc. Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Golden Northwest Aluminum, The Dalles, Oregon, who were adversely affected by increased company imports.

The amended notice applicable to TA–W–56,672 is hereby issued as follows:

''All workers of Golden Northwest Aluminum, Northwest Aluminum Specialties Company, currently known as Northwest Aluminum Specialties, Inc., The Dalles, Oregon, who became totally or partially separated from employment on or after March 12, 2005, through March 18, 2007, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC, this 18th day of August 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–14328 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,468]

Intier Automotive Seating, Warren, OH; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(c) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Intier Automotive Seating, Warren, Ohio. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–59,468; Intier Automotive Seating, Warren, Ohio (August 17, 2006).

Signed at Washington, DC, this 21st day of August 2006.

Erica R. Cantor,

Acting Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–14322 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,586C]

Klaussner Furniture Industries, Inc., Candor, NC; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated August 21, 2006, a company official requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers of the subject firm. The Department's determination was issued on July 31, 2006. The Notice of Determination was published in the **Federal Register** on August 16, 2006 (71 FR 47253).

In the request for reconsideration, the company official provided new information regarding employment declines.

The Department has carefully reviewed the request for reconsideration and has determined that the Department will conduct further investigation based on new information provided.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 23rd day of August 2006.

Elliott S. Kushner,

Certifying Officer, Division of, Trade Adjustment Assistance.

[FR Doc. E6–14326 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,402]

McArthur Professional, Inc., Professional Towel Mills Division, Abbeville, SC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974, as amended (19 U.S.C. 2813), the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on June 27, 2006, applicable to all workers of McArthur Professional, Inc., Professional Towel Mills Division, Abbeville, South Carolina. The notice was published in the **Federal Register** on July 17, 2006 (71 FR 40550).

At the request of State agency, the Department reviewed the certification for workers of the subject firm. The affected workers produced towels.

The company official has confirmed that the firm imprints/decorates towels for promotional purposes and the workers producing towels are separately identifiable from the workers in another Department decorating the towels.

The Department inadvertently issued the certification for all workers of the firm. Consequently, the Department is limiting the certification to the workers of McArthur Professional, Inc., Professional Towel Mills Division, Abbeville, South Carolina, engaged in the production of towels.

The amended notice applicable to TA–W–59,402 is hereby issued as follows:

''Workers of McArthur Professional, Inc., Professional Towel Mills Division, Abbeville, South Carolina, engaged in the production of

towels, who became totally or partially separated from employment on or after May 15, 2005 through June 27, 2008, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC, this 17th day of August 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–14327 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,555]

Michaels of Oregon, Meridian, Idaho; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(c) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Michaels of Oregon, Meridian, Idaho. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–59,555; Michaels of Oregon, Meridian, Idaho (August 15, 2006).

Signed at Washington, DC, this 21st day of August 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–14325 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,569]

OBG Distribution Company, LLC, Celina, Tennessee; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(c) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at OBG Distribution Company, LLC, Celina, Tennessee. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–58,569; OBG Distribution Company, LLC, Celina, Tennessee (August 17, 2006).

Signed at Washington, DC this 21st day of August 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–14323 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Gamma Radiation Exposure Records

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed 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 Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection related to the 30 CFR Sections 57.5047; Gamma Radiation Exposure Records.

DATES: Submit comments on or before October 30, 2006.

ADDRESSES: Send comments to U.S. Department of Labor, Mine Safety and Health Administration, John Rowlett, Director, Management Services Division, 1100 Wilson Boulevard, Room 2134, Arlington, VA 22209–3939. Commenters are encouraged to send their comments on a computer disk, or via Internet e-mail to *Rowlett.John@dol.gov*, along with an original printed copy. Mr. Rowlett can be reached at (202) 693–9827 (voice), or (202) 693–9801 (facsimile).

FOR FURTHER INFORMATION CONTACT: Contact the employee listed in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 103(c) of the Federal Mine Safety and Health Act of 1977, the Mine Safety and Health Administration (MSHA) is required to ''* * * issue regulations required operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act.''

Gamma radiation occurs anywhere that radioactive materials are present, and has been associated with lung cancer and other debilitating occupational diseases. Gamma radiation hazards may be found near radiation sources at surface operations using X-ray machines, weightometers, nuclear and diffraction units.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by accessing the MSHA home page (*http://www.msha.gov*) and then choosing ''Statutory and Regulatory Information'' and ''**Federal Register** Documents.''

III. Current Actions

Annual gamma radiation surveys are required to be conducted—in all underground mines where radioactive ores are mined. Where the average gamma radiation measurements are in excess of 2.0 milliroentgens per hour in the working place, all persons affected are to be provided with gamma radiation dosimeters and records of cumulative individual gamma radiation exposures are to be kept.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

Title: Gamma Radiation Exposure Records.

OMB Number: 1219–0039.

Recordkeeping: Records of cumulative occupational radiation exposures aid in the protection of workers, in the control of subsequent radiation exposure, and are used by MSHA in evaluation of the effectiveness of the protection program in demonstrating compliance with regulatory requirements.

Frequency: Annually.

Affected Public: Business or other for-profit.

Respondents: 3.

Average Time Per Respondent: 1 hour.

Total Burden Hours: 3 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

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 at Arlington, Virginia, this 22nd day of August 2006.

Lynnette Haywood,

Acting Director, Office of Administration and Management.

[FR Doc. E6–14319 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–43–P

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. Eastern Associated Coal, LLC

[Docket No. M–2006–024–C]

Eastern Associated Coal, LLC, HCR 78, Box 113, Wharton, West Virginia 25208 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Harris No. 1 Mine (MSHA I.D. No. 46–01271) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

2. Eastern Associated Coal, LLC

[Docket No. M–2006–025–C]

Eastern Associated Coal, LLC, HCR 78, Box 113, Wharton, West Virginia 25208 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Matewan Tunnel Mine (MSHA I.D. No. 46–08610) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

3. Eastern Associated Coal, LLC

[Docket No. M–2006–026–C]

Eastern Associated Coal, LLC, St. Rt. 85, HCR 78, P.O. Box 113, Wharton, WV 25208 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Powellton Tunnel Mine (MSHA I.D. No. 46–08762) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

4. Eastern Associated Coal, LLC

[Docket No. M–2006–027–C]

Eastern Associated Coal, LLC, P.O. Box 29, Wharton, West Virginia 25208 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Wharton 1 Tunnel Mine (MSHA I.D. No. 46–05071) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

5. Rivers Edge Mining, Inc.

[Docket No. M–2006–028–C]

Rivers Edge Mining, Inc., P.O. Box 120, Wharton, West Virginia 25208 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Rivers Edge Mine (MSHA I.D. No. 46–08890) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

6. Pine Ridge Coal Company

[Docket No. M–2006–029–C]

Pine Ridge Coal Company, 50 Schoolhouse Road, Seth, West Virginia 25181 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Big Mountain No. 16 Mine (MSHA I.D. No. 46–07908) located in Boone County, West Virginia. The petitioner requests a modification of the existing standard to permit the use of battery-powered non-permissible computers in or inby the last open crosscut, including in the return airway. The petitioner proposes to use the hand-held computers to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner asserts that the

proposed alternative method would provide at least the same measure of protection as the existing standard.

7. Orchard Coal Company

[Docket No. M–2006–030–C]

Orchard Coal Company, 214 Vaux Road, Tremont, Pennsylvania 17981 has filed a petition to modify the application of 30 CFR 75.1714–2(c) (Self-rescue devices; use and location requirements) to its Orchard Slope Mine (MSHA I.D. No. 36–08346) located in Schuylkill County, Pennsylvania. The petitioner requests a modification of the existing standard to permit self-contained self-rescue (SCSR) devices to be stored within 200 feet of the working face. The petitioner states that in steeply pitching, conventional anthracite mines, entries are advanced as far as 200 feet vertically, which exposes the miner to trip and fall hazards. The petitioner further states that the necessity of carrying supplies up narrow entries while wearing the SCSRs may result in damage to the SCSR and also may result in a diminution of safety to the miner. The petitioner asserts that modification of the standard 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 e-mail to *zzMSHA-Comments@dol.gov.* Include ''petitions for modification'' in the subject line of the e-mail. Comments can also be submitted by fax, regular mail, or hand-delivery. If faxing your comments, include ''petitions for modification'' on the subject line of the fax. Comments by regular mail or hand-delivery should be submitted to the Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. If hand-delivered, you are required to stop by the 21st floor to check in with the receptionist. All comments must be postmarked or received by the Office of Standards, Regulations, and Variances on or before September 28, 2006. Copies of the petitions are available for inspection at that address.

Dated at Arlington, Virginia, this 21st day of August 2006.

Patricia W. Silvey,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. E6–14308 Filed 8–28–06; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

Agenda

TIME AND DATE: 9:30 a.m., Wednesday, September 6, 2006.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW, Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED: 5299U, Most Wanted Safety Recommendations Program—2006 Update on State Issues.

NEWS MEDIA CONTACT: Keith Holloway, telephone: (202) 314–6100.

Individuals requesting specific accommodations should contact Chris Bisett at (202) 314–6305 by Friday, September 1, 2006.

The public may view the meeting via a live or archived Web cast by accessing a link under *News & Events* on the NTSB home page at *http:\\www.ntsb.gov.*

FOR FURTHER INFORMATION CONTACT: Vicky D'Onofrio, (202) 314–6410.

Dated: August 25, 2006.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. 06–7258 Filed 8–25–06; 2:04 pm]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* NRC Form 790, ''Classification Record''.

3. *The form number if applicable:* NRC Form 790.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* NRC licensees, contractors, and certificate holder who classify and declassify NRC information.

6. *An estimate of the number of annual responses:* 300.

7. *The estimated number of annual respondents:* 1.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 20.

9. *An indication of whether Section 3507(d), Pub. L. 104–13 applies:* Not applicable.

10. *Abstract:* Completion of the NRC Form 790 is a mandatory requirement for NRC licensees, contractors, and only certificate holder who classifies and declassifies NRC information in accordance with Executive Order 12958, as amended, ''Classified National Security Information,'' the Atomic Energy Act, and implementing directives.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by September 28, 2006. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

OMB Desk Officer, Office of Information and Regulatory Affairs (3150–0052), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 17th day of August, 2006.

For the Nuclear Regulatory Commission.

Brenda Jo Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. E6–14283 Filed 8–28–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Southern Nuclear Operating Company; Notice of Receipt and Availability of an Application for an Early Site Permit for the Vogtle ESP Site

On August 15, 2006, the Nuclear Regulatory Commission (NRC, the Commission) received an application from Southern Nuclear Operating Company filed pursuant to Section 103 of the Atomic Energy Act and 10 CFR part 52, for an early site permit (ESP) for a location in eastern Georgia (near Waynesboro, Georgia) identified as the Vogtle ESP site.

An applicant may seek an ESP in accordance with Subpart A of 10 CFR part 52 separate from the filing of an application for a construction permit (CP) or combined license (COL) for a nuclear power facility. The ESP process allows resolution of issues relating to siting. At any time during the period of an ESP (up to 20 years), the permit holder may reference the permit in an application for a CP or COL.

Subsequent **Federal Register** notices will address the acceptability of the tendered ESP application for docketing and provisions for participation of the public and other parties in the ESP review process.

A copy of the application is available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland and via the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* The accession number for the application is ML062290246.

Future publicly available documents related to the application will also be posted in ADAMS. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC Public Document Room staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.* The application is also available to local residents at the Burke County Library, in Waynesboro, Georgia, and it will be available on the NRC Web page at *http://www.nrc.gov/reactors/new-licensing/esp.html.*

Dated at Rockville, Maryland, this 21st day of August, 2006.

For the Nuclear Regulatory Commission.

David B. Matthews,

Director, Division of New Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E6–14285 Filed 8–28–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Notice

DATE: Weeks of August 28, September 4, 11, 18, 25, October 2, 2006.

PLACE: Commissioners' Conference Room, 1155 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of August 28, 2006

There are no meetings scheduled for the week of August 28, 2006.

Week of September 4, 2006—Tentative

Wednesday, September 6, 2006

1:50 p.m. Affirmation Session (Public) (Tentative)

a. Pacific Gas & Elec. Co. (Diablo Canyon ISFSI), Docket No. 72–26–ISFSI ''Motion by San Luis Obispo Mothers for Peace, Sierra Club, and Peg Pinard for Declaratory and Injunctive Relief with respect to Diablo Canyon ISFSI''. (Tentative).

b. AmerGen Energy Company, LLC (License Renewal for Oyster Creek Nuclear Generating Station) Docket No. 50–0219, Legal challenges to LBP–06–07 and LBP–06–11. (Tentative).

c. Pa'ina Hawaii, LLC, LBP–06–4, 63 NRC 99 (2006) and LBP–06–12, 63 NRC 409 (2006). (Tentative).

Week of September 11, 2006—Tentative

Monday, September 11, 2006

9:30 a.m. Discussion of Security Issues (Closed—Ex. 1).

1:30 p.m. Discussion of Security Issues (Closed—Ex. 1& 3).

Tuesday, September 12, 2006

9:30 a.m. Meeting with Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD) (Public Meeting) (Contact: Shawn Smith, 301–415–2620).

This meeting will be webcast live at the Web address *http://www.nrc.gov.*

1 p.m. Discussion of Security Issues (Closed—Ex. 1).

Week of September 18, 2006—Tentative

There are no meetings scheduled for the week of September 18, 2006.

Week of September 25, 2006—Tentative

There are no meetings scheduled for the week of September 25, 2006.

Week of October 2, 2006—Tentative

There are no meetings scheduled for the week of October 2, 2006.

* * * * *

*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) 415–1661.

* * * * *

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, Deborah Chan, at 301–415–7041, TDD: 301–415–2100, or by e-mail at *DLC@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: August 24, 2006.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 06–7236 Filed 8–25–06; 9:49 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory

Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from August 4, 2006 to August 17, 2006. The last biweekly notice was published on August 15, 2006 (71 FR 46929).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible 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/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any

limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HearingDocket@nrc.gov;* or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to (301) 415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: April 11, 2006.

Description of amendment request: The proposed amendment would modify Technical Specification 5.6.5 ''Core Operating Limits Report (COLR)'' to add two U.S. Nuclear Regulatory Commission-approved topical reports to the COLR methodologies list. These topical reports allow the use of S–RELAP5 thermal-hydraulic analysis code for accident safety analyses.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The two topical reports have been reviewed and approved by the NRC for use in determining core operating limits. The core operating limits to be developed using the new methodologies for HBRSEP [H. B. Robinson Steam Electric Plant], Unit No. 2, will be established in accordance with the applicable limitations as documented in the NRC Safety Evaluation Reports. In a May 11, 2001, NRC Safety Evaluation Report, the NRC concluded that the S–RELAP5 code is capable of addressing the thermal-hydraulic response of the target non-LOCA [loss-of-coolant accident] events in a conservative manner and is, therefore, an acceptable replacement for the ANF–RELAP code. In the May 19, 2004, Safety Evaluation Report for Revision 1 to EMF–2310(P)(A), the NRC concluded that the code remained acceptable for use for the non-LOCA events. In a March 15, 2001, Safety Evaluation Report, the NRC concluded that the code was acceptable for use for small break LOCA analyses at Westinghouse pressurized water reactors.

The proposed change, by itself, does not impact the current design bases. The proposed change enables the use of new methodologies to re-analyze certain events. Revised analyses may either result in continued conformance with design bases, or may change the design bases. If design basis changes result from a revised analysis, then the specific design changes will be evaluated in accordance with HBRSEP, Unit No. 2, design change procedures and 10 CFR 50.59.

The proposed change does not involve physical changes to any plant structure, system, or component. Therefore, the probability of occurrence for a previously analyzed accident is not significantly increased.

The consequences of a previously analyzed accident are dependent on the initial conditions assumed for the analysis, the behavior of the fission product barriers during the analyzed accident, the availability and successful functioning of the equipment assumed to operate in response to the analyzed event, and the setpoints at which these actions are initiated. The proposed methodologies will ensure that the plant continues to meet applicable design and safety analyses acceptance criteria. The proposed change does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. As a result, no analysis assumptions are impacted and there are no adverse effects on the factors that contribute to offsite or onsite dose as a result of an accident. The proposed change does not affect setpoints that initiate protective or mitigative actions. The proposed change ensures that plant structures, systems, and components are maintained consistent with the safety analysis and licensing bases. Based on this evaluation, there is no significant increase in the consequences of a previously analyzed accident.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated.

The proposed change does not involve any physical alteration of plant systems, structures, or components, other than allowing for fuel design in accordance with NRC-approved methodologies. No new or different equipment is being installed. No installed equipment is being operated in a different manner. There is no change to the parameters within which the plant is normally operated or in the setpoints that initiate protective or mitigative actions. As a result, no new failure modes are being introduced. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety.

There is no impact on any margin of safety resulting from the incorporation of these new topical reports into the Technical

Specifications. If design basis changes result from a revised analysis that uses these new methodologies, the specific design changes will be evaluated in accordance with HBRSEP, Unit No. 2, design change procedures and 10 CFR 50.59. Any potential reduction in the margin of safety would be evaluated for that specific design change.

Therefore, this change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: L. Raghavan.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: July 17, 2006.

Description of amendment request: The proposed amendment would revise the containment pressure requirements specified in Surveillance Requirements 3.6.8 and 5.5.16 due to a revision in the Loss-of-Coolant Accident (LOCA) containment pressure analysis.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated. The revised post-LOCA containment pressure and temperature analysis used more conservative assumptions and the increase in the calculated peak pressure was approximately 1 psig. The revised value of 41.49 psig remains less than the containment design pressure of 42 psig. The increase in the calculated peak temperature was approximately 2 °F, which was analyzed to have no impact on structures or equipment. Although there is an increase in the calculated pressure, the allowable containment leakage rate, as measured at the peak pressure, is not being changed. Since there is no increase in the allowable leakage, there is no increase in consequences. The proposed change is related to containment pressure analysis. There are no physical changes being made to the plant, or to the manner in which the plant is operated. Surveillance procedures for containment leakage have been conservatively testing at pressures in excess of 42 psig and surveillance procedures for the Isolation Valve Seal Water System have been conservatively testing at pressures in excess of 46.2 psig. The change can have no impact on the probability of an accident occurring. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any previously evaluated?

No. The proposed change does not create the possibility of a new or different kind of accident from any previously evaluated. There are no physical changes being made to the plant or to the manner in which the plant is operated. Surveillance procedures for containment leakage have been conservatively testing at pressures in excess of 42 psig and surveillance procedures for the Isolation Valve Seal Water System have been conservatively testing at pressures in excess of 46.2 psig. The revised containment analysis results in a calculated peak containment pressure that remains less than the containment design pressure. The increase in the calculated peak temperature was analyzed to have no impact on structures or equipment. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Do the proposed changes involve a significant reduction in the margin of safety?

No. The proposed change does not involve a significant reduction in the margin of safety. The proposed change imposes more conservative surveillance test requirements. The calculated increase in post-LOCA peak containment pressure is only 1 psig and the revised value of 41.49 psig remains less than the containment design pressure of 42 psig. The increase in the calculated peak temperature was approximately 2 °F, which was analyzed to have no impact on structures or equipment. Although there was an increase in the calculated pressure, the allowable containment leakage rate, as measured at the peak pressure, is not being changed. Therefore, this change does not involve a significant reduction in any margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: L. Raghavan.

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: July 12, 2006.

Description of amendment request: The proposed amendment would modify Conditions, Required Actions and Completion Times associated with the inoperability of one or more emergency diesel generators (EDGs) in Technical Specification (TS) 3.8.1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

This license amendment request proposes a change to extend the Technical Specification 3.8.1, ''AC Sources-Operating,'' Completion Time. This change allows a single EDG to be inoperable for 7 days more than Technical Specification 3.8.1 currently provides. The Required Actions for CTG [Combustion Turbine Generator] 11–1 are also removed from Condition A and TSTF [Technical Specification Task Force] -439 is implemented for TS 3.8.1, removing the second Completion Times.

The EDGs are safety related components which provide backup electrical power supply to the onsite ESF [Engineered Safety Feature] power distribution system. CTG 11–1 provides backup electrical power to the Division 1 power distribution system. Neither the EDGs nor CTG 11–1 are accident initiators, thus these changes do not increase the probability of a previously evaluated accident.

The plant ESF power distribution systems consist of two divisions for 100% redundancy. Accident analyses demonstrate that only one division is required for accident mitigation. Thus, with one division inoperable the other division is capable of performing the required safety function. Design basis analyses are not required to be performed assuming extended loss of all power supplies to the plant ESF power distribution system. Thus, this change does not involve a significant increase in the consequences of a previously analyzed accident.

The proposed change also eliminates the second Completion Time from TS 3.8.1. These second Completion Times are not an initiator to any accident previously evaluated. As a result, the probability of an accident previously evaluated is not affected. The consequences of an accident during the revised Completion Times are no different than the consequences of the same accident during the existing Completion Times. As a result, the consequences of an accident previously evaluated are not affected by this change. Therefore, the proposed change does not involve a significant increase in the

probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The changes do not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The changes do not alter any assumptions made in the safety analysis.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The change does not involve a significant reduction in the margin of safety.

This license amendment request proposes Technical Specification changes to extend the Technical Specification 3.8.1, ''AC Sources-Operating,'' Completion Time for an inoperable EDG to 14 days. These changes allow an emergency diesel generator to be inoperable for 7 days more than TS 3.8.1 currently provides.

Deterministic and probabilistic risk assessments evaluated the effect of the proposed TS changes on the availability of an electrical power supply to the plant emergency safeguards features systems. These assessments concluded that the proposed TS changes do not involve a significant increase in the risk of power supply unavailability.

This license amendment request proposes TS changes to remove the Required Actions for CTG 11–1 from TS 3.8.1 Condition A. If CTG 11–1 is inoperable at the same time that any single EDG is inoperable for the entire proposed 14 day period with no other equipment in maintenance, the risk remains within RG [Regulatory Guide] 1.174 (Reference 2 [in the application]) thresholds for a ''very small'' classification.

The proposed change to delete the second Completion Time does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by this change. The proposed changes will not result in plant operation in a configuration outside of the design basis.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David G. Pettinari, Legal Department, 688 WCB, Detroit Edison Company, 2000 2nd Avenue, Detroit, Michigan 48226–1279.

NRC Acting Branch Chief: Martin Murphy.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit No. 2, (MPS2) New London County, Connecticut

Date of amendment request: June 13, 2006.

Description of amendment request: The proposed amendment would allow changes to the Technical Specifications based on the radiological dose analysis margins obtained by using an alternate source term consistent with 10 CFR 50.67.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated?

No.

The proposed amendment does not involve a significant increase in the probability or consequence of an accident previously analyzed. The MPS2 control room emergency ventilation system only functions following the initiation of a design basis radiological accident. Therefore, the change to the value used for in-leakage rate test acceptance criteria following a design basis accident will not increase the probability of any previously analyzed accident. The proposed 200 cfm control room habitability envelope inleakage surveillance acceptance criteria has no adverse impact on control room habitability analyses for postulated toxic chemical release events. These habitability analyses do not credit automatic or manual isolation of the control room fresh air ventilation flow during a toxic chemical release event. The control room's forced ventilation fresh air exchange rate (*e.g.*, 800 cfm) is much greater than the proposed 200 cfm envelope inleakage rate acceptance criteria. The MPS2 containment purge valve isolation signal is not credited in the accident analyses. The requirements contained in this specification do not meet any of 10 CFR 50.36(c)(2)(ii) criteria on items for which technical specifications must be established. Deletion of this technical specification will not increase the probability of any previously analyzed accident. The MPS2 containment and the containment systems function to prevent or control the release of radioactive fission products following a postulated accident. Therefore, the change to the value used for primary to secondary leak rate acceptance criteria, and for all secondary containment bypass leakage paths following a design basis accident, will not increase the probability of any previously analyzed accident.

These systems are not initiators of any design bases accident. Revised dose calculations, which take into account the changes proposed by this amendment and the use of the alternative source term, have been performed for the MPS2 design basis radiological accidents. The results of these revised calculations indicate that public and control room doses will not exceed the limits specified in 10 CFR 50.67 and Regulatory Guide 1.183. There is not a significant increase in predicted dose consequences for any of the analyzed accidents. Therefore, the proposed changes do not involve a significant increase in the consequences of any previously analyzed accident.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated?

No.

The implementation of the proposed changes does not create the possibility of an accident of a different type than was previously evaluated in the UFSAR. Although the proposed changes could affect the operation of the control room emergency ventilation system, and the containment and containment systems following a design basis radiological accident, none of these changes can initiate a new or different kind of accident since they are only related to system capabilities that provide protection from accidents that have already occurred. These changes do not alter the nature of events postulated in the UFSAR nor do they introduce any unique precursor mechanisms. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from those previously analyzed.

3. Involve a significant reduction in the margin of safety?

No.

The implementation of the proposed changes does not reduce the margin of safety. The proposed changes for the control room ventilation system, and the containment and containment systems do not affect the ability of these systems to perform their intended safety functions to maintain dose less than the required limits during design basis radiological events. The radiological analysis results, when compared with the revised TEDE [total effective dose equivalent] acceptance criteria, meet the applicable limits. These acceptance criteria have been developed for application to analyses performed with alternative source terms. These acceptance criteria have been developed for the purpose of use in design basis accident analyses such that meeting the stated limits demonstrates adequate protection of public health and safety. It is thus concluded that the margin of safety will not be reduced by the implementation of the changes.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Nuclear Counsel, Dominion Nuclear Connecticut, Inc., Rope Ferry Road, Waterford, CT 06385.

NRC Acting Branch Chief: Brooke D. Poole.

Dominion Nuclear Connecticut, Inc., Docket No. 50–423, Millstone Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: July 19, 2006.

Description of amendment request: The proposed amendment will revise reactor core safety limits Technical Specifications (TSs) and relocate the reactor core safety limit figure to the Core Operating Limits Report (COLR) in the Millstone Power Station, Unit 3, Technical Requirements Manual.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Criterion 1:

Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The relocation of cycle-specific core operating limits from the TS to the COLR and the addition of the RCS [reactor coolant system] total flow rate to the COLR has no influence or impact on the probability or consequences of a design basis accident. Adherence to the COLR and methodologies acceptable for establishing COLR parameters continues to be controlled by TS. The proposed amendment still requires exactly the same actions to be taken when or if limits are exceeded. Each accident analysis addressed in the final safety analysis report (FSAR) will be examined with respect to changes in cycle-dependent parameters, which are obtained from application of the NRC-approved reload design methodologies, to ensure that the transient evaluation of new core designs are bounded by previously accepted analyses. This examination, which will be performed in accordance with the requirements of 10 CFR 50.59, ensures that future core designs will not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2:

Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The relocation and addition of the cycle-specific variables to the COLR and adding new document references in TS Section 6.9.1.6.b does not influence or impact, nor does it contribute in any way to the probability or consequences of an accident. No safety-related equipment, safety function, or plant operations will be altered as a result of these proposed changes. The cycle-specific variables are calculated using NRC-approved methods and submitted to the NRC to allow the staff to continue to trend the values of these limits. The TS will continue to require operation within the required core operating limits and appropriate actions will be taken when or if limits are exceeded. Therefore the proposed amendment does not in any way create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3:

Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes have no impact on plant equipment operation. The proposed changes do not revise any setpoints or acceptance criteria assumed in the accident analyses. Therefore, the proposed changes will not result in a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Nuclear Counsel, Dominion Nuclear Connecticut, Inc., Rope Ferry Road, Waterford, CT 06385.

NRC Acting Branch Chief: Brooke D. Poole.

Entergy Nuclear Operations, Inc., Docket No. 50–247, Indian Point Nuclear Generating Unit No. 2 (IP2), Westchester County, New York

Date of amendment request: July 10, 2006.

Description of amendment request: Energy Nuclear Operations, Inc., is planning to operate an Independent Spent Fuel Storage Installation (ISFSI) facility at IP2 using the HOLTEC HI-STORM 100 Cask System. To support this activity, the proposed amendment adds Spent Fuel Cask loading requirements to IP2 Technical Specifications (TSs).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change will revise the Indian Point Unit 2 TSs associated with the SFP [spent fuel pool] to assure that the regulatory requirements related to criticality in the SFP and applied to the Holtec HI-STORM 100 Multi-Purpose Canister MPC–32 when in the SFP are reflected in the IP2 TS. The proposed change does not require any physical changes to Part 50 structures, systems, or components, nor will their performance requirements be altered. Therefore, the response of the plant to previously analyzed accidents and related radiological releases will not be adversely impacted, and will bound those postulated during cask loading activities in the cask storage area.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Existing fuel handling procedures and associated administrative controls remain applicable for cask loading operations within the SFP. Additionally, the soluble boron concentration required to maintain keff ≤ 0.95 for postulated criticality accidents associated with cask loading operations was also evaluated. The results of the analyses, using a methodology previously approved by the NRC [Nuclear Regulatory Commission], demonstrate that the amount of soluble boron required to compensate for the positive reactivity associated with these postulated accidents (371 ppm [parts per million]) remains well below the existing spent fuel pit minimum boron concentration limit of 2000 ppm. Accordingly, the same limit has been proposed for cask loading operations in the cask storage area.

Therefore, the possibility of a new or different kind of accident from any accident previously evaluated is not created.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

An NRC approved methodology was used to perform the criticality analysis which provides the basis to incorporate a new family of burnup versus enrichment curves, for various cooling times, into the plant Technical Specifications to ensure criticality requirements are met during spent fuel cask loading. Accordingly, the existing minimum boron concentration limit for the spent fuel pit of 2000 ppm will continue to remain bounding during cask loading operations. This determination accounts for uncertainties at a 95 percent probability, 95 percent confidence level. Should it be postulated that a boron dilution event does occur during this time period, keff will remain less than 1.0 should the cask storage area become fully flooded with unborated water.

Therefore, there will not be a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Branch Chief: Richard J. Laufer.

Exelon Generation Company, LLC, Docket No. 50–249, Dresden Nuclear Power Station (DNPS), Unit 3, Grundy County, Illinois

Date of amendment request: July 21, 2006.

Description of amendment request: The proposed amendment would revise the values of the safety limit minimum critical power ratio (SLMCPR) in Technical Specification Section 2.1.1, ''Reactor Core SLs [Safety Limits].'' Specifically, the proposed change would require that for Unit 3, the minimum critical power ratio (MCPR) for Global Nuclear Fuel fuel shall be ≥ 1.10 for two recirculation loop operation, or ≥ 1.11 for single recirculation loop operation. Additionally, the proposed change would require that MCPR for Westinghouse fuel shall be ≥ 1.12 for two recirculation loop operation, or ≥ 1.14 for single recirculation loop operation.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The probability of an evaluated accident is derived from the probabilities of the individual precursors to that accident. The consequences of an evaluated accident are determined by the operability of plant systems designed to mitigate those consequences. Limits have been established consistent with NRC [Nuclear Regulatory Commission]-approved methods to ensure that fuel performance during normal, transient, and accident conditions is acceptable. The proposed change conservatively establishes the SLMCPR for DNPS, Unit 3, Cycle 20 such that the fuel is protected during normal operation and during plant transients or anticipated operational occurrences (AOOs).

Changing the SLMCPR does not increase the probability of an evaluated accident. The change does not require any physical plant modifications, physically affect any plant components, or entail changes in plant operation. Therefore, no individual precursors of an accident are affected.

The proposed change revises the SLMCPR to protect the fuel during normal operation as well as during plant transients or AOOs. Operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criterion (*i.e.*, that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs) is met. Since the proposed change does not affect operability of plant systems designed to mitigate any consequences of accidents, the consequences of an accident previously evaluated are not expected to increase.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Creation of the possibility of a new or different kind of accident requires creating one or more new accident precursors. New accident precursors may be created by modifications of plant configuration, including changes in allowable modes of operation. The proposed change does not involve any plant configuration modifications or changes to allowable modes of operation. The proposed change to the SLMCPR assures that safety criteria are maintained for DNPS, Unit 3, Cycle 20.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SLMCPR provides a margin of safety by ensuring that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. The proposed change will ensure the current level of fuel protection is maintained by continuing to ensure that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. The proposed SLMCPR values were developed using NRC-approved methods. Additionally, operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criterion (*i.e.*, that no more than 0.1% of the rods are expected to be in boiling transition if the MCPR limit is not violated) is met.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Bradley J. Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Daniel S. Collins.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit 1 (PNPP), Lake County, Ohio

Date of amendment request: June 6, 2006.

Description of amendment request: The proposed amendment would revise the Ventilation Filter Test Program (VFTP) in Technical Specification (TS) 5.5.7. The license amendment is a corrective action to revise the flow rate units specified in the VFTP from standard cubic feet per minute to cubic feet per minute. This amendment will ensure the PNPP TS are consistent with plant design documentation, testing criteria, and the industry.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response:

The ESF [Engineered Safety Feature] Ventilation systems reduce the concentration of airborne radioactive contaminants following a design basis accident and therefore are not initiators of design bases accidents. The proposed amendment does not change the manner in which the ESF ventilation systems are operated or tested. Implementation of the proposed amendment will ensure the ESF ventilation systems perform their function when called upon and does not affect the plant operations, design function or analysis that verifies the capability of a [plant] structures, systems or components.

The proposed amendment does not affect the design of the ESF ventilation systems, the operational characteristics of the ESF ventilation systems, the interfaces between the ESF ventilation systems and those plant systems they support, or the reliability of the ESF ventilation systems.

Therefore, the ESF ventilation systems will be capable of performing their accident mitigation function and there is no increase in the probability or consequences of an accident already evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response:

The proposed amendment introduces no new mode of plant operation and does not involve a physical modification to the plant. New equipment is not installed with the proposed amendment, nor does the proposed amendment cause existing equipment to be operated in a new or different manner.

Since the proposed changes do not involve a change to the plant design or operation, no new system interactions are created by this change. The proposed amendment does not produce any parameters or conditions that

could contribute to the initiation of accidents different from those already evaluated in the Updated Safety Analysis Report.

The changes to the VFTP do not affect the assumed accident performance of the ESF Ventilation systems, nor [*sic*] any plant structure, system or component previously evaluated.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response:

The proposed amendment does not impact the ESF ventilation systems performance, including the capability for each ESF ventilation system to attain and maintain required air flow assumed in the plant safety analysis.

The proposed amendment does not involve a significant reduction in a margin of safety since the operability of the ESF ventilations [sic] systems continues to be determined as required to support the capability of the ESF ventilations [sic] systems to provide the required ventilation, filtration and temperature control to mitigate the consequences of an accident.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: Daniel S. Collins.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant, Citrus County, Florida

Date of amendment request: May 25, 2006.

Description of amendment request: The proposed license amendment revises the requirements in the Crystal River Unit 3 Improved Technical Specification related to steam generator tube integrity. The licensee states that the changes are consistent with NRC-approved Technical Specification (TS) Task Force (TSTF) Change Traveler, TSTF–449, ''Steam Generator Tube Integrity,'' Revision 4. The availability of this technical specification improvement was announced in the **Federal Register** on May 6, 2005, as part of the consolidated line item improvement process.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change requires a SG [Steam Generator] Program that includes performance criteria that will provide reasonable assurance that the SG tubing will retain integrity over the full range of operating conditions (including startup, operation in the power range, hot standby, cooldown and all anticipated transients included in the design specification). The SG performance criteria are based on tube structural integrity, accident induced leakage, and operational LEAKAGE.

A SGTR [steam generarator tube rupture] event is one of the design basis accidents that are analyzed as part of a plant's licensing basis. In the analysis of a SGTR event, a bounding primary to secondary LEAKAGE rate equal to the operational LEAKAGE rate limits in the licensing basis plus the LEAKAGE rate associated with a double-ended rupture of a single tube is assumed.

For other design basis accidents such as MSLB [main steamline break], rod ejection, and reactor coolant pump locked rotor the tubes are assumed to retain their structural integrity (*i.e.*, they are assumed not to rupture). These analyses typically assume that primary to secondary LEAKAGE for all SGs is 1 gallon per minute or increases to 1 gallon per minute as a result of accident induced stresses. The accident induced leakage criterion introduced by the proposed changes accounts for tubes that may leak during design basis accidents. The accident induced leakage criterion limits this leakage to no more than the value assumed in the accident analysis.

The SG performance criteria proposed change to the TS identify the standards against which tube integrity is to be measured. Meeting the performance criteria provides reasonable assurance that the SG tubing will remain capable of fulfilling its specific safety function of maintaining reactor coolant pressure boundary integrity throughout each operating cycle and in the unlikely event of a design basis accident. The performance criteria are only a part of the SG Program required by the proposed change to the TS. The program, defined by NEI [Nuclear Energy Institute] 97–06, Steam Generator Program Guidelines, includes a framework that incorporates a balance of prevention, inspection, evaluation, repair, and leakage monitoring. The proposed changes do not, therefore, significantly increase the probability of an accident previously evaluated.

The consequences of design basis accidents are, in part, functions of the DOSE EQUIVALENT 1–131 in the primary coolant and the primary to secondary LEAKAGE rates resulting from an accident. Therefore, limits are included in the plant technical specifications for operational leakage and for DOSE EQUIVALENT 1–131 in primary coolant to ensure the plant is operated within its analyzed condition. The typical analysis of the limiting design basis accident assumes that primary to secondary leak rate after the accident is 1 gallon per minute with no more than [500 gallons per day or 720 gallons per day] in any one SG, and that the reactor coolant activity levels of DOSE EQUIVALENT 1–131 are at the TS values before the accident.

The proposed change does not affect the design of the SGs, their method of operation, or primary coolant chemistry controls. The proposed approach updates the current TSs and enhances the requirements for SG inspections. The proposed change does not adversely impact any other previously evaluated design basis accident and is an improvement over the current TSs.

Therefore, the proposed change does not affect the consequences of a SGTR accident and the probability of such an accident is reduced. In addition, the proposed changes do not affect the consequences of an MSLB, rod ejection, or a reactor coolant pump locked rotor event, or other previously evaluated accident.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated

The proposed performance based requirements are an improvement over the requirements imposed by the current technical specifications. Implementation of the proposed SG Program will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. The result of the implementation of the SG Program will be an enhancement of SG tube performance. Primary to secondary LEAKAGE that may be experienced during all plant conditions will be monitored to ensure it remains within current accident analysis assumptions.

The proposed change does not affect the design of the SGs, their method of operation, or primary or secondary coolant chemistry controls. In addition, the proposed change does not impact any other plant system or component. The change enhances SG inspection requirements.

Therefore, the proposed change does not create the possibility of a new or different type of accident from any accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The SG tubes in pressurized water reactors are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. As part of the reactor coolant pressure boundary, the SG tubes are unique in that they are also relied upon as a heat transfer surface between the primary and secondary systems such that residual heat can be removed from the primary system. In addition, the SG tubes isolate the radioactive fission products in the primary coolant from the secondary system. In summary, the safety function of an SG is maintained by ensuring the integrity of its tubes.

Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change does not affect tube design or operating environment. The proposed change is expected to result in an improvement in the

tube integrity by implementing the SG Program to manage SG tube inspection, assessment, repair, and plugging. The requirements established by the SG Program are consistent with those in the applicable design codes and standards and are an improvement over the requirements in the current TSs.

For the above reasons, the margin of safety is not changed and overall plant safety will be enhanced by the proposed change to the TS.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: L. Raghavan.

Nuclear Management Company, LLC, Docket No. 50–266, Point Beach Nuclear Plant (PBNP), Unit 1, Town of Two Creeks, Manitowoc County, Wisconsin

Date of amendment request: July 11, 2006.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 5.5.8, ''Steam Generator (SG) Program,'' to exclude the portion of the tube below 17 inches from the top of the tubesheet from the SG tube inspection requirements for Unit 1 on a one-time basis for a single operating cycle. In addition, administrative changes are proposed to correct a page number in the TS table of contents and delete two blank pages in TS Section 5.

Basis for proposed no significant hazards consideration determination: As required by 10CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below.

1. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a significant increase in the probability or consequences of any accident previously evaluated.

The proposed change revises Technical Specification (TS) 5.5.8, ''Steam Generator (SG) Program'' to redefine the PBNP Unit 1 primary pressure boundary for purposes of the SG tube inspection requirements on a one-time basis for Unit 1 Refueling Outage 30 and the subsequent operating cycle. The redefined primary pressure boundary is relocated from the seal weld at the bottom of the SG tube to the tube-to-tubesheet mechanical interface. The required structural integrity margins of the SG tubes in this area are unaffected by this change and will be maintained by the SG tubesheet. SG tubes are hydraulically expanded into the tubesheet. Steam generator tube rupture is constrained by the tubesheet for tubes with cracks in the tubesheet. This constraint results from the hydraulic expansion process which restricts further expansion of the tube, thermal expansion mismatch between the tube and tubesheet and from the differential pressure between the primary and secondary side. Thermal expansion and differential pressure also restrain the tube axially. For conservatism, hydraulic preload was not factored into the analysis.

The proposed change continues to require that the SG Program include performance criteria that will provide reasonable assurance that the SG tubing will retain integrity over the full range of operating conditions (including startup, operation in the power range, hot standby, cooldown and all anticipated transients included in the design specification).

The SG performance criteria are based on tube structural integrity, accident induced leakage, and operational LEAKAGE. The analysis shows that structural integrity retains acceptable safety factors against burst under normal steady state full power operation primary-to-secondary pressure differential and against burst applied to the design basis accident primary-to-secondary pressure differentials. The analysis also shows that accident induced leakage is bound by twice the normal operating leakage and well below the accident analysis assumption for each stream generator. The primary to secondary operational LEAKAGE limit is not changed.

The planned inspection and supporting analysis provide reasonable assurance that the SG tubing will remain capable of fulfilling its specific safety function of maintaining reactor coolant pressure boundary integrity throughout the operating cycle and in the unlikely event of a design basis accident. The proposed change does not, therefore, significantly increase the probability of an accident previously evaluated.

The consequences of design basis accidents are, in part, functions of the DOSE EQUIVALENT I–131 in the primary coolant and the primary to secondary LEAKAGE rates resulting from an accident. The plant technical specification limits for operational LEAKAGE and for DOSE EQUIVALENT I–131 in primary coolant, which ensure the plant is operated within its analyzed condition, are unaffected by the proposed change. Therefore, the proposed change does not significantly increase the consequences of any accident previously evaluated.

The proposed change does not significantly affect the probability of any event initiators. There will be no change to normal plant operating parameters, engineered safety feature actuation setpoints, accident mitigation capabilities, or accident analysis assumptions or inputs.

Therefore, the probability or consequences of any accident previously evaluated will not be significantly increased as a result of the proposed change.

2. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a new or different kind of accident from any accident previously evaluated.

Implementation of the proposed change will not introduce any adverse changes to the plant design basis or postulated accidents resulting from potential tube degradation. Primary to secondary leakage that may be experienced during all plant conditions will continue to be monitored to ensure it remains within current accident analysis assumptions. The proposed change does not affect the method of operation of the SGs, or primary or secondary coolant chemistry controls. In addition, the proposed change does not impact any other plant system or component.

No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures are introduced as a result of the proposed change. Equipment important to safety will continue to operate as designed. The changes do not result in any event previously deemed incredible being made credible. The changes do not result in adverse conditions or result in any increase in the challenges to safety systems. Therefore, the proposed change does not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a significant reduction in a margin of safety.

The steam generators (SGs) are an integral part of the reactor coolant pressure boundary and, as such, are relied upon to maintain the primary system's pressure and inventory. They are also relied upon to remove residual heat from the primary system. The safety function of an SG is maintained by ensuring the integrity of its tubes. Steam generator tube integrity is a function of the design, environment, and the physical condition of the tube. The proposed change redefines the PBNP Unit 1 primary pressure boundary from the tube end weld to 17 inches below the top of the tubesheet and incorporates revisions to the inspection criteria for SG tube inspection in the tubesheet. The SG operating environment is not affected by the change. The proposed change maintains the required structural margins of the SG tubes for both normal and accident conditions.

For cracking located within the tubesheet, steam generator tube rupture is constrained by the tubesheet. For circumferentially oriented cracking, the associated analysis for the proposed change validates that 17 inches of degradation free expanded tubing provides the necessary resistance to tube pullout with applicable safety factors applied.

The revised inspection criteria continue to verify SG tube integrity. The safety function of the affected components will be maintained with the redefined primary pressure boundary.

There are no new or significant changes to the initial conditions contributing to accident severity or consequences. The proposed amendment will not otherwise affect the plant protective boundaries, will not cause a release of fission products to the public, nor will it degrade the performance of any other structures, systems or components (SSCs) important to safety. Therefore, the requested change will not result in a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff

proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

NRC Acting Branch Chief: Martin Murphy.

PPL Susquehanna, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), Luzerne County, Pennsylvania

Date of amendment request: October 13, 2005.

Description of amendment request: The proposed amendment would modify the licensing bases of SSES 1 and 2 by adopting the Alternative Source Term (AST) methodology which replaces the current accident source term with an AST. The AST is characterized by the composition and magnitude of the radioactive material, the chemical and physical form of the radionuclides, and the timing of the releases of these radionuclides. The exceptions would be that the current Technical Information Document (TID)14844 accident source term would remain the licensing basis for (1) equipment qualification, (2) NUREG–0737 evaluations other than Control Room Habitability Envelope (CRHE) doses, and (3) Final Safety Analysis Report (FSAR) accidents not included in Regulatory Guide 1.183.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated?

Response: No.

Adoption of the AST and pursuant TS [Technical Specification] changes, changes to the TS's to address NRC Generic Letter 2003–01 (Reference 12.1) [see application dated October 13, 2005] and the changes to the atmospheric dispersion factors, have no impact to the initiation of DBAs [design basis accidents]. Once the occurrence of an accident has been postulated, the new accident source term and atmospheric dispersion factors are an input to analyses that evaluate the radiological consequences. Some of the proposed changes do affect the design or manner in which the facility is operated following an accident; however, the proposed changes do not involve a revision to the design or manner in which the facility is operated that could increase in the probability of an accident previously evaluated of a DBA discussed in Chapter 15 of the FSAR.

Therefore, the proposed change does not involve an increase in the probability of an accident previously evaluated.

The structures, systems and components affected by the proposed changes act as mitigators to the consequences of accidents. Based on the revised analyses, the proposed changes do revise certain performance requirements; however, the proposed changes do not involve a revision to the parameters or conditions that could contribute to the initiation of a DBA discussed in Chapter 15 of the FSAR.

Plant-specific radiological analyses have been performed using the AST methodology and new atmospheric dispersion factors. Based on the results of these analyses, it had been demonstrated that the CRHE dose consequences of the limiting events considered in the analyses meet the regulatory guidance provided for use with the AST, and the offsite doses are well within acceptable limits. This guidance is presented in 10 CFR 50.67, RG [Regulatory Guide] 1.183, and Standard Review Plan [SRP] Section 15.0.1.

Therefore, the proposed amendment does not result in a significant increase in the consequences of any previously evaluated accident.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Implementation of AST and the associated proposed TS changes and new atmospheric dispersion factors do not alter or involve any design basis accident initiators. These changes do not affect the design function or mode of operation of structures, systems and components in the facility prior to a postulated accident. Since structures, systems and components are operated essentially no differently after the AST implementation, no new failure modes are created by this proposed change.

Licensing basis changes are proposed and justified to credit use of the SLC [Standby Liquid Control] System to buffer suppression pool pH to prevent iodine re-evolution following a postulated design basis loss of coolant accident. There are new required manual operator actions associated with the SLC System that are not currently considered in the SSES design basis. Operator training will be updated to reflect the new manual operator actions for the pH control function of the of the SLC System as defined in the TS Section 3.1.7. These changes are not significant because the operators are already trained for the operation of the SLC System. Procedural changes are mostly limited to the timing of SLC initiation and termination. In addition, no new hardware changes are necessary to use SLC in this new functional mode.

Licensing basis changes are proposed and justified for the operation of the CREOASS [control room emergency outside air supply system] to respond to NRC Generic Letter 2003–01 and TSTF [Technical Specification Task Force] 448. No new hardware changes are necessary to implement these changes. Since CREOASS will not be operated differently as a result of these changes, no new failure modes are created by these changes.

Therefore, the proposed license amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The results of the accident analyses revised in support of the proposed change are subject to the acceptance criteria in 10 CFR 50.67. The analyzed events have been carefully selected, and the analyses supporting these changes have been performed using approved methodologies to ensure that analyzed events are bounding and safety margin has not been reduced. The dose consequences of these limiting events are within the acceptance criteria presented in 10 CFR 50.67, RG 1.183, and SRP 15.0.1. Thus, by meeting the applicable regulatory limits for AST, there is no significant reduction in a margin of safety.

Changes to the SLC System to credit use of the Standby Liquid Control (SLC) System to buffer suppression pool pH to prevent iodine re-evolution and the CREOASS to address NRC Generic Letter 2003–01 and TSTF–448 [to] improve the margin of safety.

New offsite and Control Room atmospheric dispersion factors (χ/Qs) based on site specific meteorological data, calculated in accordance with the guidance of RGs 1.145 and 1.194, utilizes more recent data and improved calculational methodologies.

Therefore, because the proposed changes continue to result in dose consequences within the applicable regulatory limits, the changes are considered to not result in a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bryan A. Snapp, Esquire, Assoc. General Counsel, PPL Services Corporation, 2 North Ninth St., GENTW3, Allentown, PA 18101–1179.

NRC Branch Chief: Richard J. Laufer.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: June 7, 2006.

Description of amendment request: The proposed amendment would delete Technical Specification (TS) 3/4.6.4, ''Combustible Gas Control,'' TS 3/4.6.4.1, ''Hydrogen Analyzers,'' and TS 3/4.6.4.2, ''Electric Hydrogen Recombiners.'' The changes would be consistent with NRC-approved TS Task Force (TSTF) Standard Technical Specification (STS) Change Traveler number TSTF–447, Revision 1, ''Elimination of Hydrogen Recombiners and Change to Hydrogen and Oxygen Monitors,'' as part of the Consolidated Line Item Improvement Process (CLIIP).

The NRC staff issued a notice of availability of ''Model Application Concerning Technical Specification Improvement To Eliminate Hydrogen Recombiner Requirement, and Relax the Hydrogen and Oxygen Monitor Requirements for Light Water Reactors

Using the Consolidated Line Item Improvement Process (CLIIP)'', in the **Federal Register** on September 25, 2003 (68 FR 55416). The notice included a model safety evaluation (SE), a model no significant hazards consideration (NSHC) determination, and a model application.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee presented an analysis of NSHC by endorsing the model NSHC determination for TSTF–447 which was published in the **Federal Register** on September 25, 2003 (68 FR 55416) as follows:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The revised 10 CFR 50.44 no longer defines a design-basis loss-of-coolant accident (LOCA) hydrogen release, and eliminates requirements for hydrogen control systems to mitigate such a release. The installation of hydrogen recombiners and/or vent and purge systems required by 10 CFR 50.44(b)(3) was intended to address the limited quantity and rate of hydrogen generation that was postulated from a design-basis LOCA. The Commission has found that this hydrogen release is not risk-significant because the design basis LOCA hydrogen release does not contribute to the conditional probability of a large release up to approximately 24 hours after the onset of core damage. In addition, these systems were ineffective at mitigating hydrogen releases from risk-significant accident sequences that could threaten containment integrity.

With the elimination of the design basis LOCA hydrogen release, hydrogen monitors are no longer required to mitigate design-basis accidents and, therefore, the hydrogen monitors do not meet the definition of a safety-related component as defined in 10 CFR 50.2. RG [Regulatory Guide] 1.97 Category 1, is intended for key variables that most directly indicate the accomplishment of a safety function for design-basis accident events. The hydrogen monitors no longer meet the definition of Category 1 in RG 1.97. As part of the rulemaking to revise 10 CFR 50.44 the Commission found that Category 3, as defined in RG 1.97, is an appropriate categorization for the hydrogen monitors because the monitors are required to diagnose the course of beyond design-basis accidents.

The regulatory requirements for the hydrogen monitors can be relaxed without degrading the plant emergency response. The emergency response, in this sense, refers to the methodologies used in ascertaining the condition of the reactor core, mitigating the consequences of an accident, assessing and projecting offsite releases of radioactivity, and establishing protective action recommendations to be communicated to offsite authorities. Classification of the hydrogen monitors as Category 3, and removal of the hydrogen monitors from TS will not prevent an accident management strategy through the use of the SAMGs [Severe Accident Management Guidelines], the emergency plan (EP), the emergency operating procedures (EOP), and site survey monitoring that support modification of emergency plan protective action recommendations (PARs).

Therefore, the elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, does not involve a significant increase in the probability or the consequences of any accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated.

The elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, will not result in any failure mode not previously analyzed. The hydrogen recombiner and hydrogen monitor equipment was intended to mitigate a design-basis hydrogen release. The hydrogen recombiner and hydrogen monitor equipment are not considered accident precursors, nor does their existence or elimination have any adverse impact on the pre-accident state of the reactor core or post accident confinement of radionuclides within the containment building.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety.

The elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, in light of existing plant equipment, instrumentation, procedures, and programs that provide effective mitigation of and recovery from reactor accidents, results in a neutral impact to the margin of safety.

The installation of hydrogen recombiners and/or vent and purge systems required by 10 CFR 50.44(b)(3) was intended to address the limited quantity and rate of hydrogen generation that was postulated from a design-basis LOCA. The Commission has found that this hydrogen release is not risk-significant because the design-basis LOCA hydrogen release does not contribute to the conditional probability of a large release up to approximately 24 hours after the onset of core damage. Category 3 hydrogen monitors are adequate to provide rapid assessment of current reactor core conditions and the direction of degradation while effectively responding to the event in order to mitigate the consequences of the accident. The intent of the requirements established as a result of the TMI, Unit 2 accident can be adequately met without reliance on safety-related hydrogen monitors.

Therefore, this change does not involve a significant reduction in the margin of safety. Removal of hydrogen monitoring from TS will not result in a significant reduction in their functionality, reliability, and availability.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Acting Branch Chief: Brooke D. Poole.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the

NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of application for amendment: January 31, 2006, as supplemented by letter dated July 12, 2006.

Brief description of amendment: The amendment changed the technical specifications to address issues related to an inconsistency that was inadvertently introduced during conversion to improved technical specifications when ''1 per room'' replaced ''2'' as the required channels per trip system for the reactor water cleanup area ventilation differential temperature—high isolation function.

Date of issuance: August 7, 2006.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment No.: 173.

Facility Operating License No. NPF–43: Amendment revised the Technical Specifications, Surveillance Requirements, and License.

Date of initial notice in ***Federal Register:*** March 14, 2006 (71 FR 13171). The July 12, 2006, supplement contained clarifying information and did not change the NRC staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 7, 2006.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., et al., Docket No. 50–423, Millstone Power Station, Unit No. 3, New London County, Connecticut

Date of application for amendment: September 13, 2005.

Brief description of amendment: The amendment revised the Millstone Power Station, Unit No. 3 Technical Specification (TSs) temperature requirement for the reactivity control system rod drop time test.

Date of issuance: August 15, 2006.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 231.

Facility Operating License No. NPF–49: The amendment revised the TSs.

Date of initial notice in ***Federal Register:*** October 25, 2005 (70 FR 61656).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 15, 2006.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: May 24, 2005, revised by letter dated May 2, 2006.

Brief description of amendment: The Technical Specification amendment deleted the requirements for NRC approval of the engineering evaluation justifying continued reactor operation with safety relief valve (SRV) discharge pipe temperature exceeding the limit.

Date of issuance: August 4, 2006.

Effective date: As of the date of issuance, and shall be implemented within 90 days.

Amendment No.: 222.

Facility Operating License No. DPR–35: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register:*** August 16, 2005 (70 FR 48205).

The licensee originally requested for deletion of TS 3.6.D.3 in their submittal dated May 24, 2005. The NRC staff found this unacceptable. Therefore, the licensee revised the original application by letter dated May 2, 2006, reducing the scope of the application as originally noticed. Hence, there is no change to the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 4, 2006.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: July 21, 2005, as supplemented on February 15, May 3, and June 2, 2006.

Brief description of amendment: The amendment modified the Waterford 3 Technical Specification (TS) to revise the existing steam generator (SG) tube surveillance program to be consistent with TS Task Force (TSTF) Change TSTF–449, ''Steam Generator Tube Integrity,'' Revision 4, and the model safety evaluation prepared by the NRC and published in the **Federal Register** notice on March 2, 2005 (70 FR 10298). In this regard, the scope of the application includes changes to the definition of leakage, changes to the primary-to-secondary leakage requirements, changes to the SG tube surveillance program, changes to the SG reporting requirements, and associated changes to the TS Bases.

Date of issuance: July 31, 2006.

Effective date: As of the date of issuance and shall be implemented 90 days from the date of issuance.

Amendment No.: 204.

Facility Operating License No. NPF–38: The amendment revised the Technical Specifications and the Facility Operating License.

Date of initial notice in ***Federal Register:*** October 25, 2005 (70 FR 61659). The February 15, May 3, and June 2, 2006, supplemental letters contained additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 31, 2006.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: October 25, 2005.

Brief description of amendment: The amendment modified the Waterford 3 Technical Specification 3.1.1.4, ''Minimum Temperature for Criticality,'' to raise the minimum temperature for criticality from the current value of ≥520 °F to ≥533 °F. Changes were also proposed to the associated Action statement to reflect the increase in temperature and to replace the current statement in Surveillance Requirement 4.1.1.4 with wording consistent with NUREG–1432, ''Standard Technical Specifications—Combustion Engineering Plants.''

Date of issuance: July 31, 2006.

Effective date: As of the date of issuance and shall be implemented 30 days from the date of issuance.

Amendment No.: 205.

Facility Operating License No. NPF–38: The amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** December 6, 2005 (70 FR 72672).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 31, 2006.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit 1, Ottawa County, Ohio

Date of application for amendment: May 5, 2004, as supplemented by letters dated January 17, October 10, and November 2, 2005 and May 30, 2006.

Brief description of amendment: This amendment revised the technical specifications (TSs) for instrumentation setpoints, allowable values, and calibration requirements based on updated calculations and reviews, and add a definition of ''annual'' frequency for use in the TSs.

Date of issuance: August 9, 2006.

Effective date: As of the date of issuance and shall be implemented within 120 days.

Amendment No.: 275.

Facility Operating License No. NPF–3: Amendment revised the Technical Specifications and License.

Date of initial notice in ***Federal Register****:* June 8, 2004 (69 FR 32074). The January 17, October 10, and November 2, 2005 and May 30, 2006, supplements contained clarifying information and did not change the NRC staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 9, 2006.

No significant hazards consideration comments received: No.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Date of application for amendments: January 28, 2005, as supplemented by letter dated January 12, 2006.

Brief description of amendments: The amendment revised Technical Specifications (Tss) 1.1, ''Definitions,'' 3.4, ''Reactor Coolant System [RCS],'' and 5.7, ''Reporting Requirements,'' to relocate the RCS pressure-temperature curves and limits from the TSs to a licensee-controlled document identified as the Pressure and Temperature Limit Report.

Date of issuance: July 13, 2006.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: Unit 2–203; Unit 3–195.

Facility Operating License Nos. NPF–10 and NPF–15: The amendments revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** March 1, 2005 (70 FR 9996). The January 12, 2006, supplemental letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 13, 2006.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of application for amendments: September 19, 2005, as supplemented by letter dated June 9, 2006.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) Limiting Conditions for Operation 3.3.1, ''Reactor Trip System Instrumentation,'' and TS Surveillance Requirement (SR) 3.2.4.2, ''Quadrant Power Tilt Ratio (QPTR).'' The amendments revise TS 3.3.1, Condition D and the note in SR 3.2.4.2 to clarify when a flux map for QTPR is required.

Date of issuance: August 15, 2006.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: 143 and 123.

Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register****:* March 14, 2005 (71 FR 13179). The supplement dated June 9, 2006, provided clarifying information that did not change the scope of the September 19, 2005, application nor the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 15, 2006.

No significant hazards consideration comments received: No.

TXU Generation Company LP, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: August 10, 2005.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) to relocate diesel fuel oil testing methods from TS 5.5.13 to a licensee-controlled document, provided clarifications, and corrected the format and typographical errors.

Date of issuance: July 28, 2006.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: 127 and 127.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Technical Specifications and the Facility Operating Licenses.

Date of initial notice in ***Federal Register****:* November 8, 2005 (70 FR 67754).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 28, 2006.

No significant hazards consideration comments received: No.

Virginia Electric and Power Company, et al., Docket Nos. 50–280 and 50–281, Surry Power Station, Units 1 and 2, Surry County, Virginia

Date of application for amendments: September 13, 2005, as supplemented on April 7 and May 23, 2006.

Brief Description of amendments: These amendments revised Technical Specification 5.1, ''Site,'' to redefine the exclusion area boundary as the site boundary.

Date of issuance: August 10, 2006.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment Nos.: 249, 248.

Renewed Facility Operating License Nos. DPR–32 and DPR–37: Amendments changed the licenses and the technical specifications.

Date of initial notice in ***Federal Register:*** January 3, 2006 (71 FR 156). The April 7 and May 23, 2006, supplements contained clarifying information only and did not change the initial proposed no significant hazards consideration determination or expand the scope of the initial application.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 10, 2006.

No significant hazards consideration comments received: No.

Notice of Issuance of Amendments to Facility Operating Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the

standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual Notice of Consideration of Issuance of Amendment, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible 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.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendment. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland, and electronically on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If there are problems in accessing the document, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737, or by e-mail to *pdr@nrc.gov.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a

material issue of law or fact.[1] Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Each contention shall be given a separate numeric or alpha designation within one of the following groups:

1. Technical—primarily concerns/issues relating to technical and/or health and safety matters discussed or referenced in the applications.

2. Environmental—primarily concerns/issues relating to matters discussed or referenced in the environmental analysis for the applications.

3. Miscellaneous—does not fall into one of the categories outlined above.

As specified in 10 CFR 2.309, if two or more petitioners/requestors seek to co-sponsor a contention, the petitioners/requestors shall jointly designate a representative who shall have the authority to act for the petitioners/requestors with respect to that contention. If a petitioner/requestor seeks to adopt the contention of another sponsoring petitioner/requestor, the petitioner/requestor who seeks to adopt the contention must either agree that the sponsoring petitioner/requestor shall act as the representative with respect to that contention, or jointly designate with the sponsoring petitioner/requestor a representative who shall have the authority to act for the petitioners/requestors with respect to that contention.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing. Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HearingDocket@nrc.gov;* or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to (301) 415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer or the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

Entergy Nuclear Operations, Inc., Docket No. 50–247, Indian Point Nuclear Generating Unit No. 2, Westchester County, New York

Date of amendment request: July 26, 2006.

Description of amendment request: The amendment revised Function 6 [Containment Water Level (Containment Sump)] of Table 3.3.3–1 (''Post Accident Monitoring Instrumentation''), referenced in the Technical Specification (TS) Limiting Condition for Operation (LCO) 3.3.3, ''Post Accident Monitoring Instrumentation.'' The revision changed Function 6 to specify 2 required channels for the Containment Sump water level instrumentation instead of 3 channels.

Date of issuance: July 28, 2006.

Effective date: As of its date of issuance, and shall be implemented prior to the expiration of the current 7-day allowed outage time for inoperable containment sump water level channels, which was entered on July 24, 2006.

Amendment No.: 249.

Facility Operating License No. DPR–26: The amendment revised the TS and License.

Public comments requested as to proposed no significant hazards consideration (NSHC): No. The Commission's related evaluation of the amendment, finding of emergency circumstances, state consultation, and final NSHC determination are contained in a Safety Evaluation dated July 28, 2006.

Attorney for licensee: Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

NRC Branch Chief: Richard J. Laufer.

Dated at Rockville, Maryland, this 21st day of August 2006.

For the Nuclear Regulatory Commission.

Cornelius F. Holden,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 06–7137 Filed 8–28–06; 8:45 am]

BILLING CODE 7590–01–P

[1] To the extent that the applications contain attachments and supporting documents that are not publicly available because they are asserted to contain safeguards or proprietary information, petitioners desiring access to this information should contact the applicant or applicant's counsel and discuss the need for a protective order.

POSTAL RATE COMMISSION

Sunshine Act Meetings

NAME OF AGENCY: Postal Rate Commission.

TIME AND DATE: Monday, August 28, 2006, at 3 p.m.

PLACE: Commission conference room, 901 New York Avenue, NW., Suite 200, Washington, DC 20268–0001.

STATUS: Open.

*Matters to be Considered***:** Consideration of fiscal year 2007 budget and election of vice chairman.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

Dated: August 24, 2006.

Steven W. Williams,

Secretary.

[FR Doc. 06–7234 Filed 8–24–06; 4:37 pm]

BILLING CODE 7710–FW–M

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is

necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Voluntary Customer Surveys in Accordance with Executive Order 12862; OMB 3220–0192. In accordance with Executive Order 12862, the Railroad Retirement Board (RRB) conducts a number of customer surveys designed to determine the kinds and quality of services our beneficiaries, claimants, employers and members of the public want and expect, as well as their satisfaction with existing RRB services. The information collected is used by RRB management to monitor customer satisfaction by determining to what extent services are satisfactory and where and to what extent services can be improved. The surveys are limited to data collections that solicit strictly voluntary opinions, and do not collect information which is required or regulated. The information collection, which was first approved by the Office of Management and Budget (OMB) in 1997, provides the RRB with a generic clearance authority. This generic authority allows the RRB to submit a variety of new or revised customer survey instruments (needed to timely implement customer monitoring activities) to the Office of Management and Budget (OMB) for expedited review and approval.

The average burden per response for customer satisfaction activities is estimated to range from 2 minutes for a web-site questionnaire to 2 hours for participation in a focus group. The RRB estimates an annual burden of 1,750 annual respondents totaling 717 hours for the generic customer survey clearance.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justifications, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to *Charles.Mierzwa@RRB.GOV.* Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092 or send an E-mail to *Ronald.Hodapp@RRB.GOV.* Comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. E6–14265 Filed 8–28–06; 8:45 am]

BILLING CODE 7905–01–P

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:

Rule 17g–1; SEC File No. 270–208; OMB Control No. 3235–0213.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 17g–1 (17 CFR 270.17g–1) under the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a–17(g)) governs the fidelity bonding of officers and employees of registered management investment companies (''funds'') and their advisers. Rule 17g–1 requires, in part, the following:

Independent Directors' Approval

The form and amount of the fidelity bond must be approved by a majority of the fund's independent directors at least once annually, and the amount of any premium paid by the fund for any ''joint insured bond,'' covering multiple funds or certain affiliates, must be approved by a majority of the fund's independent directors.

Terms and Provisions of the Bond

The amount of the bond may not be less than the minimum amounts of coverage set forth in a schedule based on the fund's gross assets; the bond must provide that it shall not be cancelled, terminated, or modified except upon 60-days written notice to the affected party and to the Commission; in the case of a joint insured bond, 60-days written notice must also be given to each fund covered by the bond; a joint insured bond must provide that the fidelity insurance company will provide all funds covered by the bond with a copy of the agreement, a copy of any claim on the bond, and notification of the terms of the settlement of any claim prior to execution of that settlement; and a fund that is insured by a joint bond must enter into an agreement with all other parties insured by the joint bond regarding recovery under the bond.

Filings With the Commission

Upon the execution of a fidelity bond or any amendment thereto, a fund must file with the Commission within 10 days a copy of the executed bond or any amendment to the bond, the independent directors' resolution approving the bond, and a statement as to the period for which premiums have been paid on the bond. In the case of a joint insured bond, a fund must also file (i) A statement showing the amount the fund would have been required to maintain under the rule if it were insured under a single insured bond and (ii) the agreement between the fund and all other insured parties regarding recovery under the bond. A fund must also notify the Commission in writing within five days of any claim or settlement on a claim under the fidelity bond.

Notices to Directors

A fund must notify by registered mail each member of its board of directors of (i) Any cancellation, termination, or modification of the fidelity bond at least 45 days prior to the effective date, and (ii) the filing or settlement of any claim under the fidelity bond when notification is filed with the Commission.

Rule 17g–1's independent directors' annual review requirements, fidelity bond content requirements, joint bond agreement requirement and the required notices to directors are designed to ensure the safety of fund assets against losses due to the conduct of persons who may obtain access to those assets. These requirements also facilitate oversight of a fund's fidelity bond. The rule's required filings with the Commission are designed to assist the Commission in monitoring funds' compliance with the fidelity bond requirements.

The Commission staff estimates that approximately 4033 funds are subject to the requirements of Rule 17g–1, and that on average a fund spends approximately one hour per year complying with the rule's paperwork requirements. The Commission staff therefore estimates the total annual burden of the rule's paperwork requirements to be 4033 hours.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These

estimates are not derived from a comprehensive or even a representative survey or study of Commission rules. The collection of information required by Rule 17g–1 is mandatory and 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_Roster@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312, or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: August 20, 2006.

Nancy M. Morris,

Secretary.

[FR Doc. E6–14298 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

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:

Rule 23c–1; SEC File No. 270–253; OMB Control No. 3235–0260

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 23c–1 (17 CFR 270.23c–1) under the Investment Company Act of 1940 (15 U.S.C. 80a), among other things, permits a closed-end fund to repurchase its securities for cash if in addition to the other requirements set forth in the rule: (i) Payment of the purchase price is accompanied or preceded by a written confirmation of the purchase; (ii) the asset coverage per unit of the security to be purchased is disclosed to the seller or his agent; and (iii) if the security is a stock, the fund has, within the preceding six months, informed stockholders of its intention to purchase stock. Commission staff estimates that approximately 14 closed-end funds rely on Rule 23c–1 annually to undertake approximately 122 repurchases of their securities. Commission staff estimates that, on average, a fund spends 2.5 hours to comply with the paperwork requirements listed above each time it undertakes a security repurchase under the rule. Commission staff thus estimates the total annual burden of the rule's paperwork requirements is 305 hours.

In addition, the fund must file with the Commission a copy of any written solicitation to purchase securities given by or on behalf of the fund to 10 or more persons. The copy must be filed as an exhibit to Form N–CSR (17 CFR 249.331 and 274.128). The burden associated with filing Form N–CSR is addressed in the submission related to that form.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Complying with the collection of information requirements of the rule is mandatory. The filings that the rule requires to be made with the Commission are available to the public. 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 to 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; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312, or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

August 21, 2006.

Nancy M. Morris,

Secretary.

[FR Doc. E6–14299 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54343; File No. 4–429]

Joint Industry Plan; Order Approving Joint Amendment No. 19 to the Intermarket Option Linkage Plan To Modify the Manner in Which the Fee Applicable to New Participants Is Calculated

August 21, 2006.

I. Introduction

On February 17, 2006, March 16, 2006, April 12, 2006, April 18, 2006, May 2, 2006, and May 22, 2006, International Securities Exchange, Inc. (''ISE''), Philadelphia Stock Exchange, Inc. (''Phlx''), Chicago Board Options Exchange, Incorporated (''CBOE''), Boston Stock Exchange, Inc. (''BSE''), American Stock Exchange LLC (''Amex''), and NYSE Arca, Inc. (collectively, ''Participants'') [1] respectively submitted to the Securities and Exchange Commission (''Commission'') Joint Amendment No. 19 to the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (the ''Linkage Plan'') pursuant to Section 11A of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 608 of Regulation NMS.[3] In the Joint Amendment, the Participants propose to modify the manner in which the fee applicable to new Participants is calculated.[4] The proposed Joint Amendment was published in the **Federal Register** on June 22, 2006.[5] No comments were received on the proposal. This order approves Joint Amendment No. 19 to the Linkage Plan.

II. Description and Purpose of the Amendment

The purpose of Joint Amendment No. 19 is to modify the manner in which the

[1] A ''Participant'' is an Eligible Exchange whose participation in the Linkage Plan has become effective pursuant to Section 4(c) of the Linkage Plan. *See* Section 2(24) of the Linkage Plan.

[2] 15 U.S.C. 78k–1.

[3] 17 CFR 242.608. On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket options market linkage proposed by the Amex, CBOE, and ISE. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon separate requests by the Phlx, Pacific Exchange, Inc. (n/k/a NYSE Arca, 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 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* Section 11(b) of the Linkage Plan.

[5] *See* Securities Exchange Act Release No. 54001 (June 15, 2006), 71 FR 35960.

fee applicable to new Participants is calculated. The participation fee is determined by the Participants and is assessed in connection with an Eligible Exchange [6] becoming a new Participant. The Joint Amendment provides that in determining the amount of the participation fee, the Participants shall consider one or both of the following: (i) The portion of costs previously paid by the Participants for the development, expansion, and maintenance of Linkage [7] facilities which, under generally accepted accounting principles, could have been treated as capital expenditures and, if so treated, would have been amortized over the five years preceding the admission of the new Participant (and for this purpose all such capital expenditures shall be deemed to have a five-year amortizable life); and (ii) previous participation fees paid by other new Participants. These standards are substantially consistent with the participation fee standards contained in the Consolidated Tape Association / Consolidated Quotation Plans (''CTA/CQ Plans'').[8] Further, the Participants would no longer be required to calculate the participation fee at least once a year. Instead, the participation fee would be calculated at the time an Eligible Exchange seeks to become a Participant.

III. Discussion

After careful consideration, the Commission finds that the proposed Joint Amendment to the Linkage Plan is consistent with the requirements of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the proposed Joint Amendment is consistent with Section 11A of the Act and Rule 608 thereunder, in that the revised participation fee calculation methodology appears reasonably designed to provide specific, objective factors for determining entrance fees for new Participants. The Commission also believes that the proposed new standards, if appropriately employed by the Participants, should foster a fair and reasonable method for determining a Linkage participation fee amount.[9] In making this finding the Commission notes that the proposal prescribes participation fee standards that are substantially similar to those standards already in place on the CTA/CQ Plans.[10]

IV. Conclusion

It is therefore ordered, pursuant to Section 11A of the Act [11] and Rule 608 thereunder,[12] that proposed Joint Amendment No. 19 to the Linkage Plan is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14277 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[6] *See* Section 2(6) of the Linkage Plan.

[7] *See* Section 2(14) of the Linkage Plan.

[8] *See* Section III(c)(2) of the CTA Plan.

[9] The Commission notes that the amount of the participation fee would be determined in discussions among the Participants and each Eligible Exchange seeking to become a Participant in light of the participation fee standards enumerated in the Linkage Plan.

[10] *See* Section III(c)(2) of the CTA Plan. *See* Securities Exchange Act Release No. 51391 (March 17, 2005), 70 FR 15132 (March 24, 2005) (SR–CTA/CQ–2004–01) (Order approving amendment to the CTA/CQ Plans implementing new participant fees).

[11] 15 U.S.C. 78k–1.

[12] 17 CFR 242.608.

[13] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54352, File No. 4–518]

Joint Industry Plan; Order Approving Amendment To Add the Nasdaq Stock Market LLC as Participant to National Market System Plan Establishing Procedures Under Rule 605 of Regulation NMS

August 23, 2006.

I. Introduction

On April 11, 2006, The Nasdaq Stock Market LLC (''Nasdaq'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission'') in accordance with Section 11A of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 608 of Regulation NMS,[2] a proposed amendment to the national market system plan establishing procedures under Rule 605 of Regulation NMS (''Joint-SRO Plan'' or ''Plan'').[3] Under the proposed amendment, Nasdaq would be added as a participant to the Joint-SRO Plan. Notice of filing and an order granting temporary effectiveness of the proposal through August 25, 2006 was published in the **Federal Register** on April 27, 2006.[4] The Commission did not receive any comments on the proposed amendment. This order approves the amendment on a permanent basis.

II. Discussion

The Joint-SRO Plan establishes procedures for market centers to follow in making their monthly reports required pursuant to Rule 605 of Regulation NMS, available to the public in a uniform, readily accessible, and usable electronic format. The current participants to the Joint-SRO Plan are the American Stock Exchange LLC, Boston Stock Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., Cincinnati Stock Exchange, Inc. (n/k/a National Stock Exchange℠), National Association of Securities Dealers, Inc., New York Stock Exchange, Inc. (n/k/a New York Stock Exchange LLC), Pacific Exchange, Inc. (n/k/a NYSE Arca, Inc.), and Philadelphia Stock Exchange, Inc. The proposed amendment would add Nasdaq as a participant to the Joint-SRO Plan.

Section III(b) of the Joint-SRO Plan provides that a national securities exchange or national securities association may become a party to the Plan by: (i) executing a copy of the Plan, as then in effect (with the only changes being the addition of the new participant's name in Section II(a) of the Plan and the new participant's single-digit code in Section VI(a)(1) of the Plan) and (ii) submitting such executed plan to the Commission for approval. Nasdaq submitted a signed copy of the Joint-SRO Plan to the Commission in accordance with the procedures set forth in the Plan regarding new participants.

The Commission finds that the amendment to the Joint-SRO Plan is consistent with the requirements of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the proposed amendment is consistent with the requirements of Section 11A of the Act,[5] and Rule 608 of Regulation NMS.[6] The Plan established appropriate procedures for market centers to follow in making their monthly reports required pursuant to Rule 605 of Regulation NMS available to the public in a uniform, readily accessible, and usable electronic format. The amendment to include Nasdaq as a participant in the Joint-SRO Plan should contribute to the maintenance of fair and orderly markets and remove impediments to and perfect the mechanisms of a national market system

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] 17 CFR 242.605. On April 12, 2001, the Commission approved a national market system plan for the purpose of establishing procedures for market centers to follow in making their monthly reports available to the public under Rule 11Ac1–5 under the Act (n/k/a Rule 605 of Regulation NMS). *See* Securities Exchange Act Release No. 44177 (April 12, 2001), 66 FR 19814 (April 17, 2001).

[4] *See* Securities Exchange Act Release No. 53691 (April 20, 2006), 71 FR 24875.

[5] 15 U.S.C. 78k–1.

[6] 17 CFR 242.608.

by facilitating the uniform public disclosure of order execution information by all market centers. The Commission believes that it is necessary and appropriate in the public interest, for the maintenance of fair and orderly markets, to remove impediments to, and perfect mechanisms of, a national market system to allow Nasdaq to become a participant in the Joint-SRO Plan. The Commission finds, therefore, that approving the amendment to the Joint-SRO Plan is appropriate and consistent with Section 11A of the Act.[7]

III. Conclusion

It is therefore ordered, pursuant to Section 11A(a)(3)(B) of the Act[8] and Rule 608 of Regulation NMS,[9] that the amendment to the Joint-SRO Plan to add Nasdaq as a participant is approved and Nasdaq is authorized to act jointly with the other participants to the Joint-SRO Plan in planning, developing, operating, or regulating the Plan as a means of facilitating a national market system.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14309 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54340; File No. SR–ISE–2006–40]

Self-Regulatory Organizations; International Securities Exchange, Inc.; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto Relating to the Establishment of the Second Market

August 21, 2006.

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 July 5, 2006, 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 August 16, 2006, ISE filed 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 ISE is proposing to adopt Second Market rules for the listing and trading of low-volume options classes. The text of the proposed rule change, as amended, is available on the ISE's Web site (*http://www.iseoptions.com*), at the principal office of the ISE, 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 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 ISE 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 ISE currently trades options on approximately 900 equity securities that qualify for options trading pursuant to the listing standards contained in ISE Rule 502. The listing standards for underlying securities are uniform across all of the options exchanges, and there are many additional underlying equity securities that qualify for options trading under these standards which the ISE does not currently list for trading, but are traded on one or more of the other options exchanges. In general, the Exchange has chosen not to list and trade these options classes based on the low average daily trading volume (''ADV'') they have on the other options exchanges. The purpose of this proposal is to adopt rules for the listing and trading of these low-volume options classes that qualify for listing under ISE Rule 502 in a ''Second Market.'' Establishing the Second Market would allow the Exchange to provide an opportunity for additional members to provide liquidity as market makers, and to apply a modified fee structure to this segment of the options market.

Under the proposal, the Exchange would initially list eligible equity options classes (excluding options on exchange traded funds) that trade on another options exchange and that have an ADV below 500 contracts over a six-month period in the Second Market and those with an ADV of over 1500 contracts in the existing market (the ''First Market''). The proposed rules allow the Exchange to list such options classes with an ADV between 500 and 1500 contracts initially in either market, which is necessary to take into account other factors to ensure that options classes are placed in the appropriate market (*e.g.*, whether the volume trend over the six-month period is up or down, or whether the underlying security is going to be or has been part of a corporate action). Starting one year after the Second Market initiates trading,[4] the Exchange would review the market in which options classes are listed every three months, and options classes would be moved from the First to the Second Market when their ADV in the prior six-month period falls below 300 contracts,[5] and moved from the Second to the First Market when their ADV in the prior six-month period exceeds 750 contracts.

Under the proposal, all members approved to operate ISE market maker memberships would be eligible to be Competitive Market Makers in the Second Market. In addition, members that are only approved as Electronic Access Members may also register as Competitive Market Makers in the Second Market,[6] but would pay a $0.10 transaction surcharge over those market makers that own or lease ISE market maker memberships. The Exchange believes that providing greater access to

[7] 15 U.S.C. 78k–1.

[8] 15 U.S.C. 78k–1(a)(3)(B).

[9] 17 CFR 242.608.

[10] 17 CFR 200.30–3(a)(29).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaces and supersedes the original filing in its entirety.

[4] Initially, the Exchange intends to add options classes to the Second Market over several months. The Exchange believes it is important to provide participants in the Second Market a period of continuity in Second Market products before moving options between the First Market and Second Market. Therefore, if for example, the Exchange were to initiate trading in September 2006, it would not conduct the first review to move options classes from the First Market to the Second Market, and vise versa, until September 2007. The first review would look at the industry ADV of each options class over the previous 6 months. Three months later, the Exchange would again review the industry ADV of each options class over the previous 6 months, and repeat this same review every three months thereafter.

[5] Such options classes would remain in the Second Market for at least twelve (12) months before being returned to the First Market.

[6] Under proposed ISE Rule 902, members that are only Electronic Access Members that want to become Competitive Market Makers in the Second Market would be required to complete the same market maker application and meet the same standards that are applied to Competitive Market Makers under the Exchange's existing rules. Members that are only Electronic Access Members are not eligible to be Primary Market Makers in the Second Market.

make markets in the Second Market would help it attract additional liquidity for these low-volume options classes from firms that do not currently participate on the ISE as market makers, while assuring that such market makers do not have an inappropriate cost advantage over market makers that have purchased or leased ISE market maker memberships. Only Primary Market Makers in the First Market may be Primary Market Makers in the Second Market. All market makers would pay the same $2,000 monthly access fee for the right to quote in the Second Market.

Market making requirements in the Second Market would be mostly the same as those currently applied in the First Market. As in the First Market, a Primary Market Maker would be appointed for each class traded in the Second Market (''SMPMMs''). SMPMMs would have all of the same obligations in their appointed options as Primary Market Makers in the First Market, including, among other things, entering continuous quotations in all of the series of all of the options classes to which they are appointed and satisfying requirements related to the Plan for Creating and Operating an Intermarket Option Linkage. Competitive Market Makers in the Second Market (''SMCMMs'') would be considered ''appointed'' to all of the options classes listed in the Second Market and, among other things, must continuously quote all of the series of any options class in which they choose to make markets.[7] An SMCMM would be able to choose whether to make markets in one or more Second Market options classes on a daily basis. SMCMMs would be permitted to quote in all of the options classes listed in the Second Market, but would not be required to quote a minimum number of Second Market options. Accordingly, SMCMMs would be able to choose to make markets in as many or as few options classes as they wish. Finally, SMPMMs and SMCMMs would be permitted to execute a limited percentage of their volume in Second Market options in which they are not currently making markets.[8]

The Exchange proposes several changes to its fee schedule for the Second Market as follows: (1) Members would be charged an execution fee of $.05 per contract for public customer orders; (2) a $.10 per contract surcharge would be applied to transactions executed by market makers that do not own or lease an ISE market maker membership (*i.e.*, Electronic Access Members that make markets in the Second Market); (3) Second Market options would be excluded from the payment for order flow fee; (4) market makers would be charged a $2,000 per month access fee (there would be no additional access fee for Electronic Access Members to send orders to the Second Market); and (5) firms that are only market makers in the Second Market (*i.e.*, Electronic Access Members that make markets in the Second Market) would be charged the same $5,000 annual regulatory fee paid by Competitive Market Makers in the First Market.

2. Statutory Basis

The Exchange believes that the basis under the Act for this proposed rule change is the requirement under Section 6(b)(4)[9] that an exchange have an equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities, and the requirement under Section 6(b)(5)[10] that an exchange have rules that are 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 for a free and open market and a national market system, and, in general, to protect investors and the public interest. In particular, the proposal is designed to attract liquidity in low-volume options classes by providing for open access to market makers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

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 Exchange 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 amended proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–ISE–2006–40 on the subject line.

[7] In the First Market, Competitive Market Makers are appointed to a group of options, but are only required to enter continuous quotes in a minimum number of those appointed options pursuant to ISE Rule 804(e)(2). Similarly in the Second Market, SMCMMs would be considered appointed to all of the Second Market options, but would not be required to enter continuous quotations in a minimum number of Second Market options classes. Therefore, in both the First and the Second Markets, there may be options classes to which a Competitive Market Maker is appointed for which it is not making markets. Other ISE rules regarding obligations and requirements related to market maker quotations in appointed options, such as ISE Rule 803(b), currently are (and would be) applicable only when a Competitive Market Maker is quoting in an appointed option and do not create an obligation for Competitive Market Makers to continuously quote all appointed options classes. Other than the minimum quotation requirement for Competitive Market Makers in the First Market, the rules applicable to Competitive Market Makers in the First Market and the Second Market for options classes in which they are appointed would be the same. Because SMCMMs would be appointed to all options classes in the Second Market, the rules applicable to Competitive Market Makers in the First Market in options classes to which they are not appointed would not apply to SMCMMs (*i.e.*, ISE Rule 805(b)).

[8] As explained in note 7 above, ISE Rule 805(b) regarding options classes in which a Competitive Market Maker in the First Market is not appointed would not apply to SMCMMs. The Rule permits such Competitive Market Makers to enter orders in options classes to which they are not appointed, limited to 25% of their total volume. Since SMCMMs would be considered appointed to all of the options classes in the Second Market, the Exchange proposes to adopt a parallel rule to ISE Rule 805(b) for SMCMMs that allows them to enter orders in options classes in which they *are not currently making markets* (as opposed to in which they are not appointed), limited to 25% of their total volume. The proposed rule specifies that SMCMMs may only enter orders in options classes that they are not quoting when the SMCMMs are making markets in at least one options class. If a SMCMM chooses not to make markets in any Second Market options classes on a particular day, it would not be permitted to enter any orders in Second Market options.

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f(b)(5).

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2006–40. 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 ISE. 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–ISE–2006–40 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14273 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54347; File No. SR–CBOE–2006–72]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Extension of the Pilot Period Applicable to CBOE's Listing and Trading of Options on the iShares MSCI Emerging Markets Index Fund

August 22, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 21, 2006, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed this 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 renders the proposed rule change effective upon filing with the commission.[5] 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 Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') proposes to extend the pilot period applicable to CBOE's listing and trading of options on the iShares MSCI Emerging Markets Index Fund (''Fund Options''). CBOE is not proposing any textual changes to the rules of CBOE. The text of the proposed rule change is available on the Exchange's website (*http://www.cboe.com*), the Office of the Secretary, CBOE, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange requested the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay, as specified in Rule 19b–4(f)(6)(iii). 17 CFR 240.19b–4(f)(6)(iii).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On April 10, 2006, the Securities and Exchange Commission (''Commission'') approved a CBOE proposal (SR–CBOE–2006–32) to list and trade Fund Options.[6] SR–CBOE–2006–32 was approved for a sixty-day pilot period that was due to expire on June 9, 2006 (''Pilot''). On May 31, 2006, CBOE filed SR–CBOE–2006–56 which extended the Pilot for an additional 90 days, until September 7, 2006.[7]

The Fund Options will continue to meet substantially all of the listing and maintenance standards in CBOE Rules 5.3.06 and 5.4.08, respectively. For the requirements that are not met, the Exchange continues to represent that sufficient mechanisms exist that would provide the Exchange with adequate surveillance and regulatory information with respect to the Fund. Continuation of the Pilot would permit the Exchange to continue to work with the Bolsa Mexicana de Valores (''Bolsa'') to develop a surveillance sharing agreement.[8]

CBOE now proposes to extend the Pilot for an additional 90 days, until December 7, 2006.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the

[6] *See* Securities Exchange Act Release No. 53621 (April 10, 2006), 71 FR 19568 (April 14, 2006) (SR–CBOE–2006–32).

[7] *See* Securities Exchange Act Release No. 53930 (June 1, 2006), 71 FR 33322 (June 8, 2006) (granting immediate effectiveness to SR–CBOE–2006–56).

[8] Telephone conference between Patrick Sexton, Associate General Counsel, Exchange and Geoffrey Pemble, Special Counsel, Division of Market Regulation, Commission, on August 22, 2006.

Act [9]. Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) Act [10] 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

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder [12] because the 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 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest pursuant to Section 19(b)(3)(A) of the Act [13] and Rule 19b–4(f)(6) [14] thereunder.

The Exchange has requested that the Commission waive the five-day pre-filing notice requirement and the 30-day operative delay.[15] The Commission is exercising its authority to waive the five-day pre-filing notice requirement and believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Waiver of the five-day pre-filing and 30-day operative periods will extend the Pilot, which would otherwise expire on September 7, 2006, and allow the Exchange to continue in its efforts to obtain a surveillance agreement with the Bolsa. Accordingly, the Commission designates the proposal to be effective and operative upon filing with the Commission.[16]

At any time within 60 days of the filing of the proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in the 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–2006–72 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2006–72. 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, 100 F Street, NE, Washington, DC 20549–1090. 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–2006–72 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14274 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] 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).

[17] CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54354; File No. SR–Amex–2006–73]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Clarify the Applicability of Certain Rules to Securities Also Listed on the Nasdaq Capital Market and the Nasdaq Global Market

August 23, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 9, 2006, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Amex. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b-4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission.[5] 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 Amex proposes minor, technical changes to Rules 7 (Commentary .02), 24, 109 (Commentary .02), 115

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Amex asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. *See* Rule 19b 4(f)(6)(iii). 17 CFR 240.19b-4(f)(6)(iii).

(Commentary .01), 118, 131 (Commentary .02), 131A, 156 (Commentary .01), 170 (Commentary .11), 190 (Commentary .06) and 1301 and Section 142 of the Company Guide to clarify the applicability of such rules to securities that are also listed on the Nasdaq Capital Market (''NCM'') and the Nasdaq Global Market (formerly referred to as the Nasdaq National Market,[6] ''NGM'') (NCM and NGM are collectively referred to as ''Nasdaq.'') The text of the proposed rule change is available at the Amex, at the Commission's Public Reference Room, and at *www.amex.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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

On May 9, 2006, the Commission approved a proposed rule change by the Exchange that reduced the initial and annual listing fees for companies listed on another securities market that dual list on the Amex and made appropriate rule changes to accommodate the listing and trading of Nasdaq securities on the Amex.[7] Specifically, the Exchange expanded the scope of Rule 118 to include the trading of (i) NCM securities, in addition to NGM securities, pursuant to unlisted trading privileges (''UTP'') and (ii) Nasdaq securities that are listed on the Amex. As a result, the following provisions which were previously only applicable to NGM securities traded on a UTP basis on the Amex now cover NCM securities traded on a UTP basis on the Amex and Nasdaq securities with dual listings on the Amex: Rule 1 (Commentary .05); Rule 3; Rule 7 (Commentary .02); Rule 24; Rule 109 (Commentary .02); Rule 115 (Commentary .01); Rule 118; Rule 126 (Commentary .06); Rule 128A; Rule 131 (Commentaries .02 and .03); Rule 131A; Rule 135A; Rule 156 (Commentary .01); Rule 170 (Commentary .11); Rule 175; Rule 190 (Commentary .06); Rule 205 (Commentary .05); Rule 1301; and Section 142 of the Company Guide.

The purpose of this filing is to make minor changes to certain of the above provisions to make explicit their applicability to both Nasdaq securities traded on the Amex on a UTP basis and Nasdaq securities with dual listings on the Amex. Specifically, the Exchange proposes deleting the phrase ''pursuant to unlisted trading privileges'' following the defined term ''Nasdaq securities'' and, where appropriate, to add a reference to Rule 118. Furthermore, the Exchange proposes augmenting the references in Commentary .01 to Rule 118 to include all of the rules applicable to trading in Nasdaq securities. The Exchange believes that the proposed rule change will clearly identify the Amex rules that should be consulted by members and member organizations trading Nasdaq securities on the Amex.

2. Statutory Basis

The Amex believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 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; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by the Act matters not related to the purpose of the Act or the administration of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

Amex believes the proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

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.

The Amex has requested that the Commission waive the five-day pre-filing notice requirement and the 30-day operative delay contained in Rule 19b-4(f)(6)(iii) under the Act.[12] Because the proposed rule change raises no novel issues, and serves to clarify the applicability of certain rules to securities that are also listed on the Nasdaq Capital Market and the Nasdaq Global Market, the Commission believes such waiver is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposal to be effective and operative upon filing with the Commission.[13]

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:

[6] *See* Securities Exchange Act Release No. 54071 (June 29, 2006), 71 (June 29, 2006,) 71 FR 38922 (July 10, 2006)(SR–NASD–2006–068).

[7] Securities Exchange Act Release No. 53778 (May 9, 2006), 71 FR 28057 (May 15, 2006) (SR–Amex–2005–125).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b 4(f)(6)(iii).

[13] 13 For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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–2006–73 on the subject line.

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2006–73. 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 Amex. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2006–73 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14301 Filed 8–28–06; 8:45 am]

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[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54351; File No. SR–Amex–2006–44]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing of a Proposed Rule Change and Amendments No. 1 and 2 Thereto Relating to the Listing and Trading of the DB Currency Index Value Fund

August 23, 2006.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 2, 2006, 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 Amex. On July 31, 2006, Amex filed Amendment No. 1 to the proposed rule change.[3] On August 18, 2006, Amex filed Amendment No. 2 to the proposed rule change.[4] 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

Pursuant to Commentary .07 to Amex Rule 1202, which permits the listing and trading of shares of trust issued receipts (''TIRs'') that invest in shares or securities (the ''Investment Shares'') of a trust, partnership, commodity pool or other similar entity that holds investments comprising, or otherwise based on, any combination of securities, futures contracts, swaps, forward contracts, options on futures contracts, commodities or portfolios of investments, the Exchange seeks to list and trade the DB Currency Index Value Fund (the ''Trust'' or ''Fund''). In connection with the proposal, Amex also seeks to amend Commentary .02 to Amex Rule 1200. The text of the proposed rule change, as amended, is below. Proposed new language is in *italics*.

* * * * *

Rules of General Applicability

Amex Rule 1200

(a) No Change.
(b) No Change.

* * * Commentary

.01 No Change.
.02 Transactions in Trust Issues Receipts may be effected until 4 p.m. *or 4:15 p.m.* each business day.
.03 No Change.

* * * * *

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, and the most significant aspects of such statements are set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Introduction

Pursuant to Commentary .07 to Amex Rule 1202, the Exchange may approve for listing and trading TIRs investing in Investment Shares that hold investments in any combination of securities, futures contracts, options on futures contracts, swaps, forward contracts, commodities, or portfolios of investments. The Amex proposes to list for trading the shares of the Fund (the ''Shares''), which represent beneficial ownership interests in the Fund's net assets, consisting solely of the common units of beneficial interests of DB Currency Index Value Master Fund (the ''Master Fund''). The Master Fund is a statutory trust created under Delaware law whose investment portfolio will consist primarily of futures contracts on the currencies comprising the Deutsche Bank G10 Currency Future Harvest Index™—Excess Return (the ''DBCHI'' or ''Index'') and securities for margin purposes. Both the Fund and the Master Fund will be commodity pools operated by DB Commodity Services LLC (the ''Managing Owner''). The Managing Owner is registered as a commodity

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, Amex made clarifying changes to the proposal regarding the index methodology, the structure of the Fund, and the dissemination of information relating to the Index and Fund. In Amendment No. 1, the Exchange also amended Commentary .02 to Amex Rule 1200 to conform to Amex's current trading hours.

[4] In Amendment No. 2, Amex made additional clarifying changes to the proposal, including among others, details regarding the dissemination of the Index value, intraday indicative value, and net asset value of the Investment Shares.

pool operator (the ''CPO'') and commodity trading advisor (the ''CTA'') with the Commodity Futures Trading Commission (''CFTC'') and is a member of the National Futures Association (''NFA'').

The Managing Owner will serve as the CPO and CTA of the Fund and the Master Fund. For the Master Fund, the Managing Owner will manage the futures contracts with the investment objective of tracking the performance of the Index over time.[5] The Master Fund will hold a portfolio of both long and short futures contracts with a notional value to equity ratio of approximately two to one (2:1)[6] on the currencies that comprise the Index (the ''Index Currencies'') and will include cash and U.S. Treasury securities for margin purposes and other high credit quality short-term fixed income securities. The Master Fund will not engage in borrowing. The Managing Owner will manage the Master Fund by making adjustments to the portfolio on a quarterly basis to conform to periodic changes in the composition and relative weightings of the Index Currencies. The Managing Owner may also make certain adjustments or changes to the portfolio more frequently in the case of significant changes in the foreign currency markets due to volatility.

The Exchange submits that Commentary .07 to Amex Rule 1202 accommodates the listing and trading of the Shares.

Under Commentary .07(c) to Amex Rule 1202, the Exchange may list and trade TIRs investing in Investment Shares such as the Shares. The Shares will conform to the initial and continued listing criteria under Commentary .07(d) to Amex Rule 1202. The Exchange notes that the Commission has permitted the listing and trading of products linked to the performance of underlying currencies and commodities.[7]

Index Description

The Index is structured to provide a return that assumes an asset coverage ratio of 2:1.[8] DBCHI is intended to reflect the return from investing assets in long currency futures positions for certain currencies associated with relatively high yielding interest rates and an equal amount in short currency futures positions for certain currencies associated with relatively low yielding interest rates. The Index is designed to exploit the trend of currencies associated with relatively high interest rates, on average, tending to rise in value relative to currencies associated with relatively low interest rates. The Index exploits this trend using both long and short futures positions, which is expected to provide more consistent and less volatile returns than could be obtained by taking long positions only or short positions only. This is known as the ''Interest Rate Parity'' or ''Covered Interest Arbitrage'' formula. In particular, the Fund, which is not managed on a discretionary basis but instead seeks to track the Index pursuant to established rules and procedures, will reflect the composition and weightings of the Index Currencies with adjustments made by the Managing Owner on a quarterly basis to conform to the changes in the Index. The Managing Owner will not otherwise effect changes to the portfolio that deviate from the Index except in extraordinary circumstances (*e.g.*, if the Managing Owner is unable to enter into or close out a futures position because of a market disruption event).[9] Therefore, if positions in any of the one or more Index Currencies are declining in value, the Fund will not close out such positions, except in connection with a mandated change in the composition or weighting of the Index. The Managing Owner will seek to cause the NAV (as defined herein)[10] of the Fund to track the Index during periods in which the Index is flat or declining, as well as when the Index is rising. In this manner, the Managing Owner believes that the Index and the Fund will provide the advantages of market diversification and the reduction of country-specific foreign exchange risk (*i.e.*, volatility).

The Index, at any time, is comprised of futures positions on six (6) currencies from The Group Ten (''G10'') countries,[11] each of which is traded on the Chicago Mercantile Exchange (the ''CME'').[12] The notional amounts of each Index Currency included in the Index are based on the Index closing level as of the Index Re-Weighting Period (as defined herein).[13] The Index closing level reflects an arithmetic weighted average of the change in the futures positions on the Index Currencies' exchange rates against the U.S. Dollar (''USD'') since March 12, 1993.[14] On such date, the closing Index level was $100. The sponsor of the Index is Deutsche Bank AG London (''DB London'' or ''Index Sponsor'').

The Index is calculated by DB London on both an excess return basis and a total return basis. The excess return index reflects the return of the applicable underlying currencies. The total return is the sum of the return of the applicable underlying currencies, *plus* the return of three-month U.S. Treasury Bills. The Exchange states that the Fund will trade in a manner consistent with the excess return calculation of the Index. As described below, the Index will be calculated and disseminated every fifteen (15) seconds on the Consolidated Tape (''CT'') and through major market data vendors. The closing level of the Index is calculated by DB London on the basis of closing prices on the CME for the applicable futures contracts relating to the Index Currencies and applying a set of rules to these values to calculate the closing level of the Index. The CME-traded futures contract of each applicable Index Currency that is closest to

[5] Telephone conversation between Jeffery Burns, Associate General Counsel, Amex, and Brian Trackman, Special Counsel, Division of Market Regulation (''Division''), Commission, on August 22, 2006 (''August 22 Conference'').

[6] Such ratio is generally intended to be comparable to the limits imposed on registered investment companies pursuant to the asset coverage requirements of section 18(a) of the Investment Company Act of 1940 (''1940 Act''). Even though the Master Fund is not registered or regulated as an investment company under the 1940 Act, the Exchange represents that it is structured in a manner that is sensitive to the capital structure limitations imposed on registered investment companies by the 1940 Act.

[7] *See* Securities Exchange Act Release Nos. 53105 (January 11, 2006), 71 FR 3129 (January 19, 2006) (approving the listing and trading of the DB Commodity Index Tracking Fund); 53059 (January 5, 2006), 71 FR 2072 (January 12, 2006) (approving the listing and trading of the Euro Currency Trust); 51058 (January 19, 2005), 70 FR 3749 (January 26, 2005) (approving the listing and trading of the iShares COMEX Gold Trust); 50603 (October 28, 2004), 69 FR 64614 (November 5, 2004) (approving the listing and trading of streetTRACKS Gold Shares); 36885 (February 26, 1996), 61 FR 8315 (March 4, 1996) (approving the listing and trading of commodity indexed preferred or debt securities linked to the value of single commodity); and 35518 (March 21, 1995), 60 FR 15804 (March 27, 1995) (approving the listing and trading of commodity linked notes or COINS). *See also* Central Fund of Canada Limited (Registration No. 033–15180) (closed-end fund listed and traded on the Amex that invests in gold) and Salmon Phibro Oil Trust (Registration No. 033–33823) (trust units listed and traded on the Amex that held the right to a forward contract for the delivery of crude oil).

[8] *See supra* note 6.

[9] *See* discussion *infra* at ''Events Requiring Notice to and/or Approval by the Commission'' and ''Criteria for Initial and Continued Listing'' (describing the Exchange's obligations in the event of a disruption in connection with the trading of the futures contracts comprising the Index).

[10] *See infra* note 23 (defining net asset value or ''NAV'').

[11] The G10 currencies are the United States Dollar, the Euro, the Japanese Yen, the Canadian Dollar, the Swiss Franc, the British Pound, the Australian Dollar, the New Zealand Dollar, the Norwegian Krone, and the Swedish Krona (collectively, the ''Eligible Index Currencies'').

[12] August 22 Conference (clarifying that the Index is comprised of futures positions).

[13] *See infra* note 15 and accompanying text (defining and discussing the ''Index Re-Weighting Period'').

[14] August 22 Conference (clarifying the Index calculation methodology).

expiration is used in the Index calculation. The futures contracts on the Index Currencies are rolled during the period in which the Index is re-weighted (the ''Index Re-Weighting Period'').[15] The new futures contract on an Index Currency that has the next closest expiration date is selected. The calculation of the Index on an excess-return basis is the weighted average return on the change in price of the futures contracts relating to the Index Currencies.[16]

In order to determine which Eligible Index Currencies to include in the Index from time to time, the Sponsor will review the composition of the Index on a quarterly basis. The Sponsor will review the three-month LIBOR rate for each Eligible Index Currency, other than the Swedish Krona and Norwegian Krone, and will review the three-month STIBOR rate and the three-month NIBOR rate for the Swedish Krona and Norwegian Krone, respectively.[17] The Eligible Index Currencies are then ranked according to yield. The three highest yielding and three lowest yielding are selected as Index Currencies for inclusion in calculating the Index. If two Index Currencies have the same yield, then the previous quarter's ranking will be used. Upon re-weighting, the high yielding Index Currencies are allocated a base weight of 33⅓%, and the low yielding Index Currencies are allocated a base weight of −33⅓%. These new weights are applied during the Index Re-Weighting Period.

The Managing Owner represents that it will seek to arrange to have the Index calculated and disseminated on a daily basis through a third party if DB London ceases to calculate and disseminate the Index. If, however, the Managing Owner is unable to arrange for the calculation and dissemination of the Index (or another index which succeeds the Index), the Exchange will undertake to delist the Shares.[18]

The composition of the Index may be adjusted in the event that the Index Sponsor is not able to obtain information from the relevant futures exchanges to calculate the closing prices of the futures contracts related to the Index Currencies.[19] In such an event, the Index Sponsor may use a currency futures contract on the same Index Currency from a different futures exchange, provided that, if such use is more than of a temporary nature, the Exchange will file a proposed rule change pursuant to Rule 19b–4 seeking Commission approval to continue to trade the Shares. Unless approved for continued trading, the Exchange would commence delisting proceedings.

If futures prices are not available as a result of a temporary disruption of futures contracts on the Index Currencies, the Managing Owner will typically use the prior day's futures price. In exceptional cases (such as when a daily price limit is reached on a futures exchange), the Managing Owner may employ a ''fair value'' price (*i.e.*, the price for unwinding the futures position by dealers over-the-counter (''OTC'')). The Exchange states that this is similar to the case for index options when prices are unavailable or unreliable. The Options Clearing Corporation (''OCC''), pursuant to Article XVII, Section 4 of its By-Laws, permits options exchanges to use the prior day's closing price to fix an index options exercise settlement value. In addition, OCC may also use the next day's opening price, a price or value at such other times as determined by OCC, or an average of prices or values as determined by OCC. The Exchange represents that if the use of a prior day's price or ''fair value'' price for an Index Currency or Currencies is more than of a temporary nature, the Exchange will file a proposed rule change pursuant to Rule 19b–4 under the Act seeking Commission approval for the continued trading of the Shares. Unless approved for continued trading, the Exchange would commence delisting proceedings.

Investment Objective and Strategy

The Master Fund's portfolio is managed with a view to reflect the performance of the Index over time. The Exchange states that the Master Fund is not traditionally ''managed,'' which typically involves effecting changes in the composition of a portfolio on the basis of judgments relating to economic, financial, and market considerations. Instead, the Managing Owner seeks to maintain the relationship between the composition and weightings of the CME futures positions in the Index Currencies to the Master Fund's long and short currency futures positions from time to time.[20] The Managing Owner adjusts the portfolio on a quarterly basis to conform to periodic changes in the composition and relative weightings of the Index Currencies and may make certain adjustments or changes to the portfolio more frequently in the case of significant changes in the foreign currency markets due to volatility.

The Fund will pursue its investment objective by investing substantially all of its assets in the Master Fund. To track the Index, the Master Fund generally will establish long futures positions in the three Index Currencies associated with the highest interest rates and short futures positions in the three Index Currencies associated with the lowest interest rates[21] and will adjust its holdings quarterly as the Index is adjusted. However, if the USD is among the Index Currencies, the Master Fund will not establish a long or short futures position (as the case may be) in USD because USD is the Fund's home currency and, as a consequence, the Master Fund never can enjoy profit or suffer loss from long or short futures positions in USD. When the USD is not associated with the highest or lowest interest rates among the Eligible Index Currencies, the aggregate notional value of the Master Fund's futures contracts at the time they are established will be double the value of the Master Fund's holdings of U.S. Treasury Bills and other high credit quality short term fixed income securities, (*i.e.*, a ratio of 2:1).[22]

If the USD is associated with the highest or lowest interest rates among the Eligible Index Currencies, the aggregate notional value of the Master Fund's futures contracts at the time they are established will be approximately 1.66 times the value of the Master Fund's holdings of U.S. Treasury Bills and other high credit quality short-term fixed income securities (*i.e.*, a ratio of

[15] The Index Sponsor reviews and re-weights the Index on a quarterly basis, in accordance with its rules. The futures contracts held by the Fund are, therefore, three (3) months in duration. The Index Re-Weighting Period takes place just prior to the third Wednesday in each of March, June, September, and December months, which are traditional settlement dates in the International Money Market (the ''IMM Dates''). The futures contracts on the Index Currencies are rolled during the Index Re-Weighting Period, which will occur over the fourth and third business days prior to each of the IMM Dates.

[16] August 22 Conference (clarifying the Index calculation methodology).

[17] The LIBOR, STIBOR, and NIBOR rates for the Eligible Index Currencies, as applicable, mean the London, Stockholm, and Norway inter-bank offered rates for overnight deposits, respectively.

[18] If the Index is discontinued or suspended, the Managing Owner, in its sole discretion, may substitute the Index with an index substantially similar to the discontinued or suspended Index (the ''Successor Index''). The Successor Index may be calculated and/or published by any other third party. *See* discussion *infra* at ''Events Requiring Notice to and/or Approval by the Commission.''

[19] *See id.* (describing the Exchange's obligations if substantial changes are made by the Index Sponsor to the Index component selection or weighting methodology). *See also supra* note 14.

[20] August 22 Conference, *supra* note 12.

[21] The use of long and short positions in the construction of the Index causes the Index to rise as a result of any upward price movement of Index Currencies expected to gain relative to the USD and to rise as a result of any downward price movement of Index Currencies expected to lose relative to the USD.

[22] *See supra* note 6.

1.66:1). Holding futures positions with a notional amount in excess of the Master Fund's NAV [23] increases the potential for both trading profits and losses, depending on the performance of the Index. The Master Fund's ability to track the Index will not be affected by the presence or absence of the USD among the Index Currencies. Because the notional value of the Master Fund's futures positions can rise or fall over time, the ratio of long and short futures positions could be higher or lower between quarterly adjustments of the Index Currencies.

Foreign Currency Futures

The Exchange states that the advent of financial futures began in the early 1970s because some commodity traders at CME established the International Monetary Market (now a division of CME), which launched trading in seven currency futures contracts on May 16, 1972 creating the world's first financial futures. Whether the trading venue is open outcry or electronic, the Exchange submits that prices for exchange traded foreign currency products are disseminated worldwide via major quote vendors such as Reuters, Bloomberg, and others. Electronic trading on computerized trading systems (*e.g.*, GLOBEX® at CME) takes place on a nearly 24-hour basis.

The Exchange states that foreign exchange rates are influenced by national debt levels and trade deficits, domestic and foreign inflation rates and investors' expectations concerning inflation rates, domestic and foreign interest rates and investors' expectations concerning interest rates, currency exchange rates, investment and trading activities of mutual funds, hedge funds and currency funds, and global or regional political, economic, or financial events and situations. Additionally, foreign exchange rates on the Index Currencies may also be influenced by changing supply and demand for a particular Index Currency, monetary policies of governments (including exchange control programs, restrictions on local exchanges or markets and limitations on foreign investment in a country or on investment by residents of a country in other countries), changes in balances of payments and trade, trade restrictions, currency devaluations, and currency revaluations. Also, the Exchange states that governments from time to time intervene in the currency markets, directly and by regulation, in order to influence prices directly. Additionally, expectations among market participants that a currency's value soon will change may also affect exchange rates on the Index Currencies.

The Exchange submits that the foreign currency market is the largest and most liquid financial market in the world. As of April 2004, the Exchange states that the foreign currency exchange market experienced average daily turnover of approximately $1.88 trillion, which was a 57% increase (at current exchange rates) from 2001 daily averages.[24] The foreign currency market is predominantly an OTC market, with no fixed location, and it operates 24 hours a day, seven days a week. London, New York, and Tokyo are the principal geographic centers of the world-wide foreign currency market, with approximately 58% of all foreign currency business executed in the United Kingdom, United States, and Japan. Other, smaller markets include Singapore, Zurich, and Frankfurt. The Exchange states that the primary market participants in foreign currencies are banks (including government-controlled central banks), investment banks, money managers, multinational corporations, and institutional investors.

The Exchange states that there are three major kinds of transactions in the traditional foreign currency markets: Spot transactions, outright forwards, and foreign exchange swaps. ''Spot'' trades are foreign currency transactions that settle typically within two business days with the counterparty to the trade. Spot transactions account for approximately 35% of reported daily volume in the traditional foreign currency markets. ''Forward'' trades, which are transactions that settle on a date beyond spot, account for 12% of the reported daily volume, and ''swap'' transactions, in which two parties exchange two currencies on one or more specified dates over an agreed period and exchange them again when the period ends, account for the remaining 53% of volume. There also are transactions in currency options, which trade both OTC and, in the United States, on the Philadelphia Stock Exchange, Inc. (''Phlx''). Foreign currency futures are transactions in which an institution buys or sells a standardized amount of foreign currency on an organized exchange for delivery on one of several specified dates. Currency futures are traded on a number of regulated markets, including the CME, the Singapore Exchange Derivatives Trading Limited (''SGX''), and the London International Financial Futures Exchange (''LIFFE''). Over 85% of currency derivative products (swaps, options, and futures) are traded OTC.[25]

Futures Regulation

The Exchange states that the CEA governs the regulation of commodity interest transactions, markets, and intermediaries. The Exchange states that the CFTC administers the CEA, which requires commodity futures exchanges, such as the CME, to have rules and procedures to prevent market manipulation, abusive trade practices, and fraud. The CEA provides for varying degrees of regulation of commodity interest transactions depending upon the variables of the transaction. In general, these variables include (1) the type of instrument being traded (*e.g.*, contracts for future delivery, options, swaps, or spot contracts), (2) the type of commodity underlying the instrument (distinctions are made between instruments based on agricultural commodities, energy and metals commodities, and financial commodities), (3) the nature of the parties to the transaction (retail, eligible contract participant, or eligible commercial entity), (4) whether the transaction is entered into on a principal-to-principal or intermediated basis, (5) the type of market on which the transaction occurs, and (6) whether the transaction is subject to clearing through a clearing organization.

Among other things, the Exchange states that the CEA provides that the trading of commodity interest contracts generally must be upon exchanges designated as contract markets or Derivatives Transaction Execution Facilities and that all trading on those exchanges must be done by or through exchange members. Commodity interest trading between sophisticated persons may be traded on a trading facility not regulated by the CFTC. As a general matter, the Exchange states that trading in spot contracts, forward contracts, options on forward contracts or commodities, or swap contracts between eligible contract participants is not within the jurisdiction of the CFTC and may therefore be effectively unregulated.

[23] NAV is the total assets of the Master Fund, *less* total liabilities of the Master Fund, determined on the basis of generally accepted accounting principles. NAV per Master Fund share is the NAV of the Master Fund divided by the number of outstanding Master Fund shares. This will be the same for the Shares of the Fund because of a one-to-one correlation between the Shares and the shares of the Master Fund.

[24] The Exchange, however, did not specify the foreign currencies or types of transactions that underlie the statistics.

[25] *See* Bank for International Settlements, Triennial Central Bank Survey of Foreign Exchange and Derivatives Market Activity in April 2004, September 2004 (Tables 2 and 6).

The Exchange submits that trading on non-U.S. exchanges may differ from trading on U.S. exchanges in a variety of ways and, accordingly, may subject the Fund to additional risks. Non-U.S. futures exchanges are not subject to regulation by the CFTC, but rather are regulated by their home country regulator. In contrast to U.S. designated contract markets, some non-U.S. exchanges are principals' markets, where trades remain the liability of the traders involved, and the exchange or an affiliated clearing organization, if any, does not become substituted for any party. Due to the absence of a clearing system, the Exchange states that such exchanges are significantly more susceptible to disruptions. Further, participants in such markets must often satisfy themselves as to the individual creditworthiness of each entity with which they enter into a trade. Trading on non-U.S. exchanges is often in the currency of the exchange's home jurisdiction. Consequently, the Fund may be subject to the additional risk of fluctuations in the exchange rate between such currencies and USD and the possibility that exchange controls could be imposed in the future.

The Exchange states that CFTC and U.S. designated contract markets have established limits or position accountability rules (*i.e.*, speculative position limits or position limits) on the maximum net long or net short speculative position that any person or group of persons under common trading control (other than a hedger) may hold, own, or control in commodity interests. Among the purposes of speculative position limits is to prevent a corner or squeeze on a market or undue influence on prices by any single trader or group of traders.

The Exchange also states that most U.S. futures exchanges limit the amount of fluctuation in some futures contract or options on futures contract prices during a single trading session. These regulations specify what are referred to as daily price fluctuation limits (*i.e.*, daily limits). The daily limits establish the maximum amount that the price of a futures contract or options on futures contract may vary either up or down from the previous day's settlement price. Once the daily limit has been reached in a particular futures contract or options on futures contract, no trades may be made at a price beyond the limit.

Foreign Currency Regulation

Most trading in the global OTC foreign currency markets is conducted by regulated financial institutions such as banks and broker-dealers. In addition, in the United States, the Foreign Exchange Committee of the New York Federal Reserve Bank has issued guidelines for foreign exchange trading, and central-bank sponsored committees in Japan and Singapore have published similar best practice guidelines. In the United Kingdom, the Bank of England has published the Non-Investment Products Code, which covers foreign currency trading. The Financial Markets Association, whose members include major international banking organizations, has also established best practices guidelines called the ''Model Code.''

In addition, in the United States, the Commission regulates the trading of options on foreign currencies on Phlx, and the CFTC regulates trading of futures, options, and options on futures on foreign currencies on regulated futures exchanges.[26]

Structure of the Fund

Fund. The Fund will be formed as a Delaware statutory trust pursuant to a Certificate of Trust and a Declaration of Trust and Trust Agreement among Wilmington Trust Company, as trustee, the Managing Owner, and the holders of the Shares.[27] The Fund will issue common units of beneficial interest or shares that represent units of fractional undivided beneficial interest in and ownership of the Fund. The term of the Fund is perpetual (unless terminated earlier in certain circumstances). The investment objective of the Fund is to reflect the performance of the DBCHI, over time, less the expenses of the operation of the Fund and the Master Fund. The Fund will pursue its investment objective by investing substantially all of its assets in the Master Fund. Each Share will correlate with a Master Fund share issued by the Master Fund and held by the Fund.

Master Fund. The Master Fund is a statutory trust formed pursuant to the Delaware Statutory Trust Act and will issue common units of beneficial interest or shares that represent units of fractional undivided beneficial interest in and ownership of the Master Fund. The term of the Master Fund is perpetual (unless terminated earlier in certain circumstances). The investment objective of the Master Fund is to reflect the performance of the DBCHI, less the expenses of the operations of the Fund and the Master Fund. The Master Fund will pursue its investment objective by taking long positions in the three (3) highest-yielding Index Currencies and, as reflected in the Index, will take three (3) short positions in the lowest yielding Index Currencies. In addition, the Master Fund will also hold cash and U.S. Treasury securities for deposit with futures commission merchants (''FCMs'') as margin and other high credit quality short-term fixed income securities.

Trustee. The Wilmington Trust Company is the trustee of the Fund and the Master Fund. The Trustee has delegated to the Managing Owner the power and authority to manage and operate the day-to-day affairs of the Fund and the Master Fund.

Managing Owner. The Managing Owner is a Delaware limited liability company which is registered with the CFTC as a CPO and CTA and is an affiliate of DB London. The Managing Owner will serve as the CPO and CTA of the Fund and the Master Fund and will manage and control all aspects of the business of both.

Commodity Broker. Deutsche Bank Securities, Inc., the Commodity Broker, is an affiliate of the Managing Owner and is registered with the CFTC as a FCM. The Commodity Broker will execute and clear each of the Master Fund's futures contract transactions and will perform certain administrative services for the Master Fund.

Administrator. The Bank of New York is the administrator for both the Fund and the Master Fund (the ''Administrator''). The Administrator will perform or supervise the performance of services necessary for the operation and administration of the Fund and the Master Fund (other than making investment decisions), including NAV calculations, accounting, and other administrative services. The Administrator will retain certain financial books and records, including: Financial accounting records, ledgers with respect to assets, liabilities, capital, income and expenses, the register, transfer journals and related details, and trading and related documents received from FCMs.

Distributor. ALPS Distributors, Inc. is the distributor for both the Fund and the Master Fund (the ''Distributor''). The Distributor will assist the Managing Owner and the Administrator with certain functions and duties relating to the creation and redemption of Baskets (as defined below), including receiving and processing orders from Authorized Participants (as defined below) to create and redeem Baskets, coordinating the

[26] In addition to its oversight of regulated futures exchanges, the Exchange states that the CFTC has jurisdiction over certain foreign currency futures, options, and options on futures transactions occurring other than on a regulated exchange and involving retail customers.

[27] The Exchange states that the Fund will not be subject to registration and regulation under the 1940 Act.

processing of such orders and related functions and duties. The Distributor will also retain all marketing materials and Basket creation and redemption books and records.

Product Description

A. Creation and Redemption of Shares

Issuances of the Shares will be made only in one or more blocks of 200,000 Shares (the ''Basket''). The Fund will issue and redeem the Shares on a continuous basis, by or through participants that have entered into participant agreements (each, an ''Authorized Participant'')[28] with the Managing Owner at the NAV per Share next determined after an order to purchase the Shares in a Basket is received in proper form. Following issuance, the Shares will be traded on the Exchange similar to other equity securities. The Shares will be registered in book entry form through DTC.

Baskets will be issued in exchange for a cash amount equal to the NAV per Share times 200,000 Shares (the ''Basket Amount''). The Basket Amount will be determined on each business day by the Administrator. Authorized Participants that wish to purchase a Basket must transfer the Basket Amount to the Administrator (the ''Cash Deposit Amount''). Authorized Participants that wish to redeem a Basket will receive cash in exchange for each Basket surrendered in an amount equal to the NAV per Basket (the ''Cash Redemption Amount''). The Commodity Broker will be the custodian for the Master Fund and responsible for safekeeping the Master Fund's assets.

All purchase orders received by the Administrator prior to 1 p.m. ET will be settled by depositing with the Commodity Broker the Cash Deposit Amount disseminated by the Administrator shortly after 10 a.m. ET on the next business day. The Basket Amount necessary for the creation of a Basket will change from day to day. On each day that the Amex is open for regular trading, the Administrator will adjust the Cash Deposit Amount as appropriate to reflect the prior day Fund NAV (as described below) and accrued expenses. The Administrator will determine the Cash Deposit Amount for a given business day by multiplying the NAV for each Share by the number of Shares in each Basket (200,000).

Likewise, all redemption orders received by the Administrator prior to 1 p.m. ET will be settled by the Commodity Broker's payment of the Cash Redemption Amount shortly after 10 a.m. ET on the next business day.[29] The Shares will not be individually redeemable but will only be redeemable in Baskets. To redeem, an Authorized Participant will be required to accumulate enough Shares to constitute a Basket (*i.e.*, 200,000 shares). Upon the surrender of the Shares and payment of applicable redemption transaction fee, taxes, or charges, the Administrator will deliver to the redeeming Authorized Participant the Cash Redemption Amount.

On each business day, the Administrator will make available immediately prior to the opening of trading on the Amex via the facilities of the CT,[30] the most recent Basket Amount for the creation of a Basket. The Amex will disseminate every fifteen (15) seconds throughout the trading day, via the CT, an amount representing on a per Share basis, the current value of the Basket Amount. It is anticipated that the deposit of the Cash Deposit Amount in exchange for a Basket will be made primarily by institutional investors, arbitrageurs, and the Exchange specialist. Baskets are then separable upon issuance into identical Shares that will be listed and traded on the Amex.[31] The Shares are expected to be traded on the Exchange by professionals, as well as institutional and retail investors. Thus, the Shares may be acquired in two (2) ways: (1) Through a deposit of the Cash Deposit Amount with the Administrator during normal business hours by Authorized Participants, or (2) through a purchase on the Exchange by investors.

B. Net Asset Value (NAV)

Shortly after 4 p.m. Eastern time (''ET'') each business day, the Administrator will determine the NAV for the Fund, utilizing the current settlement value of the particular long and short exchange-traded futures contracts on the Index Currencies. At or about 4 p.m. ET each business day, the Administrator will determine the Basket Amount for orders placed by Authorized Participants received before 1 p.m. ET that day. Thus, although Authorized Participants place orders to purchase Shares throughout the trading day until 1 p.m. ET, the actual Basket Amount is determined at 4 p.m. ET or shortly thereafter.

Shortly after 4 p.m. ET each business day, the Administrator, Amex, and the Managing Owner will disseminate the NAV for the Shares and the Basket Amount (for orders placed during the day). The Basket Amount and the NAV are communicated by the Administrator to all Authorized Participants via facsimile or electronic mail message and will be available on the Index Sponsor's Internet Web site at *http://index.db.com.* The Amex will also disclose the NAV and Basket Amount on its Internet Web site (*http://www.amex.com*). Amex represents that the NAV will be made available to all market participants at the same time. If the NAV is not disseminated to all market participants at the same time, the Exchange will halt trading of the Shares.[32]

When calculating NAV for the Fund and Master Fund, the Administrator will value U.S. futures contracts held by the Master Fund on the basis of their then current market value. All non-U.S. futures contracts will be calculated based upon the liquidation value. Forward contracts will be calculated based on the mean of the bid-ask as provided by the counterparty.

The NAV for the Fund is total assets of the Master Fund less total liabilities of the Master Fund. The NAV is calculated by including any unrealized profit or loss on futures contracts and any other credit or debit accruing to the Master Fund but unpaid or not received by the Master Fund. The NAV is then used to compute all fees (including the management and administrative fees) that are calculated from the value of Master Fund assets. The Administrator will calculate the NAV per share by dividing the NAV by the number of Shares outstanding.

The Exchange believes that the Shares will not trade at a material discount or premium to the NAV of the Shares based on potential arbitrage opportunities. Due to the fact that the Shares can be created and redeemed

[28] An ''Authorized Participant'' is a person, who at the time of submitting to the trustee an order to create or redeem one or more Baskets, (i) is a registered broker-dealer, (ii) is a Depository Trust Company (''DTC'') participant and (iii) has in effect a valid participant agreement.

[29] Telephone conversation between Jeffrey Burns, Associate General Counsel, Amex, and Florence Harmon, Senior Special Counsel, Division, Commission, on June 26, 2006.

[30] *Id.*

[31] The Shares are separate and distinct from the shares of the Master Fund. The Exchange expects that the number of outstanding Shares will increase and decrease from time to time as a result of creations and redemptions of Baskets.

[32] However, if the Fund temporarily does not disseminate the NAV to all market participants at the same time, the Exchange will immediately contact the Commission to discuss measures that may be appropriate under the circumstances. *See* discussion *infra* at ''Events Requiring Notice to and/or Approval by the Commission'' and ''Criteria for Initial and Continued Listing'' (discussing delisting procedures in the event of a disruption to the dissemination of the NAV); *see also* discussion *infra* at ''Trading Halts'' (noting that the Exchange would halt trading in the Shares if the NAV is no longer calculated or disseminated for the benefit of market participants at the same time).

only in Baskets at NAV, the Exchange submits that arbitrage opportunities should provide a mechanism to mitigate the effect of any premiums or discounts to or from NAV per Share that may exist from time to time. The value of a Share may be influenced by non-concurrent trading hours between the Amex and the various futures exchanges on which the Index Currencies are traded. As a result, during periods when the Amex is open and the futures exchanges on which the Index Currencies are traded are closed, trading spreads and the resulting premium or discount on the Shares may widen, and, therefore, increase the difference between the price of the Shares and the NAV of the Shares.

C. Dissemination of the Index and Underlying Futures Contracts Information

DB London, as the Index Sponsor, will publish the value of the Index at least once every fifteen (15) seconds throughout each trading day on the CT, Bloomberg, Reuters, and on its Internet Web site at *http://index.db.com.* The Exchange states that the disseminated value of the Index will not reflect changes to the prices of the Index Currencies between the close of trading of each respective futures contract on the relevant futures exchange, *i.e.*, 3 p.m. ET (close of trading on the CME futures market), and the close of trading on the Amex at 4:15 p.m. ET.[33] The closing Index level will similarly be provided by DB London. In addition, any adjustments or changes to the Index will also be provided by DB London and the Exchange on their respective Internet Web sites.[34]

The daily settlement prices for the futures contracts held by the Master Fund are publicly available on the Internet Web sites of the futures exchanges trading the particular contracts. All of the futures contracts in which the Master Fund currently expects to invest are traded on the CME, although currency futures contracts on the Eligible Index Currencies also trade on other futures exchanges in the United States and the Master Fund may invest in such contracts.[35] In addition, various data vendors and news publications publish futures prices and data. The Exchange represents that futures quotes and last sale information for the Index Currencies are widely disseminated through a variety of market data vendors worldwide, including Bloomberg and Reuters. In addition, the Exchange further notes that complete real-time data for such futures is available by subscription from Reuters and Bloomberg. The specific contract specifications for the futures contracts are also available from the futures exchanges on their Internet Web sites, as well as other financial informational sources.

D. Availability of Information Regarding the Shares

The Internet Web sites for the Fund and/or the Exchange, which are publicly accessible at no charge, will contain the following information: (a) Current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the mid-point of the bid-ask price in relation to the NAV as of the time the NAV is calculated (the ''Bid-Ask Price''); [36] (c) the calculation of the premium or discount of such price against such NAV; (d) data in chart form displaying the frequency of distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four (4) previous calendar quarters; (e) the prospectus; and (f) other applicable quantitative information. The Exchange will also make available on its Internet Web site the daily trading volume of the Shares. The closing price and settlement prices of the futures contracts comprising the Index and held by the Master Fund are also readily available from the relevant futures exchanges, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. In addition, the Exchange will provide a hyperlink on its Internet Web site to the Index Sponsor's Internet Web site.

Investors may obtain, on a 24-hour basis, currency pricing information from various financial information service providers. The Exchange states that current currency spot prices are also generally available with bid/ask spreads from foreign exchange dealers. Complete real-time data for futures and options prices traded on CME and Phlx are also available by subscription from information service providers. CME and Phlx also provide delayed futures and options information on current and past trading sessions and market news free of charge on their respective Web sites. There are a variety of other public Internet Web sites that provide information on currency, such as Bloomberg (*http://www.bloomberg.com/markets/currecies/eurafr_currencies.html*), which regularly reports current foreign currency pricing for a fee. Other service providers include CBS Market Watch (*http://marketwatch.com/tools.stockresearch/globalmarkets*) and Yahoo! Finance (*http://finance.yahoo.com/currency*). Many of these Internet Web sites offer price quotations drawn from other published sources, and as the information is supplied free of charge, it generally is subject to time delays.

E. Dissemination of Indicative Fund Value

As noted above, the Administrator calculates the NAV of the Fund once each trading day and disseminates such NAV to all market participants at the same time. In addition, the Administrator causes to be made available on a daily basis the Cash Deposit Amount to be deposited in connection with the issuance of the Shares in Baskets. Other investors can also request such information directly from the Administrator.

In order to provide updated information relating to the Fund for use by investors, professionals, and persons wishing to create or redeem the Shares, the Exchange will disseminate through the facilities of the CT an updated Indicative Fund Value (the ''Indicative Fund Value''). The Indicative Fund Value will be disseminated on a per Share basis every fifteen (15) seconds during regular Amex trading hours of 9:30 a.m. to 4:15 p.m. ET. The Indicative Fund Value will be calculated based on the cash required for creations and redemptions (*i.e.,* NAV × 200,000), adjusted to reflect the price changes of the Index Currencies through investments held by the Master Fund, *i.e.,* futures contracts and options on futures and/or forwards.

The Indicative Fund Value will not reflect price changes to the price of an underlying currency between the close of trading of the futures contract at the relevant futures exchange and the close of trading on the Amex at 4:15 p.m. ET. While the Shares will trade on the Amex from 9:30 a.m. to 4:15 p.m. ET, regular trading hours for each of the Index Currencies on the CME are 8:20 a.m. to 3 p.m. ET. Therefore, the value

[33] August 22 Conference.

[34] The Sponsor has in place procedures to prevent the improper sharing of information between different affiliates and departments. Specifically, an information barrier exists between the personnel within DB London that calculate and reconstitute the Index and other personnel of the Sponsor, including but not limited to the Managing Owner, sales and trading, external or internal fund managers, and bank personnel who are involved in hedging the bank's exposure to instruments linked to the Index, in order to prevent the improper sharing of information relating to the composition of the Index.

[35] Other futures exchanges may include, for example, the New York Board of Trade and HedgeStreet, Inc.

[36] The Bid-Ask Price of the Shares is determined using the highest bid and lowest offer as of the time of calculation of the NAV.

of a Share may be influenced by non-concurrent trading hours between the Amex and the various futures exchanges on which the futures contracts based on the Index Currencies are traded.

While the market for futures trading for each of the Index Currencies is open, the Indicative Fund Value can be expected to closely approximate the value per Share of the Basket Amount. However, during Amex trading hours and when the futures contracts have ceased trading, spreads and resulting premiums or discounts may widen, and therefore, increase the difference between the price of the Shares and the NAV of the Shares. Indicative Fund Value on a per Share basis disseminated during Amex trading hours should not be viewed as a real time update of the NAV, which is calculated only once a day.

The Exchange believes that dissemination of the Indicative Fund Value based on the cash amount required for a Basket provides additional information that is not otherwise available to the public and is useful to professionals and investors in connection with the Shares trading on the Exchange or the creation or redemption of the Shares.

F. Events Requiring Notice to and/or Approval by the Commission

The Exchange represents that should the Index Sponsor substantially change either the Index component selection or weighting methodology, the Exchange would file a proposed rule change pursuant to Rule 19b–4 under the Act, which must be approved by the Commission for continued trading of the Shares.[37]

The Exchange represents that if a successor or substitute index is used by the Managing Owner, Amex will file with the Commission a proposed rule change pursuant to Rule 19b–4 under the Act to address, among other things, the listing and trading characteristics of the successor index and Amex's surveillance procedures applicable to the successor index, which must be approved by the Commission to continue trading the Shares relating to the successor index.

Additionally, in the case of a temporary disruption in connection with the trading of the futures contracts comprising the Index, the Exchange believes that it is unnecessary for a filing pursuant to Rule 19b–4 under the Act to be filed with the Commission. The Exchange submits that for a temporary disruption of such futures contracts, the Index Sponsor would typically use the prior day's price for an Index Currency. In exceptional cases, the Index Sponsor may employ a ''fair value'' price (*i.e.,* the price for unwinding the position by dealers in the OTC market). However, the Exchange represents that if the use of a prior day's price or ''fair value'' pricing for an Index Currency is more than of a temporary nature, the Exchange will file a proposed rule change with the Commission pursuant to Rule 19b–4 under the Act seeking Commission approval to continue trading the Shares. Unless approved for continued trading, the Exchange would commence delisting proceedings.

The Exchange represents that it would halt trading of the Shares if (a) the value of the Index is no longer calculated or available on at least a fifteen (15) second basis through the facilities of the CT or major market data vendors during the time the Shares trade on Amex, (b) if the Indicative Fund Value, updated at least every fifteen (15) seconds, is no longer calculated or available, or (c) the NAV is no longer disseminated to all market participants at the same time.[38] In any event, unless approval is received from the Commission to continue to list and trade the Shares after a proposed rule change filing is properly filed pursuant to Rule 19b–4 under the Act, the Exchange represents that will commence delisting procedures for the Shares if: (i) The Index Sponsor substantially changes either the Index component selection or weighting methodology; (ii) more than a temporary disruption exists with trading of the futures contracts comprising the Index; or (iii) a Successor Index is used by the Managing Owner; or (iv) the calculation and/or dissemination of the NAV is more than temporarily disrupted.

Termination Events

The Exchange states that the Fund will be terminated if any of the following circumstances occur: (1) The filing of a certificate of dissolution or revocation of the Managing Owner's charter or upon the withdrawal, removal, adjudication, or admission of bankruptcy or insolvency of the Managing Owner, or an event of withdrawal unless (i) there is at least one remaining Managing Owner who carries on the business of the Fund or (ii) within 90 days of such event of withdrawal all the remaining shareholders agree in writing to continue the business of the Fund and to select one or more successor Managing Owners; (2) the occurrence of any event which would make unlawful the continued existence of the Fund; (3) the suspension, revocation, or termination of the Managing Owner's registration as a CPO, or membership as a CPO with the NFA; (4) the Fund becomes insolvent or bankrupt; (5) the holders of at least 50% of the outstanding Shares notify the Managing Owner that they elect to terminate the Fund; (6) the determination of the Managing Owner that the aggregate net assets of the Fund in relation to the operating expenses of the Fund make it unreasonable or imprudent to continue the business of the Fund, or the determination by the Managing Owner to dissolve the Fund because the aggregate NAV of the Fund as of the close of business on any business day declines below $10 million; (7) the Commission finds that the Fund should be registered as an investment company under the 1940 Act; or (8) the DTC is unable or unwilling to continue to perform its functions, and a comparable replacement is unavailable. Upon termination of the Fund, holders of the Shares will surrender their Shares and receive from the Administrator, in cash, their portion of the value of the Fund.

Criteria for Initial and Continued Listing

The Fund will be subject to the criteria in Commentary .07(d) of Amex Rule 1202 for initial and continued listing of the Shares. The proposed continued listing criteria provides for the delisting or removal from listing of the Shares under any of the following circumstances:

- Following the initial twelve-month period from the date of commencement of trading of the Shares: (i) If the Fund has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of the Shares for 30 or more consecutive trading days; (ii) if the Fund has fewer than 50,000 Shares issued and outstanding; or (iii) if the market value of all Shares is less than $1,000,000;
- If the value of the underlying Index is no longer calculated or available on at least a 15-second delayed basis through one or more major market data vendors; [39]

[37] *See supra* note 19 and accompanying text (noting that the Index Sponsor may also use a currency futures contract on the same Index Currency from a different futures exchange, provided that, if such use is more than of a temporary nature, the Exchange will file a proposed rule change pursuant to Rule 19b–4 seeking Commission approval to continue to trade the Shares. Unless approved for continued trading, the Exchange would commence delisting proceedings.

[38] The Exchange further represents that it would immediately contact the Commission to discuss measures that may be appropriate under the circumstances.

[39] In the event the Index value is no longer calculated or disseminated by one or more major

• The Indicative Fund Value is no longer made available on at least a 15-second delayed basis through the facilities of the CT; [40]

• The calculation or dissemination of the NAV is disrupted such that the NAV is no longer disseminated to all market participants at the same time; [41]

• Unless approval is received from the Commission to continue to list and trade the Shares after a proposed rule change pursuant to Rule 19b–4 under the Act is properly filed by the Exchange, (i) more than a temporary disruption exists in connection with the pricing of the futures contracts comprising the Index, (ii) a successor or substitute index is used by the Managing Owner in connection with the Shares, (iii) calculation or dissemination of the NAV is more than temporarily disrupted, or (iv) the Index Sponsor substantially changes either the Index component selection methodology or weighting methodology; or

• If such other event shall occur or condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

The initial purchaser (the ''Initial Purchaser'') will initially purchase and take delivery of 200,000 Shares, which comprises the initial Basket, at a purchase price of $25.00 per Share ($5,000,000 per Basket) pursuant to an Initial Purchaser Agreement. The Initial Purchaser proposes to offer to the public these 200,000 Shares at a per-Share offering price that will vary depending on, among other factors, the trading price of the Shares on the Amex, the NAV per Share, and the supply of and demand for the Shares at the time of the offer. Shares offered by the Initial Purchaser at different times may have different offering prices. The Initial Purchaser will not receive from the Fund, the Managing Owner, or any of their affiliates, any fee or other compensation in connection with the sale of the Shares to the public. The Fund will not bear any expenses in connection with the offering or sales of the Shares composing the initial Baskets. The Managing Owner has agreed to indemnify the Initial Purchaser against certain liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments that the Initial Purchaser may be required to make in respect thereof.

The Initial Purchaser will not act as an Authorized Participant with respect to the initial Baskets, and its activities with respect to the initial Baskets will be distinct from those of an Authorized Participant. The Exchange believes that the anticipated minimum number of Shares outstanding at the start of trading is sufficient to provide adequate market liquidity and to further the Fund's objective to seek to provide a simple and cost effective means of accessing the currency futures markets. The Exchange represents that, for the initial and continued listing, the Shares must be in compliance with Section 803 of the Amex Company Guide and Rule 10A–3 under the Act. [42]

The Amex original listing fee applicable to the listing of the Fund is $5,000. In addition, the annual listing fee applicable under Section 141 of the Amex Company Guide will be based upon the year-end aggregate number of Shares in all series of the Fund outstanding at the end of each calendar year.

Trading Rules

The Shares are equity securities subject to Amex rules governing the trading of equity securities, including, among others, rules governing priority, parity and precedence of orders, specialist responsibilities and account opening and customer suitability (Amex Rule 411). Initial equity margin requirements of 50% will apply to transactions in the Shares. Shares will trade on the Amex until 4:15 p.m. ET each business day and will trade in a minimum price variation of $0.01 pursuant to Amex Rule 127. Trading rules pertaining to odd-lot trading in Amex equities (Amex Rule 205) will also apply.

Amex Rule 154, Commentary .04(c), provides that stop and stop limit orders to buy or sell a security (other than an option, which is covered by Amex Rule 950(f) and Commentary thereto) the price of which is derivatively priced based upon another security or index of securities, may with the prior approval of a Floor Official, be elected by a quotation, as set forth in Commentary .04(c)(i)–(v). The Exchange has designated the Shares as eligible for this treatment. [43]

The Shares will be deemed ''Eligible Securities'', as defined in Amex Rule 230, for purposes of the Intermarket Trading System (''ITS'') plan and therefore will be subject to the trade-through provisions of Amex Rule 236, which require that Amex members avoid initiating trade-throughs for ITS securities.

Specialist transactions of the Shares made in connection with the creation and redemption of Shares will not be subject to the prohibitions of Amex Rule 190. [44] Unless exemptive or no-action relief is available, the Shares will be subject to the short sale rule, Rule 10a–1 and other rules under the Act. [45] If exemptive or no-action relief is provided, the Exchange will issue a notice detailing the terms of the exemption or relief. The Shares will generally be subject to the Exchange's stabilization rule, Amex Rule 170, except that specialists may buy on ''plus ticks'' and sell on ''minus ticks,'' in order to bring the Shares into parity with the underlying currency and/or futures contract price. Commentary .07(f) to Amex Rule 1202 sets forth this limited exception to Amex Rule 170.

The trading of the Shares will be subject to certain conflict of interest provisions set forth in Commentary .07(e) to Amex Rule 1202. Specifically, Commentary .07(e) provides that the prohibitions in Amex Rule 175(c) apply to a specialist in the Shares so that the specialist or affiliated person may not act or function as a market maker in an underlying asset, related futures contract or option, or any other related derivative. An affiliated person of the specialist consistent with Amex Rule 193 may be afforded an exemption to act in a market making capacity, other than as a specialist in the Shares on another market center, in the underlying asset, related futures, or options or any other related derivative. Commentary .07(e) further provides that an approved person of an equity specialist that has established and obtained Exchange approval for procedures restricting the flow of material, non-public market information between itself and the

market data vendors, the Exchange would immediately contact the Commission to discuss measures that may be appropriate under the circumstances.

[40] In the event the Indicative Fund Value is no longer calculated or disseminated through the facilities of the CT, the Exchange would immediately contact the Commission to discuss measures that may be appropriate under the circumstances.

[41] In the event the NAV is no longer calculated or disseminated to all market participants at the same time, the Exchange would immediately contact the Commission to discuss measures that may be appropriate under the circumstances.

[42] *See* 17 CFR 240.10A–3.

[43] *See* Securities Exchange Act Release No. 29063 (April 10, 1991), 56 FR 15652 (April 17, 1991) (noting the Exchange's designation of equity derivative securities as eligible for such treatment under Amex Rule 154, Commentary .04(c)).

[44] *See* Commentary .05 to Amex Rule 190.

[45] The Fund expects to seek relief, in the near future, from the Commission in connection with the trading of the Shares from the operation of the short sale rule, Rule 10a7–1 under the Act. If granted, the Shares would be exempt from Rule 10a–1 permitting sales without regard to the ''tick'' requirements of Rule 10a–1. Rule 10a–1(a)(1)(i) provides that a short sale of an exchange-traded security may not be effected (i) below the last regular-way sale price or (ii) at such price unless such price is above the next preceding different price at which a sale was reported.

specialist member organization, and any member, officer, or employee associated therewith, may act in a market making capacity, other than as a specialist in the Shares on another market center, in the underlying asset or commodity, related futures or options on futures, or any other related derivatives.

Commentary .07(e) to Amex Rule 1202 also ensures that specialists handling the Shares provide the Exchange with all the necessary information relating to their trading in physical assets or commodities, related futures contracts and options thereon, or any other derivative. As a general matter, the Exchange has regulatory jurisdiction over its members, member organizations, and approved persons of a member organization. The Exchange also has regulatory jurisdiction over any person or entity controlling a member organization as well as a subsidiary or affiliate of a member organization that is in the securities business. A subsidiary or affiliate of a member organization that does business only in commodities or futures contracts would not be subject to Exchange jurisdiction, but the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

Trading Halts

Prior to the commencement of trading, the Exchange will issue an Information Circular (described below) to members informing them of, among other things, Exchange policies regarding trading halts in the Shares. First, the circular will advise that trading will be halted in the event the market volatility trading halt parameters set forth in Amex Rule 117 have been reached. Second, the circular will advise that, in addition to the parameters set forth in Amex Rule 117, the Exchange will halt trading in the Shares if trading in the underlying related futures contract(s) is halted or suspended. Third, with respect to a halt in trading that is not specified above, the Exchange may also consider other relevant factors and the existence of unusual conditions or circumstances that may be detrimental to the maintenance of a fair and orderly market. The Exchange will halt trading in the Shares if the value of the Index is no longer calculated or available on at least a fifteen (15) second basis through one or more major market data vendors during the time the Shares trade on Amex, or if the Indicative Fund Value per Share updated at least every fifteen (15) seconds is no longer calculated or available the facilities of the CT, or if the NAV is no longer calculated or disseminated for the benefit of all market participants at the same time.[46]

Suitability

The Information Circular (described below) will inform members and member organizations of the characteristics of the Fund and of applicable Exchange rules, as well as of the requirements of Amex Rule 411 (Duty to Know and Approve Customers).

The Exchange notes that pursuant to Amex Rule 411, members and member organizations are required in connection with recommending transactions in the Shares to have a reasonable basis to believe that a customer is suitable for the particular investment given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such member.

Information Circular

The Amex will distribute an Information Circular to its members in connection with the trading of the Shares. The Circular, will discuss the special characteristics and risks of trading this type of security, such as currency fluctuation risk. Specifically, the Circular, among other things, will discuss what the Shares are, how a Basket is created and redeemed, applicable Amex rules, dissemination information, trading information, and applicable suitability rules. The Circular will also explain that the Fund is subject to various fees and expenses described in the Registration Statement. The Circular will also reference the fact that the CFTC has regulatory jurisdiction over the trading of futures contracts.

The Circular will also notify members and member organizations about the procedures for purchases and redemptions of Shares in Baskets, and that Shares are not individually redeemable but are redeemable only in one or more Baskets. The Circular will advise members of their suitability obligations with respect to recommended transactions to customers in the Shares. The Circular will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

Additionally, the Circular will disclose that the NAV for Shares will be calculated shortly after 4 p.m. ET each trading day and that information about the Shares and the Index will be publicly available on the Internet Web site of Amex and the Fund. In the Information Circular, the Exchange will inform members and member organizations, prior to commencement of trading, of the prospectus delivery requirements applicable to the Fund. The Exchange notes that investors purchasing Shares directly from the Fund (in exchange for cash) will receive a prospectus. Amex members purchasing Shares from the Trust for resale to investors will deliver a prospectus to such investors. Also, in the Information Circular, Amex will inform members and member organizations that procedures for purchases and redemptions of Shares in Baskets are described in the Prospectus and that Shares are not individually redeemable but are redeemable by Basket or multiples thereof and that individual shareholders may only redeem through an Authorized Participant, not from the Fund.

Surveillance

The Exchange represents that its surveillance procedures are adequate to properly monitor the trading of the Shares and to deter and detect violations of Amex rules. Specifically, Amex will rely on its existing surveillance procedures governing Index Fund Shares. Amex represents that its surveillance procedures for the Shares will be similar to those used for other TIRs (such as the Currency Trust Shares and the DB Commodity Index Tracking Fund) and exchange-traded funds and will incorporate and rely upon existing Amex surveillance procedures governing options and equities. The Exchange also notes that the CME is a member of the Intermarket Surveillance Group. As a result, the Exchange asserts that market surveillance information is available from the CME, if necessary, due to regulatory concerns that may arise in connection with the CME futures.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with section 6 of the Act,[47] in general, and furthers the objectives of section 6(b)(5),[48] 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

[46] *See supra* notes 39–41 and accompanying text.

[47] 15 U.S.C. 78f.

[48] 15 U.S.C. 78f(b)(5).

open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange did not receive any written comments on the proposed rule change.

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 Amex 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.

The Commission is considering granting accelerated approval of the proposed rule change, as amended, at the end of a 15-day comment period.[49]

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–Amex–2006–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2006–44. 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–Amex–2006–44 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[50]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14304 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[49] Amex has requested accelerated approval of this proposed rule change, as amended, prior to the 30th day after the date of publication of the notice of the filing thereof, following the conclusion of a 15-day comment period.

[50] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54353; File No. SR–NASD–2006–090]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto Regarding Fees and Credits for the NASD/Nasdaq Trade Reporting Facility and To Adopt a Transaction Credit Program for Securities Listed on the Nasdaq Stock Market

August 23, 2006.

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 July 21, 2006, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by NASD. On August 7, 2006, NASD amended the proposed rule change.[3] NASD again amended the proposed rule change on August 14, 2006.[4] NASD filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder,[6] which renders it effective upon filing with the Commission. 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

NASD proposes to adopt a new NASD Rule 7000B Series relating to fees and credits for The Trade Reporting Facility LLC (''NASD/Nasdaq TRF'') established by NASD and The Nasdaq Stock Market, Inc. (''Nasdaq''). NASD filed the proposed rule change for immediate effectiveness. NASD proposes that the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Amendment No. 1. Amendment No. 1 made clarifying changes to the proposed rule change.

[4] *See* Amendment No. 2. Amendment No. 2 made clarifying changes to the proposed rule change. For purposes of calculating the 60-day abrogation period, the Commission considers the period to have commenced on August 14, 2006, the day NASD filed Amendment No. 2. NASD provided the Commission with written notice of its intention to file the proposed rule change on July 13, 2006. *See* Section 19(b)(3)(A) of the Act, and Rule 19b–4(f)(6)(iii) thereunder. 15 U.S.C. 78s(b)(3)(A), 17 CFR 240.19b–4(f)(6)(iii).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–(f)(6).

proposed rule change will be effective with respect to Nasdaq-listed securities as of August 1, 2006, the day on which the NASD/Nasdaq TRF commenced operating with respect to such securities. NASD proposes to implement the proposed rule change with respect to non-Nasdaq exchange-listed securities when the NASD/Nasdaq TRF receives Commission approval and commences operation with respect to such securities.

The text of the proposed rule change is available at the Commission's Public Reference Room, at NASD, and on the NASD Web site at *www.nasd.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD 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. NASD 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

NASD proposes to adopt a new NASD Rule 7000B Series relating to fees and credits applicable to the NASD/Nasdaq TRF, which was recently approved by the Commission for collecting over-the-counter trade reports in Nasdaq-listed securities.[7] In accordance with NASD policy regarding the NASD/Nasdaq TRF and other trade reporting facilities that NASD may establish with other registered national securities exchanges, the fees and credits reflected in the proposal have been developed and approved by the officers and the Board of Directors of the NASD/Nasdaq TRF, and have also been reviewed and approved by NASD staff and the NASD Board as consistent, in the view of the NASD, with the requirements of the Act.

The fee schedule set forth in proposed new Rule 7002B is identical to Nasdaq's current fee schedule for its Automated Confirmation Transaction (''ACT'') system contained in NASD Rule 7010(g) (Nasdaq Market Center Trade Reporting). Under the proposed fee schedule, reporting of trades that do not use the NASD/Nasdaq TRF's comparison functionality (*i.e.*, ''locked-in trades'') in Nasdaq-listed securities is free. Reporting of locked-in trades in other securities will be subject to a charge of $0.029 per side, but market participants reporting an average daily volume of more than 5000 trades per day in stocks reported to the Consolidated Tape Association (''CTA'') during a month will pay the charge only for a number of trades equal to 5000 times the number of trading days in the month. Under proposed Rule 7003B, which is identical to current NASD Rule 7020 (Aggregation of Activity of Affiliated Members), affiliated members using the NASD/Nasdaq TRF may aggregate their activity for purposes of determining eligibility for this volume based-discount.

The comparison charge in proposed Rule 7002B is $0.0144 per side per 100 shares, with a minimum charge of 400 shares and a maximum charge of 7,500 shares. The Late Report fee is $0.288 per side, the Query charge is $0.50 per query, and the Corrective Transaction Charge is $0.25, paid by the reporting party or both parties, depending on the nature of the correction. The NASD/Nasdaq TRF will assess a compounding late charge of 1–½% per month for fees past due 45 days or more.

In addition, NASD is proposing to adopt a transaction credit program under proposed NASD Rule 7001B with respect to trades reported to the NASD/Nasdaq TRF that would allow participants to share market data revenue associated with trades in stocks listed on the New York Stock Exchange (''Tape A'') and the American Stock Exchange (''Tape B''). Under the program, NASD members reporting trades in those stocks to the NASD/Nasdaq TRF will receive 50% of the market data revenue earned by the NASD/Nasdaq TRF with respect to those trade reports, after deducting any amounts that the NASD/Nasdaq TRF will be required to pay to the CTA for capacity usage. The credits are paid on a quarterly basis. The proposed transaction credit program is identical to Nasdaq's current transaction credit program for Tape A and Tape B stocks pursuant to NASD Rule 7010(b)(2) (Exchange-Listed Securities Transaction Credit).

NASD is also proposing to adopt under new Rule 7001B an equivalent transaction credit program for securities listed on the Nasdaq Stock Market (''Tape C''). The proposed program for Tape C stocks is not identical to the existing Tape A and B programs because there is a difference in the manner in which the underlying Tape A and Tape B revenue versus Tape C revenue is distributed to NASD and the exchanges. Tape A and Tape B revenue is currently distributed to NASD and exchanges based on the number of trades reported, while Tape C revenue is distributed based on an average of number of trades and number of shares reported. There is no difference, however, in the manner in which members will share in Tape A and B revenue versus Tape C revenue because the proposed rule language bases the credits on the pro rata share of revenue attributable to a member's trade reports. Thus, a member will receive 50% of the revenue attributable to its trade reports in each of the three tapes. The proposed transaction credit program for Tape C stocks is identical to the National Stock Exchange's (''NSX'') existing Tape C program. The NSX's program provides a 50% transaction credit on revenue generated by transactions in Tape C securities and is allocated to members on a pro rata basis based upon the Tape C revenue generated by such member.[8]

NASD has filed the proposed rule change for immediate effectiveness. NASD proposes that the proposed rule change, with respect to Nasdaq-listed securities, will be implemented as of August 1, 2006, the day on which the NASD/Nasdaq TRF commenced operating with respect to such securities. NASD proposes to implement the proposed rule change with respect to non-Nasdaq exchange-listed securities when the NASD/Nasdaq TRF receives Commission approval and commences operation with respect to such securities.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,[9] in general, and with Section 15A(b)(5) of the Act,[10] in particular, which requires, among other things, that NASD rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that NASD operates or controls. NASD believes that the proposed rule change is a reasonable and equitable fee and credit structure in that the proposed fees are identical to pre-existing fees established by Nasdaq during its operation as a facility of

[7] *See* Securities Exchange Act Release No. 54084 (June 30, 2006), 71 FR 38935 (July 10, 2006)(SR–NASD–2005–087). NASD intends to file an additional proposed rule change to allow the NASD/Nasdaq TRF to collect trade reports for non-Nasdaq exchange-listed securities.

[8] *See* Securities Exchange Act Release No. 53860 (May 24, 2006), 71 FR 31250 (June 1, 2006)(SR-NSX–2006–07).

[9] 15 U.S.C. 78*o*–3.

[10] 15 U.S.C. 78*o*–3(b)(5).

NASD and the credits are identical to pre-existing credits established by Nasdaq and the NSX.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change will result in 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

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

NASD has requested that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) under the Act[13] because the NASD/Nasdaq TRF commenced operating with respect to Nasdaq-listed securities on August 1, 2006. In light of the foregoing, the Commission believes such waiver is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposal to be effective and operative upon filing with the Commission.[14]

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–NASD–2006–090 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASD–2006–090. 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 NASD. 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–NASD–2006–090 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14297 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54346; File No. SR–NYSE–2006–62]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Extension of the Pilot Program Amending Listed Company Manual Section 102.01A

August 22, 2006.

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 18, 2006, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange has amended on a three month pilot program basis (''Pilot Program'') Section 102.01A of the Exchange's Listed Company Manual (''Manual'') regarding minimum numerical standards. The Pilot Program is due to expire on August 31, 2006. The Exchange proposes to extend the Pilot Program until the earlier of: (i) November 30, 2006; or (ii) the approval by the Commission of the Exchange's proposed permanent amendment to Section 102.01A.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.nyse.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,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

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 has amended, through the Pilot Program,[5] Section 102.01A of the Manual regarding minimum numerical standards. The Exchange has also filed a proposed rule change [6] seeking to make permanent the Pilot Program's amendments to Section 102.01A of the Manual. The Pilot Program is due to expire on August 31, 2006.[7] The Exchange proposes to extend the Pilot Program until the earlier of: (i) November 31, 2006; or (ii) the Commission's approval of the proposed permanent amendment to Section 102.01A of the Manual.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirement under Section 6(b)(5) of the Act [8] that an Exchange have rules that are 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 Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change, as amended.

[5] *See* Securities Exchange Act Release No. 52887 (December 5, 2005), 70 FR 73501 (December 12, 2005) (File No. SR–NYSE–2005–82).

[6] *See* File No. SR–NYSE–2006–22, filed with the Commission on March 20, 2006.

[7] *See* Securities Exchange Act Release No. 53777 (May 9, 2006), 71 FR 28059 (May 15, 2006) (File No. SR–NYSE–2006–27).

[8] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the five-day pre-filing requirement and the 30-day operative delay, as specified in Rule 19b–4(f)(6)(iii), and designate the proposed rule change immediately operative.

The Commission believes that waiving the five-day pre-filing provision and the 30-day operative delay is consistent with the protection of investors and the public interest.[12] By waiving the pre-filing requirement and 30-day operative date, the Pilot Program can continue without interruption. 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:

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] *Id.*

[12] For purposes 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).

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–NYSE–2006–62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–62. 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 available publicly. All submissions should refer to File Number SR–NYSE–2006–62 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14300 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54350; File No. SR–NYSE–2006–64]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change and Amendment No. 1 Thereto To Amend Section 102.01 of the Listed Company Manual To Reduce its Distribution Requirements for Companies Listing Common Equity Securities in Connection with an IPO, Transfer or Quotation

August 22, 2006.

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 18, 2006, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a ''non-controversial'' rule change under Section 19(b)(3)(A)(iii) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. On August 21, 2006, the Exchange filed Amendment No. 1 to the proposed rule change.[5] 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 NYSE proposes to amend Section 102.01A of the NYSE's Listed Company Manual (the ''Manual'') to reduce its distribution requirements from 2,000 to 400 round lot U.S. holders for companies listing common equity securities in connection with an initial public offering (''IPO''), transfer or quotation. The text of the proposed rule change is available on the NYSE's Web site (*http://www.nyse.com*), at the NYSE'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. 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

Section 102.01A of the Manual sets out minimum distribution requirements for size and volume that must be met in order for U.S. companies to list common equity securities. The Exchange proposes to amend Section 102.01A of the Manual to reduce its distribution requirements from 2,000 to 400 round lot U.S. holders for companies listing common equity securities in connection with an IPO, transfer or quotation. As amended, Section 102.01A of the Manual would continue to allow the Exchange to include all North American holders toward the 400 round lot U.S. holder threshold under Section 102.01B when considering a listing application from a company organized under the laws of Canada, Mexico or the United States. In addition, all other financial standards included in the distribution requirements will remain the same.

Generally speaking, U.S. companies that are listing equity securities in connection with an IPO, transfer or quotation must demonstrate that a security to be listed is held by a minimum of 2,000 round lot U.S. holders.[6] Under Section 102.01B, when considering a listing application from a company organized under the laws of Canada, Mexico or the United States, the Exchange will include all North American holders and North American trading volume in applying the minimum holder threshold.[7] All U.S. companies listing common equity securities must also demonstrate that there are at least 1,100,000 publicly held shares outstanding at the time of listing.

According to the Exchange, the current 2,000 round lot U.S. holder threshold was established several decades ago when the composition of the investor population was such that the Exchange anticipated that specialists might be called upon to play more of a role in providing necessary liquidity in its stocks. In the NYSE's view, the Exchange's current round lot holder requirement helped facilitate an environment in which there would be healthy liquidity in an issuer's stock independent of the specialist. Because both retail and institutional participation in the marketplace have grown tremendously over the last few decades, the Exchange now believes that it is less necessary to require such a large number of round lot holders. The Exchange notes that other U.S. markets currently require fewer round lot holders than the Exchange currently does, and that the Exchange has not had any negative experience with its current, albeit limited, pilot program.[8] The Exchange notes that the reduced requirement meets the requirements set forth in Rule 3a51–1 under the Exchange Act.[9]

2. Statutory Basis

The Exchange believes that the basis under the Act for this proposed rule change, as amended, is the requirement under Section 6(b)(5)[10] that an exchange have rules that are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism 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 Exchange does not believe that the proposed rule change, as amended, will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] In Amendment No. 1, the NYSE made clarifying changes to the Purpose Section of the Exchange's 19b–4 filing. *See* Amendment No. 1.

[6] A quotation is the listing of a foreign private issuer without a concurrent offering.

[7] The Exchange currently has a pilot program in effect that establishes a 400 round lot holder requirement for companies listing following emergence from bankruptcy or which are affiliated with listed companies. *See* Exchange Act Release No. 52887 (December 5, 2005), 70 FR 73501 (December 12, 2005) (SR–NYSE–2005–82). The Exchange has filed a proposed rule change to extend this pilot (SR–NYSE–2006–62).

[8] *See, e.g.*, Nasdaq Stock Market LLC Marketplace Rule 4420 (requiring 400 round lot holders).

[9] 17 CFR 240.3a51–1.

[10] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change, as amended.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change, as amended: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6) [13] normally does not become operative prior to thirty days after the date of filing. NYSE 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. 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 the extension will allow NYSE to have substantially similar distribution requirements to other Exchanges and does not unduly burden the marketplace.[14] For these reasons, the Commission designates the proposed rule change, as amended, as effective and operative immediately.

At any time within 60 days of the filing of the proposed rule change, as amended, 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.[15]

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–NYSE–2006–64 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–64. 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–NYSE–2006–64 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14307 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement. The Commission has determined to waive this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change, as amended, under Section 19(b)(3)(C) of the Act, the Commission considers the period to commence on August 21, 2006, the date on which the Exchange submitted Amendment No. 1. *See* 15 U.S.C. 78s(b)(3)(C).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54344; File No. SR–NYSE–2005–68]

Self-Regulatory Organizations; New York Stock Exchange, Inc. (n/k/a New York Stock Exchange LLC); Order Approving Proposed Rule Change and Amendment No. 1 Thereto, and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 3, Relating to Annual Financial Statement Distribution Requirements and Listed Company Manual Sections 103.00, 202.05, 203.00, 203.01, 203.02, 203.03, 204.00 Through .33, 303A.14, 313.00, 401.04, and 703.09

August 21, 2006.

I. Introduction

On September 30, 2005, the New York Stock Exchange LLC (''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 proposed rule change relating to the Exchange's annual financial statement distribution requirements and Listed Company Manual Sections 103.00, 202.05, 203.00, 203.01, 203.02, 203.03, 204.00 through .33, 303A.14, 313.00, 401.04, and 703.09. On June 9, 2006, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The proposed rule change, as amended, was published for comment in the **Federal Register** on June 29, 2006.[4] The Commission received five comments regarding the proposal.[5] On August 10, 2006, the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Amendment No. 1 dated June 9, 2006 (''Amendment No. 1''). In Amendment No. 1, the Exchange eliminated from the present filing other proposed rule changes to Section 103 and 302 of the Listed Company Manual, and clarified certain details of its proposal.

[4] *See* Securities Exchange Act Release No. 54029 (June 21, 2006), 71 FR 37147 (June 29, 2006) (''Notice'').

[5] *See* Letter from Richard J. Daly, Group Co-President, ADP Brokerage Services Group (''ADP''),

Exchange filed Amendment No. 3 to the proposed rule change.[6] On August 11, 2006, the Exchange submitted a letter to the Commission responding to the comments.[7] This order approves the proposed rule change, as amended by Amendments Nos. 1 and 3, provides notice of Amendment No. 3, solicits comments from interested persons on Amendment No. 3, and grants accelerated approval of Amendment No. 3.

II. Description of the Proposal

The Exchange proposes to amend Section 203.01 of the Listed Company Manual to allow a listed company to satisfy NYSE's annual financial statement distribution requirement by making the company's annual report on Form 10–K, 20–F, 40–F or N–CSR available on or by a link through its corporate Web site. In Amendment No. 3, the Exchange modified the proposal to provide that in the case of a listed company that is a closed-end fund, if the company does not maintain its own Web site, the company may utilize a Web site that the company is allowed to use to satisfy the Web site posting requirement in Rule 16a–3(k) of the Act.[8] Included with this link or posting, the listed company must also include a prominent undertaking in English that it would deliver a paper copy of the company's complete audited financial statements free of charge to any shareholder who requests it. The Exchange would also require a listed company to issue a press release simultaneously with its Web site posting stating that its annual report has been filed with the Commission. This press release must also specify the company's Web site address[9] and indicate that shareholders have the ability to receive a hard copy of the company's complete audited financial statements free of charge upon request within a reasonable period of time.

The Exchange also proposes to amend Section 203.01 of the Listed Company Manual to eliminate the following provisions: (i) That a company inform the NYSE if it is unable to file its annual report with the Commission in a timely manner; (ii) that a company notify the NYSE prior to the filing deadline if it will not file its annual report with the Commission on time, as well as the language setting out the date by which a company must distribute its annual report once the late annual report has been filed with the Commission; (iii) the Exchange's requirements regarding the content of annual reports and annual financial statements; and (iv) requirements regarding the publication and distribution of annual financial statements.[10]

The Exchange also proposes to amend Section 203.02 of the Listed Company Manual to consolidate and summarize the Exchange's reporting requirements for interim financial statements and to eliminate those provisions of Section 203.02 of the Listed Company Manual that are no longer applicable or that do not contain actual listing requirements.[11]

The Exchange also proposes to amend Section 103.00 of the Listed Company Manual to eliminate the requirement that foreign private issuers distribute to shareholders at least a summary annual report that includes summary financial information reconciled to U.S. generally accepted accounting principles and provide a full annual report to shareholders upon request, as well the requirement that a company that proposes to distribute a summary annual report contact an Exchange representative to determine whether the proposed use of the summary annual report meets the Exchange's requirements. NYSE also proposes to eliminate language from the first and sixth paragraphs of Section 103.00 of the Listed Company Manual to the extent that such language does not set forth actual listing requirements.[12]

The Exchange also proposes conforming amendments to Sections 202.05, 203.03, 204.00 through .33 and 313.00 of the Listed Company Manual.[13] These amendments include renumbering of sections and the elimination of references to annual report obligations throughout the Listed Company Manual, including with respect to procedures relating to the distribution of annual reports.

The Exchange also proposes to amend Section 204.00 of the Listed Company Manual to consolidate the requirements for companies to provide notice to and file certain documents with the Exchange.[14] In particular, the Exchange proposes to limit the need for companies to provide information to the Exchange that is available via the Commission's Electronic Data Gathering Analysis and Retrieval (EDGAR) system. The Exchange also proposes to eliminate certain explanatory language from Section 204.00 of the Listed Company Manual that the Exchange represented to be superfluous as a result of the proposed changes.

The Exchange also proposes to add a new Section 303A.14 to the Listed Company Manual that specifically requires listed companies to have and maintain a Web site.[15] This proposed section also includes the information required under Section 303A of the Listed Company Manual that listed companies must post to their Web sites, including committee charters, corporate governance guidelines and their code of business conduct and ethics. In Amendment No. 3, the Exchange modified the proposal to provide that in the case of a listed company that is a closed-end fund, if the company does not maintain its own Web site, the company may utilize a Web site that the company is allowed to use to satisfy the Web site posting requirement in Rule 16a–3(k) of the Act.[16]

The Exchange also proposes to eliminate Section 401.04 of the Listed Company Manual which provides guidance regarding the interval between

to Nancy M. Morris, Secretary, Commission, dated July 20, 2006 (''ADP Letter''); Letter from Dorothy M. Donohue, Associate Counsel, Investment Company Institute, to Nancy M. Morris, Secretary, Commission, dated July 20, 2006 (''ICI Letter''); Letter from David P. Cosper, Chief Financial Officer, Executive Vice President, Sonic Automotive, Inc., to Nancy M. Morris, Secretary, Commission, dated July 6, 2006 (''Sonic Letter''); Letter from Philip Broadley, Chair, The Hundred Group of Finance Directors, and Mark Harding, Chair, General Counsel 100 Group, to Nancy M. Morris, Secretary, Commission, dated June 19, 2006 (''Hundred Group Letter''); Letter from Scott Lamb, Vice President, Investor Relations, Coeur d'Alene Mines Corporation, to Jonathan G. Katz, Secretary, Commission, dated October 18, 2005 (''Coeur Letter'').

[6] *See* Amendment No. 3 dated August 10, 2006 (''Amendment No. 3''). In Amendment No. 3, the Exchange modified the proposed rule language in Section 303A.14 in response to the ICI Letter. ICI recommended that the Exchange modify the proposed rule change to make it clear that investment companies that do not have their own Web sites can use a related Web Site. *See infra* Part III. In Amendment No. 3, the Exchange also modified the proposed rule change to require that when a listed company issues a press release announcing the filing of its annual report with the Commission, that this press release also state the Web site where shareholders may access the annual report. The Exchange submitted Amendment No. 2 to the Commission on August 4, 2006 and withdrew Amendment No. 2 on August 10, 2006.

[7] *See* Letter from Mary Yeager, Assistant Secretary, NYSE, to Nancy M. Morris, Secretary, Commission, dated August 11, 2006 (''NYSE Response Letter'').

[8] 17 CFR 240.16a–3(k) states, in pertinent part, that: ''In the case of an issuer that is an investment company that does not maintain its own Web site; if any of the issuer's investment advisor, sponsor, depositor, trustee, administrator, principal underwriter, or any affiliated person of the investment company maintains a Web site that includes the name of the issuer, the issuer shall comply with the posting requirements by posting the forms on one such Web site.'' *See also* Amendment No. 3, *supra* note 6.

[9] *See* Amendment No. 3, *supra* note 6.

[10] *See* Notice at 37148–49.

[11] *See id.* at 37149–50.

[12] *See id.* at 37147–48.

[13] *See id.* at 37148, 37150–51.

[14] *See id.* at 37150–51.

[15] *See id.* at 37150–51.

[16] *See id.* at 37151.

the end of a listed company's fiscal year and its annual meeting of shareholders.[17] Lastly, the Exchange proposes to amend Section 703.09 of the Listed Company Manual to eliminate requirements relating to the disclosure of options, stock purchase and other remuneration plans.[18]

III. Comments

The Commission received five comment letters regarding the proposal.[19] Four comment letters supported the Exchange's proposed rule change. The ICI stated that the Exchange's proposal was ''highly appropriate'' given the tremendous growth in the Internet and its importance to investors as an information source.[20] The ICI also stated that internet access provides a more efficient way to access the reports, as well the ability to search in the reports for information of particular interest to investors. Finally, the ICI recommended that in the case of an investment company that does not maintain its own Web site, the investment company make its annual report available on, or by a link through, a Web site maintained, for example, by the company's investment adviser.[21]

Another commenter, Sonic Automotive, an NYSE-listed company, commented that it was sensible to deliver information in the most expeditious and efficient manner in a day and age of instant communications.[22] Coeur d'Alene Mines Corporation, also an NYSE-listed company, expressed support for the proposal, citing its own experience that most investors prefer the immediacy and ease of access associated with electronic delivery, and that the rule change would permit it to materially reduce costs associated with distributing the annual report.[23] This commenter also noted that the company's annual report and other Commission filings are already routinely available on or through the company's Web site, and on other sites such as EDGAR, long before they are available through mass mailings or individual mailings. In this regard, the commenter noted that each year's newly published annual report is already ''old news'' by the time it arrives in an investor's mailbox. Another commenter expressed the view that shareholders prefer immediately available electronic information, and that hard copies provided later are of limited use.[24] Moreover, this commenter stated that these benefits would be achieved while allowing for a ''significant'' cost reduction for foreign private issuers listed on the Exchange.

One commenter, ADP, opposed the proposed rule change.[25] ADP argued that the Exchange's proposal to eliminate the annual financial statement distribution requirement in Section 203.01 of the Listed Company Manual could have adverse affects on U.S. holders of securities of NYSE-listed foreign private issuers. ADP expressed a broad concern regarding the ''access equals delivery'' model upon which the proposed amendments are based, and stated that the Exchange has proposed making the change to Section 203.01 in the absence of any meaningful data supporting its underlying premise. ADP disagrees with the Exchange's belief that the vast majority of people in this country that review company financials access them online—either through the company's own Web site, EDGAR, or some other service provider. In particular, ADP asserted that (i) fewer shareholders would have access to annual financial statements, (ii) fewer shareholders would look at annual financial statements, (iii) more votes being cast without the benefit of financial statement review, and (iv) costs would be shifted to shareholders.[26]

The Exchange responded by stating that the Commission did not receive any negative comment letters from a retail or institutional investor with respect to the proposed rule change.[27] The Exchange also noted that the proposed rule change would not confine investors to online access. Rather, the Exchange explained that the proposed rule requires listed companies to issue a press release to inform investors that the annual report filed with the Commission is available on the listed company's Web site, and that the Exchange will also require that shareholders have the ability to receive a hard copy of the complete audited financial statements free of charge upon request within a reasonable period of time. Finally, the NYSE noted that the proposed rule change simply provides listed companies with an alternative to physical delivery, and that a listed company may continue to physically distribute an annual report if it wishes to do so.

IV. Discussion

After careful consideration of the proposal and the comments received, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[28] Specifically, the Commission finds that the proposal, as amended, is consistent with Section 6(b)(5) of the Act,[29] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

With respect to the Exchange's proposal to amend Section 203.01 of its Listed Company Manual to allow companies to satisfy the Exchange's annual financial distribution requirement by making the company's annual report on Form 10–K, 20–F, 40–F or N–CSR available on its corporate Web site, the Exchange and several of the commenters have stated that the new rule will be a more efficient way for listed companies to deliver, and shareholders to utilize, annual financial statements.[30] The Commission believes that electronic delivery may offer shareholders immediate access to financial information and greater ability to search such information. The Commission also believes that the proposed rule change may lead to significant cost savings for listed companies, savings that will ultimately accrue to those companies' shareholders.

The Commission also notes the concern raised by ADP that such an approach may have the unintended effect of preventing certain shareholders

[17] *See id.* at 37152.

[18] *See id.*

[19] *See Supra* note 5.

[20] ICI Letter, *supra* note 5.

[21] *Id.; see also* Amendment No. 3, *Supra* note 6.

[22] Sonic Automotive Letter, *supra* note 5.

[23] Coeur Letter, *supra* note 5.

[24] Hundred Group Letter, *supra* note 5. This commenter also noted that its clientele, many publicly traded United Kingdom companies, must incur the costs of distributing two annual reports to shareholders, one consisting of the annual report and accounts required under the relevant U.K. laws, and the other containing financial statements reconciled to U.S. GAAP.

[25] ADP Letter, *supra* note 5.

[26] *Id.*

[27] *See* NYSE Response Letter, *supra* note 7.

[28] In approving this proposal, the Commission has considered its impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78f(b)(5).

[30] The Commission notes that because U.S. companies listed on the Exchange must still distribute annual financial information as required by the Commission's proxy solicitation rules, the Exchange's proposed rule change will currently have minimal impact on U.S. issuers. *See* 17 CFR 240.14a–3. For foreign private issuers listed on the Exchange, however, the proposed rule change will eliminate the only mandated physical distribution requirement for annual financial statements.

from obtaining annual financial information from listed companies.[31] The Commission believes, however, that this risk is minimized by virtue of the fact that the proposed rule change requires the listed company to issue a press release simultaneously with the posting of the annual report stating that the annual report is available, listing the Web site where the annual report may be accessed, and requiring the listed company to send paper copies to those shareholders that request one within a reasonable time at no charge. The Commission believes that it is reasonable to assume that individual shareholders will follow the public announcements of those companies in which they own stock, and that these shareholders will either be able to access the Web site with the annual report or request a free paper copy if they wish. Further, as noted by one commenter on the proposal,[32] because of existing Internet and EDGAR access to annual reports, the information received in hard copy can be ''old news.'' Indeed, information in the annual report can already be incorporated into the market price of the listed company's stock by the time investors receive the hard copy.[33]

ADP also expressed concern that the proposed rule change is based upon an ''access equals delivery'' model of disclosure.[34] The Commission notes that it considered the NYSE's elimination of its annual report distribution requirement for listed companies under Section 19(b) of the Act.[35] The Commission's determination of what constitutes an appropriate SRO rule under Section 19(b) of the Act is distinct from the Commission's consideration of rulemaking under the Act, and will not have any impact on the Commission's consideration of the proposal concerning amendments to the proxy rules.[36]

In connection with the Exchange's proposed amendments to the annual financial distribution requirements in Section 203.01 of the Listed Company Manual, the Commission notes that the Exchange has proposed conforming amendments to Section 203.01 and other sections of the Listed Company Manual. For example, the Exchange's proposal would also eliminate the requirements currently contained in Section 203.01 that detail the procedures for physical distribution of the annual financial statements as well as the notice requirement that companies have followed if they could not meet these physical distribution requirements.[37] Additionally, the Exchange proposes to eliminate provisions in Section 203.01 of the Listed Company Manual that detail the form and substance of the annual financial statements.[38] The Commission notes that the Exchange has represented that the notice requirement for companies that fail to distribute annual financial statements is no longer necessary because the Exchange monitors listed companies for timely filing of their Commission reports on an ongoing basis.[39] Given this monitoring, and the Exchange's representation that it monitors listed companies for timely filing on an ongoing basis, the Commission believes this aspect of the proposed rule change is reasonable. The Commission believes that the Exchange's deletion of the provisions of Section 203.01 of the Listed Company Manual regarding the form and substance of the annual financial statements eliminates duplicative, and potentially confusing, disclosure requirements for companies that are fully described in the Act.[40]

The Exchange also proposes to amend Section 103.00 of the Listed Company Manual to eliminate the requirement that foreign private issuers distribute at least summary annual reports to shareholders. The elimination of this requirement is consistent with the Exchange's proposal in Section 203.01 of the Listed Company Manual because the Exchange is no longer requiring companies to physically distribute annual financial information to shareholders. The Commission notes that the Exchange's proposal would still require foreign private issuers to send hard copies of the annual financial statements to shareholders, free of charge, upon request, within a reasonable period of time.

The Exchange also proposes to delete Section 401.04 from the Listed Company Manual. In approving this portion of the proposed rule change, the Commission notes that the Exchange has specifically stated that it is not disavowing that best practice is for a listed company to hold its annual meeting within a reasonable time after the close of the company's fiscal year.[41] While the Commission also agrees that best practice is for a listed company to hold its annual meeting within a reasonable time after the close of its fiscal year, the Commission believes that it is not unreasonable for the Exchange to eliminate from the Listed Company Manual language that is, by its express terms, not an enforceable requirement, both to prevent confusion amongst listed companies and to reduce the Listed Company Manual to a codification of mandatory requirements for listed companies.

Lastly, the Exchange proposes to eliminate certain provisions of Section 703.09 of the Listed Company Manual regarding disclosure of options, stock purchase and other remuneration plans. The Commission believes the Exchange's deletion of these provisions from Section 703.09 of the Listed Company Manual is consistent with the Act since it eliminates duplicative, and potentially confusing, disclosure requirements for companies that are already more fully described in the Act.[42]

Notice of Filing of and Order Granting Accelerated Approval to Amendment No. 3 to the Proposed Rule Change

In Amendment No. 3, the Exchange modified the proposal to provide that in the case of a listed company that is a closed-end fund, if the company does not maintain its own Web site, the company may utilize a Web site that the company is allowed to use to satisfy the Web site posting requirement in Rule 16a–3(k) of the Act.[43] The Exchange also added a requirement that when a company issues the press release

[31] *See* ADP Letter, *supra* note 5.

[32] Coeur Letter, *supra* note 5.

[33] The Commission also notes that in its response letter, the NYSE stated that all of the comment letters, with the exception of ADP's comment letter, were positive, that there were no negative comments from individual or institutional investors, and that the proposed rule change provides listed companies with an alternative to physical delivery, but that listed companies may continue to physically distribute annual reports if they so wish.

[34] ADP Letter, *supra* note 5.

[35] Section 19(b)(2) of the Act states, in pertinent part, that: ''The Commission shall approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of this title and the rules and regulations thereunder applicable to such organization.'' 15 U.S.C. 78s(b)(2).

[36] *See* Securities Exchange Act Release No. 52926 (December 8, 2005), 70 FR 74598 (December 15, 2005) (proposing amendments to the proxy rules that would provide an alternative method for issuers and other persons to furnish proxy materials to shareholders by posting them on an Internet Web site and providing shareholders with notice of the availability of the proxy materials with copies being made available to shareholders on request, at no cost).

[37] *See* Notice at 37148.

[38] *Id.*

[39] *See* Notice at 37153 (stating that the Exchange monitors listed companies for timely filing of their Commission reports on an ongoing basis).

[40] *See, e.g.*, 17 CFR 210.1–01 *et seq.*

[41] *See* Notice, 71 FR at 37154 (stating that the Exchange is not disavowing that best practice is to hold the annual meeting within a reasonable interval after the close of the fiscal year).

[42] *See, e.g.*, 17 CFR 229.201(d) and 17 CFR 229.402.

[43] 17 CFR 240.16a–3(k); *see also* Amendment No. 3, *supra* note 6.

announcing that its annual report has been filed, it must also specify in the press release the Web site address where shareholders may access the annual report.[44]

The changes proposed by the Exchange in Amendment No. 3 respond to a concern raised by the ICI and are designed to ensure that the proposed rule change works as intended with respect to investment companies.[45] The proposed change also improves the press release proposal by requiring that the Web site address where financial statement can be accessed be included in the press release. The Commission believes that these proposed changes strengthen the proposed rule change and do not raise any new regulatory issues beyond those raised by the original proposal. Therefore, the Commission finds good cause, consistent with Sections 19(b) and 6(b)(5) of the Act, to approve Amendment No. 3 to the proposed rule change prior to the 30th day after the amendment is published for comment in the **Federal Register**.

V. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 3, including whether Amendment No. 3 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NYSE–2005–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSE–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 will also be available for inspection and copying at the principal office of the NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSE–2005–68 and should be submitted on or before September 19, 2006.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[46] that the proposed rule change (SR–NYSE–2005–68), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[47]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14276 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54348; File No. SR–NYSEArca–2006–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Amendment No. 1 Thereto of Proposed Rule Change Relating to Voluntary Withdrawal Procedures by Listed Issuers

August 22, 2006.

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 4, 2006, NYSE Arca, Inc. (''NYSE Arca'' 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. On August 17, 2006, the Exchange filed 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

NYSE Arca, through its wholly-owned subsidiary NYSE Arca Equities, Inc. (''NYSE Arca Equities'' or ''Corporation''), proposes to amend NYSE Arca Equities Rule 5.4(b) relating to the voluntary withdrawal by issuers of their securities listed on NYSE Arca, L.L.C. (also referred to as the ''NYSE Arca Marketplace''), the equities trading facility of NYSE Arca Equities, including with respect to dually-listed issuers. Below is the text of the proposed rule change, as amended. Proposed new language is *italics*; proposed deletions are in brackets.

* * * * *

Rule 5 Listings

* * * * *

[Issuer Proposing to Withdraw]

Rule 5.4(b). Issuer Proposing to Withdraw

[An issuer proposing to withdraw a security from listing on the Corporation shall submit to the Corporation a certified copy of a resolution adopted by the board of directors of the issuer authorizing withdrawal from listing and registrations, a letter from an authorized officer of the issuer providing the specific reasons cited by the board of directors of the issuer for the proposed withdrawal, and a copy of the Form 25 that the issuer has filed with the Securities and Exchange Commission in accordance with Rule 12d2–2 promulgated under Section 12(d) of the Securities Exchange Act of 1934, as amended, no later than the date of such filing. The issuer may be required, under special circumstances, to submit the proposed withdrawal to the shareholders for their vote at a meeting

[44] *See* Amendment No. 3, *supra* note 6.

[45] The Commission notes that in its comment letter, the ICI's proposed modifications to Section 303A.14 referred to ''investment companies,'' whereas the Exchange's proposed rule text contained in Amendment No. 3 refers to ''closed-end funds.'' *See* ICI Letter, *supra* note 5; *see also* Amendment No. 3, *supra* note 6. The Exchange has represented that the reason that it made this change to the ICI's suggested language is because under the Exchange's rules, the only listed ''investment companies'' to which the proposed rule change can apply are closed-end funds. *See* Telephone Conference between Annmarie Tierney, Assistant General Counsel, NYSE, and Raymond Lombardo, Special Counsel, Division of Market Regulation, Commission, on August 14, 2006.

[46] 15 U.S.C. 78s(b)(2).

[47] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange replaced Exhibit 5 with the correct rule text and corrected a typographical error in the heading of Exhibit 1.

for which proxies are solicited provided the security is not also listed on another exchange having similar requirements.]

An issuer may delist a security from the Exchange after its board approves the action and the issuer (i) furnishes the Exchange with a copy of the Board resolution authorizing such delisting certified by the secretary of the issuer and (ii) complies with all of the requirements of Rule 12d2–2(c) under the Securities Exchange Act of 1934. The issuer must thereafter file a Form 25 with the Securities and Exchange Commission to withdraw the security from listing on the Exchange and from registration under the Securities Exchange Act of 1934. In addition, the issuer must provide a copy of the Form 25 to the Exchange simultaneously with the filing of such Form 25 with the Securities and Exchange Commission. If an issuer delists a class of stock from the Exchange pursuant to this Rule, but does not delist other classes of listed securities, the Exchange will give consideration to delisting one or more of such other classes.

If, however, an issuer proposing to withdraw from listing is also listed on a national securities exchange or the Nasdaq Stock Market (including the Nasdaq Capital Market or any successor thereto), it need not submit the board resolution required by Rule 5.4(b)(i) above, but, in lieu thereof, must provide a letter signed by an executive officer of the issuer setting forth the reasons for the proposed withdrawal. Such issuers must still otherwise comply with the other requirements of this Rule and Rule 12d2–2(c) under the Securities Exchange Act of 1934.

The *Exchange* [Corporation], upon receiving written notification of the issuer's intent to withdraw its securities from listing and registration, shall post notice of such intent on the Exchange's website by the next business day and until the delisting becomes effective. An issuer seeking to voluntarily apply to withdraw a class of securities from listing on NYSE Arca pursuant to this paragraph that has received notice from NYSE Arca, pursuant to Rule 5.3, Rule 5.5 or otherwise, that it is below NYSE Arca's continued listing policies and standards, or that is aware that it is below such continued listing policies and standards notwithstanding that it has not received such notice from NYSE Arca, must disclose that it is no longer eligible for continued listing (identifying the specific continued listing policies and standards with which it does not comply) in: (i) Its statement of all material facts relating to the reasons for withdrawal from listing provided to NYSE Arca along with written notice of its determination to withdraw from listing required by Rule 12d2–2(c)(2)(ii) under the Exchange Act; and (ii) its public press release and Web site notice required by Rule 12d2–2(c)(2)(iii) under the Exchange Act.

* * * * *

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

On March 7, 2006, Archipelago Holdings, Inc. and the New York Stock Exchange, Inc. completed the merger creating the NYSE Group, Inc. (''NYSE Group''). The NYSE Group is a holding company that operates, among other things, two securities exchanges: New York Stock Exchange LLC (''NYSE'') and NYSE Arca Marketplace.[4] In connection with the merger, NYSE Arca Marketplace examined its listings program, and determined to revitalize and refocus its primary listings program. In particular, with this filing, NYSE Arca proposes to: (1) Substantially align its voluntary withdrawal requirements with those of the NYSE,[5] and (2) eliminate—for all issuers listed on NYSE Arca, on the one hand, and either a national securities exchange or the Nasdaq Stock Market (including the Nasdaq Capital Market or any successor thereto), on the other hand (which will be referred to as ''dually-listed issuers'')—the requirement set forth in the current NYSE Arca Equities Rule 5.4(b) that issuers which propose to withdraw a security from listing shall submit a certified copy of a resolution adopted by the board of directors authorizing withdrawal from listing and registration. Instead, a dually-listed issuer wishing to voluntarily withdraw will be required to submit a letter from an executive officer of the issuer setting forth the reasons for the proposed withdrawal.

The elimination of the board resolution requirement applies to dually-listed issuers only; the board resolution requirement will continue to apply to all issuers listed exclusively on NYSE Arca. Furthermore, all other requirements of NYSE Arca Equities Rule 5.4(b) will continue to apply to dually-listed issuers. The Exchange also notes that dually-listed issuers will still be required to comply with any applicable state laws.

Additionally, based on informal discussions with its dually-listed issuers, NYSE Arca believes that removing the board resolution requirement will ease the process for any dually-listed issuer who wishes to voluntarily withdraw from NYSE Arca. Furthermore, the Exchange believes that the removal of this requirement would not create or raise any new or significant regulatory issues. While a dually-listed issuer will not be listed and traded on NYSE Arca following its withdrawal from the NYSE Arca Marketplace, the issuer will continue to be listed and traded on either a registered securities exchange or the Nasdaq Stock Market (or any successor thereto). Consequently, transparent last sale reporting information regarding trading in the issuer's securities will continue to be disseminated, and the continued listing and trading of such securities will remain subject to the same or substantially similar protections and requirements to which such listing and trading is currently subject on NYSE Arca. Moreover, in lieu of the board resolution requirement, an executive officer of the dually-listed issuer will be required to present a detailed rationale for the proposed withdrawal. In contrast, those issuers exclusively listed on NYSE Arca that wish to delist will continue to be required to comply with the board resolution requirement.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with Section 6(b)(5) of the Act[6] because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation

[4] The Commission notes that NYSE Group operates two national securities exchanges: NYSE and NYSE Arca. NYSE Arca Marketplace is a facility of NYSE Arca Equities.

[5] For example, current Section 806.02 of the NYSE Listed Company Manual states that if an issuer delists a class of stock from NYSE but does not delist other classes of securities, NYSE will give consideration to the delisting of one or more of such other classes. Proposed NYSE Arca Equities Rule 5.4 will provide the Exchange with similar flexibility.

[6] 15 U.S.C. 78f(b)(5).

and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and 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 Exchange does not believe that the proposed rule change, as amended, will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change, as amended.

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 self-regulatory organization 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, 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–NYSEArca–2006–47 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2006–47. 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 available publicly. All submissions should refer to File Number SR–NYSEArca–2006–47 and should be submitted on or before September 19, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Nancy M. Morris,

Secretary.

[FR Doc. E6–14275 Filed 8–28–06; 8:45 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before September 28, 2006. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and *David_Rostker@omb.eop.gov,* fax number 202–395–7285 Office of Information and Regulatory Affairs, Office of Management and Budget.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, *jacqueline.white@sba.gov* (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: Statement of Personal History.
Form No: 912.
Frequency: On Occasion.
Description of Respondents: Applicants for Assistance or Temporary Employment in Disaster.
Annual Responses: 55,000.
Annual Burden: 13,750.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. E6–14351 Filed 8–28–06; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10569 and # 10570]

Virginia Disaster # VA–00003

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the Commonwealth of Virginia dated August 17, 2006.

Incident: Severe Storms and Flooding.
Incident Period: June 25, 2006 through June 30, 2006.
Effective Date: August 17, 2006.
Physical Loan Application Deadline Date: October 16, 2006.
Economic Injury (EIDL) Loan Application Deadline Date: May 17, 2007.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, National Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

[7] 17 CFR 200.30–3(a)(12).

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Alexandria (City), Fairfax.

Contiguous Counties:

Virginia: Arlington, Fairfax (City), Falls Church (City), Loudoun, and Prince William.

District of Columbia: District of Columbia.

Maryland: Charles, Montgomery, and Prince George's.

The Interest Rates are:

	Percent
Homeowners with Credit Available Elsewhere	5.875
Homeowners without Credit Available Elsewhere	2.937
Businesses with Credit Available Elsewhere	7.763
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) with Credit Available Elsewhere	5.000
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 10569 6 and for economic injury is 10570 0.

The States which received an EIDL Declaration # are Virginia, District of Columbia, and Maryland.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: August 17, 2006.

Steven C. Preston,

Administrator.

[FR Doc. E6–14270 Filed 8–28–06; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Application of Partner Aviation Enterprises D/B/A Empire Airways for Commuter Air Carrier Authorization

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 2006–8–21); Docket OST–2006–24223.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Partner Aviation Enterprises d/b/a Empire Airways fit, willing, and able, and awarding it a commuter air carrier authorization to engage in scheduled passenger air transportation as a commuter air carrier.

DATES: Persons wishing to file objections should do so no later than September 5, 2006.

ADDRESSES: Objections and answers to objections should be filed in Docket OST–2006–24223 and addressed to U.S. Department of Transportation, Docket Operations, (M–30, Room PL–401), 400 Seventh Street, SW., Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Lauralyn J. Remo, Air Carrier Fitness Division (X–56, Room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9721.

Dated: August 22, 2006.

Michael W. Reynolds,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. E6–14330 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. OST–2006–25603]

Senior Executive Service Performance Review Boards Membership

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice of Performance Review Board (PRB) appointments.

SUMMARY: DOT publication of the names of the persons selected to serve on the various Departmental PRBs as required by 5 U.S.C. 4314(c)(4).

FOR FURTHER INFORMATION CONTACT: Patricia A. Prosperi, Departmental Director, Office of Human Resource Management, (202) 366–4088.

SUPPLEMENTARY INFORMATION: The persons named below have been selected to serve on one or more Departmental PRBs.

Issued in Washington, DC, on August 22, 2006.

Patricia A. Prosperi,

Director, Departmental Office of Human Resource Management.

Federal Railroad Administration

Jane H. Bachner, Deputy Associate Administrator for Industry and Intermodal Policy, Federal Railroad Administration

Mark Yachmetz, Associate Administrator for Railroad Development, Federal Railroad Administration

Margaret Reid, Associate Administrator for Financial Management and Administration, Federal Railroad Administration

Judy Kaleta, Senior Counsel for Dispute Resolution, Office of the Secretary

Terry Shelton, Chief Information Officer, Federal Motor Carrier Safety Administration

Suzanne TeBeau, Chief Counsel, Federal Motor Carrier Safety Administrator

Joseph Kanianthra, Associate Administrator for Vehicle Safety Research, National Highway Traffic Safety Administration

Federal Transit Administration

Richard H. Doyle, Regional Administrator, Cambridge, MA, Federal Transit Administration

Thomas Herlihy, Assistant General Counsel for Legislation, Office of the Secretary

Rosalind Knapp, Deputy General Counsel, Office of the Secretary

Linda J. Washington, Deputy Assistant Secretary for Administration, Office of the Secretary

John W. Irvin, Associate Administrator for Communications and Congressional Affairs, Federal Transit Administration

National Highway Traffic Safety Administration

Dan Smith, Associate Administrator for Enforcement, National Highway Traffic Safety Administration

Marlene Markison, Associate Administrator for Injury Control Operations and Resources, National Highway Traffic Safety Administration

Margaret O'Brien, Chief Information Officer, National Highway Traffic Safety Administration

Terry Shelton, Associate Administrator for Research, Technology and Information Management, Federal Motor Carrier Safety Administration

Larry Minor, Director, Office of Bus and Truck Standards and Operations, Federal Motor Carrier Safety Administration

Jeffrey Lindley, Associate Administrator for Safety, Federal Highway Administration

Anthony Cooke, Chief Counsel, National Highway Traffic Safety Administration

Federal Highway Administration

Christine M. Johnson, Director of Field Services—West, Federal Highway Administration
James D. Ray, Chief Counsel, Federal Highway Administration
Michael J. Vecchietti, Associate Administrator for Administration, Federal Highway Administration
King W. Gee, Associate Administrator for Infrastructure, Federal Highway Administration
Rose McMurray, Associate Administrator for Policy and Program Development, Federal Motor Carrier Safety Administration

Maritime Administration

Eileen Roberson, Associate Administrator for Administration, Maritime Administration
Bruce Carlton, Associate Administrator for Policy and International Trade, Maritime Administration
Jim Zok, Associate Administrator for Financial Approvals and Cargo Preference, Maritime Administration
Jean E. McKeever, Associate Administrator for Shipbuilding, Maritime Administration
Margaret D. Blum, Associate Administrator for Port, Intermodal, and Environmental Activities, Maritime Administration
Brigham McCown, Deputy Administrator, Pipeline and Hazardous Materials Safety Administration

Office of the Secretary, Research and Innovative Technology Administration, Saint Lawrence Seaway Development Corporation

Roberta D. Gabel, Assistant General Counsel for Environmental, Civil Rights, and General Law, Office of the Secretary
Craig Middlebrook, Deputy Administrator, Saint Lawrence Seaway Development Corporation
Stacey Gerard, Associate Administrator, Office of Pipeline Safety, Pipeline and Hazardous Materials Safety Administration
Michael Trujillo, Departmental Director, Office of Civil Rights, Office of the Secretary
Eileen Roberson, Associate Administrator for Administration, Maritime Administration
Daniel Mintz, Chief Information Officer, Office of the Secretary

Pipeline and Hazardous Materials Safety Administration

Jane Bachner, Deputy Associate Administrator for Industry and Intermodal Policy, Federal Railroad Administration
Eileen Roberson, Associate Administrator for Administration, Maritime Administration
Daniel C. Smith, Associate Administrator for Enforcement, National Highway Traffic Safety Administration
Michael Trujillo, Departmental Director of Civil Rights, Office of the Secretary
Theodore Willke, Deputy Associate Administrator for Pipeline Safety, Pipeline and Hazardous Materials Safety Administration

Federal Motor Carrier Safety Administration

Rose McMurray, Associate Administrator for Policy and Program Development, Federal Motor Carrier Safety Administration
Bruce Carlton, Associate Administrator for Policy and International Trade, Maritime Administration
Mike Halladay, Director, Office of Program Integration and Delivery, Federal Highway Administration
Alexis Stefani, Deputy Assistant Secretary for Budget and Programs, Office of the Secretary
Michael Trujillo, Departmental Director of Civil Rights, Office of the Secretary
Krista Edwards, Chief Counsel, Pipeline and Hazardous Materials Safety Administration

Office of Inspector General

George W. Collard, Assistant Inspector General for Audit Operations, Department of Energy
Michael Delgado, Assistant Inspector General for Investigations, Treasury Inspector General for Tax Administration
Melissa Heist, Assistant Inspector General for Audit, Environmental Protection Agency
Samuel Holland, Assistant Inspector General for Investigations, Federal Deposit Insurance Corporation
Helen Lew, Assistant Inspector General for Auditing, Department of Education
David Montoya, Assistant Inspector General for Investigations, Department of the Interior
Michael Stephens, Deputy Inspector General, Department of Housing and Urban Development
Robert Taylor, Deputy Assistant Inspector General for Audit Program Operations, Department of Treasury
Kathleen S. Tighe, Deputy Inspector General, Department of Agriculture
Eugene Wesley, Assistant Inspector General for Auditing, General Services Administration
Mark Woods, Assistant Inspector General for Investigations, Department of Agriculture

[FR Doc. E6–14335 Filed 8–28–06; 8:45 am]
BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

National Resource Center for Human Service Transportation Coordination; Solicitation for Proposals

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice; request for proposals.

SUMMARY: This solicitation is for proposals from national non-profit organizations with transportation coordination and technical assistance expertise for a cooperative agreement to develop and implement a National Resource Center for Human Service Transportation Coordination (NRC). The NCR will manage a program to improve and enhance the coordination of Federal resources for human service transportation with those of the Department of Transportation (DOT). The major goal of the NRC is to assist local communities and States in the expansion and provision of coordinated human service transportation for older adults, people with disabilities, and individuals with lower incomes. Federal Transit Administration (FTA) will award one four year agreement. Year one of the cooperative agreement is for one million, five hundred eighty-four thousand dollars ($1,584,000) as authorized in the Safe, Accountable, Flexible, and Efficient Transportation Equity Act—A Legacy for Users (SAFETEA–LU) and subsequently appropriated. Funding for subsequent years will be based on annual appropriations as well as annual performance reviews.

DATES: Proposals must be submitted electronically by October 30, 2006.

ADDRESSES: Proposals shall be submitted electronically to *http://www.grants.gov.* Grants.Gov allows organizations to find and apply for funding opportunities electronically from all Federal grant-making agencies. Grants.Gov is the single access point for over 1,000 cooperative agreement programs offered by the 26 Federal grant-making agencies.

Proposals can also be submitted in hard copy accompanied by an electronic version to Bryna Helfer, 400 7th Street, SW., Room 9114, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Bryna Helfer at 202–366–1663; FAX: 202–366–3136; *bryna.helfer@dot.gov.*

SUPPLEMENTARY INFORMATION: Section 3046 of the Safe, Accountable, Flexible, and Efficient Transportation Equity Act—a Legacy for Users (SAFETEA–LU); Pub. L. 109–059, authorized $1,600,000 in each of fiscal years 2006, 2007, 2008, and 2009 under 49 U.S.C. 5314(c) for the management of a program to improve and enhance the coordination of Federal resources for human service transportation with those of the Department of Transportation, as follows:

(1) Establishment. The Secretary of Transportation shall competitively select a national non-profit organization to manage the program.

(2) Eligibility. To be eligible, an organization shall have demonstrated expertise in issues of transportation coordination and in providing technical assistance to local transportation organizations.

(3) Use of Funds. The organization selected shall (i) Establish an advisory panel consisting of Federal, State and local officials and organizations; (ii) prepare an inventory of human service transportation agencies operating in the United States; (iii) prepare an inventory of Federal transportation spending; (iv) develop a program of technical assistance and training for human service transportation organizations that shall include on-site technical assistance, a resource clearinghouse, and preparation of technical manuals; (v) prepare an annual report for the Secretary of Transportation on activities under this program and make recommendations for improving coordination.

I. Funding Opportunity Description

The Federal Transit Administration (FTA) is soliciting proposals for a cooperative agreement to implement the human service transportation coordination program authorized in SAFETEA–LU. FTA will award a single four-year cooperative agreement, which will be funded annually at up to $1.6 million per year subject to the availability of appropriations. The purpose of this cooperative agreement is to develop and implement a NRC. The major goal of the NRC is to assist States in the coordination of human service transportation service at both the State and local levels. The tasks of the NRC include: (1) Collaboration with FTA and the Federal Interagency Coordinating Council on Access and Mobility; (2) research and development; (3) technical assistance and training; (4) strategic development in partnership, community involvement in human service transportation coordination; (5) communication and management information activities; and (6) administration. The NRC will follow a number of strategies in its development, especially partnerships, leadership development, knowledge management and customer-focused service in order to facilitate capacity building at the State level this is targeted to enhance local coordination efforts. NRCHST personnel will engage early and often with technical assistance (TA) recipients to ensure knowledge is transferred and relationships are developed. The NRC will develop an information and referral system as a key focal point to disseminate models, and identify useful practices for innovations in human service transportation service and systems. The NRC also will build coordination with and referrals to other TA centers focused in targeted areas related to human service transportation to build capacity and integrate aspects of coordination activities at the local levels. This project will entail creative, engaging and collaborative public and private partnerships at all levels—local, tribal, State and Federal, including a broad range of stakeholders interested in facilitating transportation access to employment, health, education, recreation and other community services for people with disabilities, older adults, and individuals with lower incomes.

II. Background

In recognition of the fundamental importance of human service transportation and the continuing need to enhance coordination, President Bush issued an Executive Order on Human Service Transportation Coordination (EO) directing multiple Federal departments and agencies to work together to ensure that transportation services are seamless, comprehensive and accessible. Secretaries from the Departments of Transportation, Health and Human Services, Labor, Education, Interior, Housing and Urban Development, Agriculture, and Veterans Affairs; the Commissioner of the Social Security Administration; the Attorney General; and the Chairperson of the National Council on Disability are members of the Federal Interagency Coordinating Council on Access and Mobility (CCAM). Specifically, the CCAM is tasked with seeking ways to simplify access to transportation services for persons with disabilities, persons with lower incomes, and older adults. The EO requires that CCAM members work together to provide the most appropriate, cost effective services within existing resources, and reduce duplication to make funds available for more services. To meet the requirements of the EO, the CCAM has developed a comprehensive action plan and launched United We Ride (UWR), a national initiative on human service transportation coordination. The NRC will be linked with UWR and related technical assistance initiatives in the area of human service transportation. FTA will be the administering agency for this activity and will be collaborating with other members of CCAM on the implementation of the EO. Therefore, the technical assistance provided under this solicitation will seek to complement and optimize, not duplicate the technical assistance and related work funded in this area by other CCAM partners.

The Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), (Pub. L. 109–59, August 10, 2005) requires that projects selected for funding under the Elderly Individuals and Individuals with Disabilities, Job Access Reverse Commute, and New Freedom programs administered by the Federal Transit Administration be ''derived from a locally developed, coordinated public transit-human service transportation plan'' and that the plan be ''developed through a process that includes representatives of public, private, and nonprofit transportation and human service providers and participation by members of the public.'' This new requirement leads to a need for an increased level of technical assistance related to the development and implementation of a coordinated public transit-human service transportation plan as well as ensuring broad based participation by diverse stakeholders.

Human service transportation is defined as a network of transportation services for older adults, individuals with disabilities, and people with lower incomes, including but not limited to vehicle acquisition, adaptation and driver transition; pedestrian access; public transportation; demand response (curb to curb, door to door, door through door); vanpooling and other ridesharing services; taxi services; and volunteer services. The technical assistance, to be funded through this cooperative arrangement is a process that enables a goal-focused, strategy-oriented, accountable organization to transfer knowledge to human service agencies, transportation providers, consumers, and other interested stakeholders. Technical assistance is intended to provide extensive information and assistance to facilitate adoption or application of research-based or

practice-based products, policies, or knowledge in order to improve the provision of transportation services for people with disabilities, older adults, and individuals with lower incomes. In order to ensure that all communities have access to technical assistance, the NRC will assist States with building capacity and accessing resources to be used in local communities across their States. In addition, the NRC will work closely with other technical assistance centers focused in areas of human service transportation when working with local communities to address coordination issues.

Technical assistance will need to focus on creating one-stop access to transportation services, streamlining eligibility, enhancing transportation coordination, mobility management, identifying solutions for coordinating policy and funding issues, implementing technology solutions, and social marketing to get information out to providers, policy makers and consumers. Technical assistance may include information dissemination, training, and enhancing capacity for building more efficient transportation services at the local and State levels. However, it is also intended to provide more intensive interaction to facilitate systems change related to practice, policy, research, resources, and programs at the Federal regional, State, and local levels. The NRC also will coordinate with other technical assistance initiatives related to human service transportation to ensure a coordinated approach in this area. In addition, all efforts of the NRC shall ensure consumer input and involvement such that all technical assistance to human service transportation organizations has a person centered, self-determination and independence focus in addition to a focus on the institutional relationships between transit and human service transportation.

Task 1—Collaboration with FTA and the Federal Coordinating Council on Access and Mobility

a. The grantee, in coordination with the Federal Project Officer shall provide technical assistance to the Coordinating Council on Access and Mobility (CCAM). This may include organizing monthly conference calls, providing input regarding infrastructure development of the CCAM activities related to human service transportation, formulating agendas, developing briefing materials, coordinating speakers for CCAM and their executive council meetings.

b. The grantee shall provide research-related technical assistance to project directors involved with human service transportation funded activities in CCAM member agencies. This includes queries regard specific information, publications, existing tools, strategies, and available data as requested.

c. Assist Federal program staff to conduct one special interest meeting each year on a targeted topic selected in consultation with FTA, members of the CCAM, and the NRS steering committee. Special interests meetings should target topics that require input and consultation from a broad perspective, and are targeted to include stakeholders from National, State, and local levels that have expertise on the selected topic addressed at the meeting. Participant lists and invitations for the meeting should be submitted to the Federal Project Officer for review at least 60 days prior to the targeted meeting date for approval. Briefing materials should be submitted to the Project Officer at least two weeks prior to the meeting for review and approval. The meeting should lead to the outcome of a publications (*e.g.*, strategy paper, tool, fact sheet, etc.) related to the topic discussed. In addition, the grantee should submit a summary report of the meeting within 30 working days.

Task 2—Research and Development

SAFETEA–LU outlines several specific research projects to be conducted by the recipient and include the following:

a. In year one, the NRC shall prepare an inventory of human service transportation agencies operating in the United States and a plan to update the information on a regular schedule. The applicant should present a detailed methodology for conducting this specific research project as part of the submission in the initial application for this funding.

b. In year two, the NRC shall prepare an inventory of Federal transportation spending and a plan to update this information on an ongoing basis.

c. Each year, the NRC shall submit an annual report to the Secretary of Transportation on activities under this program and make recommendations for improving coordination.

d. In addition, the NRC shall conduct relevant research in years 3–5 for coordinating human service transportation identified by the Federal Interagency Coordinating Council, members of the national coalition, and other stakeholders. This specific scope of the research agenda will be determined in collaboration with the Federal Project Officer for each targeted year.

Each of these reports must be submitted to the Project Officer and steering committee for review and approval prior to final publication. All documents produced are subject to internal policy reviews from senior management within the Department of Transportation and other members of the CCAM. All revisions will be made by the grantee on behalf of FTA and the CCAM.

Task 3—Technical Assistance and Training

Technical Assistance and Training. When conducting and coordinating technical assistance, sites should have individual technical assistance plans that outline the specific need, intended outcome, plan for assistance, and evaluation components. Technical assistance will be provided via E-mail, phone, Web-based strategies, and on-site strategies, using the following principles:

- *Assessment and Planning:* Assistance should be provided for facilitating assessment of resources available for human service transportation and facilitating planning for coordinating services based on needs identified at the State and local levels.
- *Knowledge Management:* Constant assessment should be made of areas of technical assistance focus to ensure useful practices are disseminated, issue briefs are developed as needed, and expert relationships with technical assistance recipients result in long-term information and knowledge transfer.
- *Training:* Training should be made available via various media to target specific topics related to human service transportation across the range of service options. Outreach regarding training should be available for human service providers, transportation providers, and consumers.
- *Facilitation, Coalition Building, and Strategic Planning.* Assistance should be provided to States in order to build coordinated strategies and dialogue across organizational cultures and agencies. Assistance should also be offered to assist States in identifying strategies for facilitating the adoption and implementation of useful practices at both the State and local levels.
- *Follow up and Monitoring:* Following any intervention (*e.g.,* assessment, planning, training, *etc.*), follow up through E-mail, phone, and through on-site contacts are necessary to facilitate implementation of any key activities identified as part of the individual technical assistance plans.

• *Evaluation:* Assistance should provide skill development and process related assistance to States in order to establish mechanisms for monitoring and evaluating coordination activities at the State and local levels.

Technical Assistance Activities: The grantee will develop the following initiatives using the principles outlined above: the NRC role is to assist States and communities to build the capacity for coordinating human service transportation; to facilitate access to existing resources and training, and to work with other TA centers to effectively establish triage and referral mechanisms for States and local communities. The applicant will submit a detailed methodology and approach for providing for the activities identified below:

a. Provide ongoing technical assistance to the 50 States, the District of Columbia, and territories on the development and implementation of coordinated human service transportation systems through the activities through a proactive management approach that includes information sharing, training, site visits, telephone, electronic interfaces and other forms of ongoing interaction.

b. During the life of the cooperative agreement, develop and implement a technical assistance plan with each of the 50 States and territories to facilitate the implementation of coordinated human service transportation at the State and local levels.

c. Organize a systematic approach for annual site visits annually with States. The grantee shall work with the Federal project officer to develop criteria for determining the appropriateness of a site visit, selection of staff or consultants to conduct the site visits, actions needed prior to site visit by both staff and recipient, and intended goals/outcomes for the site visit. Prior to each site visit, the staff or grantee shall develop, with input from stakeholders (*e.g.,* consumers, public and private transportation agencies, human service providers), an agenda and goals for the site visit. The grantee shall maintain documentation regarding all site visits to be included in quarterly reports.

d. Develop a strategy for ensuring that local communities and associated stakeholders have access to technical assistance for building and implementing coordinated human service transportation plans and strategies.

e. Coordinate technical assistance activities with other federally funded technical assistance centers focused on human service transportation. These centers include Project ACTION, JobLinks, the Community Transportation Assistance Program, the National Rural Transportation Assistance Program, the Planning Peer to Peer project, the Intelligent Transportation Systems (ITS) Peer to Peer project, the National Center for Senior Transportation, and others. In coordination with the Project Officer, the grantee shall develop efficient strategies and methods of establishing linkages, triage, referral, and data sharing processes with other federally funded technical assistance centers in the areas of human service transportation and others interested in building access and mobility. The role of the grantee is to ensure that technical assistance, training, and other activities are coordinated between the centers to avoid duplication, and maximize resources and available expertise.

f. Coordinate with other federally funded technical assistance centers to facilitate the development and implementation of a coordinated human service transportation system when working with local communities. This includes three components: (1) Strategies that address interdisciplinary approaches for providing transportation services that enhance access to employment, education, health, and other community activities for targeted populations; (2) strategies to develop, implement, and connect a family of services including auto acquisition and modification programs, driving transition, pedestrian environments, fixed route transit, paratransit services, flex route, vanpooling and ridesharing, taxi programs, door through door or escort options, voucher models, and volunteer transportation programs; and (3) strategies for integrating concepts for mobility management.

g. Measure and evaluate the performance of the NRC in providing technical assistance, and monitor progress towards targeted goals and outcomes.

Task 4—Strategic Development in Partnerships, Community Involvement in Human Service Transportation Coordination

Human service transportation coordination is very dynamic and new areas of significance continually emerge. It is essential that the grantee respond appropriately and address emerging issues. Additionally, the grantee shall provide expertise in strategic direction in human service transportation related to community involvement and public awareness as follows:

a. The grantee shall assess, analyze, and measure trends in the implementation of human service transportation activities on a State and regional basis and submit this information to FTA on an annual basis.

b. The grantee shall provide quarterly updates to FTA on pending and enacted legislation at all governmental levels related to human service transportation coordination, and the United We Ride initiative.

c. The grantee shall develop and maintain a comprehensive national coalition on human service transportation that is inclusive of advocacy organizations; public interest organizations; and provider organizations. This coalition shall include a network of transportation professionals, human service professionals, consumers, and policymakers at every level who understand the issues involved in the coordination of human service transportation and how coordination can be accomplished. The NRC will develop a strategic plan for the coalition that includes education, outreach, technical assistance and advocacy oriented activities that can be addressed collectively or by individual organizations. This coalition will serve to facilitate the development of state and local coalitions in all States and territories over the course of the cooperative agreement.

d. The grantee, shall assess, analyze and monitor key activities and milestones related to human service transportation of national organizations and Federal agencies, interagency liaison groups, private industry, workforce development organizations, faith-based/community organizations, professional organizations and others involved in the coalition on an annual basis.

e. Establish and/or expand up to 10 State coalitions annually that mirror the national coalition in regard to membership and strategy. The grantee shall provide guidance, direction, tools and strategies on establishing coalitions, which can be integrally involved in providing strategic direction for State and community involvement in human service transportation. Analyze, assess and evaluate the value of these coalitions and their activities with the Project Officer.

Task 5—Communication and Management Information Activities

The grantee must provide on-site assistance as needed at the U.S. Department of Transportation for tasks outlined in this section.

a. Coordinate all aspects (*e.g.*, planning, logistics, design, travel, speakers, materials, briefing, *etc.*) of 10 interdisciplinary UWR regional

meetings on behalf of the CCAM during this four year cooperative agreement. The planning of these meetings shall be conducted in consultation with a planning committee in each region that includes, at a minimum, Federal partners at the regional level, State agencies, and representatives from stakeholder groups representing different audiences targeted for participation. The Planning Committee and FTA Project Officer must review all documentation, plans, speaker information, invitation letters, participant lists, and information related to these meetings prior to any dissemination.

b. The grantee shall coordinate the development and dissemination of products and publications as needed based on an assessment of existing products, publications, training, and resources available through various sources. The grantee shall manage the United We Ride clearinghouse for all UWR products, publications, and information. This includes the availability and dissemination of hard and electronic copies upon request by individuals, agencies, organizations, speakers, and all others, including for distribution at meetings and events. Alternative formats (*e.g.*, braille, electronic, large print) must be made available for all publications and products.

c. The grantee will develop at least one new publication each year. The type and nature of the product or publication will be determined in coordination with the Project Officer and the steering committee and shall be based on the needs assessment from states and local communities. All new publications must be reviewed and approved by the Project Officer and are subject to review by senior level management within DOT and other members of the CCAM. The grantee shall work collaboratively with FTA to coordinate input, direction and advice regarding required Federal clearances on all publications regardless of the medium (*e.g.*, print, video, electronic, etc).

d. The grantee shall coordinate all aspects of the management and implementation of the United We Ride Web site (*http://www.unitedweride.gov*), which includes: (a) Maintaining and updating all information for each section of the Web site using Red Dot technology on a regularly scheduled basis; (b) updating the front page once each month; (c) entering up to 5 useful practices in the database each month; (d) posting up to 10 documents and/or announcements per month; (e) maintain an active list serve and consistent distribution of real-time information using GovDocs technology; (f) responding to submissions to the United We Ride electronic mailbox within 3 business days; and (g) providing ongoing recommendations for improvement strategies as needed. All documents and information posted on the Web site must meet the requirements and compliance of Section 508 of the Rehabilitation Act. The grantee must have a staff person with knowledge and experience relating to knowledge management available to be trained in Red-Dot technology and also available to work on-site at the U.S. Department of Transportation to post information directly. The grantee shall work with the Project Officer to establish a plan for approval of content for posting and disseminating information using these mechanisms.

e. Develop and disseminate a minimum of four electronic newsletters per year. The grantee shall submit the newsletter to the FTA Project Officer for approval three weeks prior to publication for approval.

f. In the first year, the grantee shall develop a database to be compatible with and integrated into the UWR Web site. This database shall include products and publications developed by various resources (including other technical assistance centers, national organizations, States, local organizations, *etc.*) that could potentially provide added value for human service transportation coordination. This includes video, curricula, and fact sheets and other publications. This database shall include the title, description, and information on how to obtain the documents included in the database. The database will also include any evaluation information related to the publication(s).

g. The grantee shall plan for at least ten (10) presentations at National meetings annually that involve other than local travel. The grantee shall submit a plan to the Project Officer at the beginning of each calendar year and coordinate with FTA and other federally funded TA centers to reduce duplication of effort. The presentations NRC staff intends to make at a local, State and national level are to be fully coordinated, with an ample timeline for discussion and approval by the Project Officer.

h. The grantee shall plan to coordinate and manage the UWR exhibit for up to 10 national, regional, and State meetings. These exhibits can be the same meetings where presentations are also taking place. It is expected that the grantee will use the newly developed United We Ride exhibits already available. In addition, the grantee will make the exhibit and handouts available to members of the national coalition, States, and other TA centers for use at targeted meetings. The grantee shall submit a plan to the Project Officer at the beginning of each calendar year and coordinate the FTA and other federal funded TA centers to reduce duplication of effort.

Task 6—Project Management and Administration

a. The grantee shall meet with the Project Officer and task order monitor within ten (10) working days after issuance of the task order to discuss the objectives of the cooperative agreement and any related projects.

b. The grantee will hold monthly meetings with the Project Officer to review the status of the project. Areas of discussion will include: (1) Accomplishments to date, (2) reviewing progress on tasks, and (3) challenges or problems in addressing specific tasks or meeting targeted deliverable dates. The grantee shall provide minutes of the meeting to the Project Officer five business days after the meeting.

c. The Project Coordinator of the NRC shall submit quarterly progress reports to the FTA project manager. The reports shall include the following items and provide information relevant for the particular period:

- General assessment of the progress of the NRC development and design;
- Significant accomplishments by objective and task;
- Project issues/concerns and recommended solutions;
- Updated project schedule:
  - Status of current tasks;
  - List of completed tasks;
  - Percent complete by task;
  - If slips in the schedule occur, the grantee shall propose how to mitigate the schedule deviations).
- Total budget by task:
  - Amount spent to date by task;
  - Amount remaining by task;
- Travel expense report.

d. The grantee will brief FTA and other members of the CCAM semi-annually on their technical assistance findings, key themes and results.

e. The NRC shall include a national steering committee to provide guidance and feedback throughout the life of the technical assistance center. Steering committee members shall consist of Federal, State, and local officials and organizations. Participation from organizations representing human service agencies representing various interests (*e.g.,* Medicaid, workforce investment, rehabilitation services, aging networks, *etc.*), transportation

organizations, and consumers are strongly encouraged. The steering committee shall participate in the review and development of products, publications, materials, and information. The NRC shall host full face to face committee meetings at least two times during the year. Other meetings can be held more often by phone.

II. Award Information

FTA will fund one cooperative agreement for a four year award. Year one of the cooperative agreement is for one million, five hundred eighty-four thousand dollars ($1,584,000). The anticipated notification date is the fall of 2006, with an anticipated starting date for the successful applicant of October 2006. Subsequent annual funding will be based on annual appropriations. FTA grantees with existing FTA projects are eligible to complete for this cooperative agreement.

The FTA will participate in activities by attending review meetings, commenting on technical reports, maintaining frequent contact with the project manager and approving key decisions and activities any redirecting activities if needed.

III. Eligibility Information

FTA is particularly interested in proposals for this cooperative agreement from national non-profit organizations with demonstrated capacity in State and community transportation services for older adults, people with disabilities, and individuals with lower incomes. A strong applicant has the following characteristics:

- An understanding of concepts and strategies for developing integrated access, including single entry point and one-stop transportation systems;
- An understanding of strategies for building a coordinated human service transportation program that utilizes and connects a comprehensive family of services;
- Demonstrated success with interdisciplinary strategies in human service and transportation related work;
- Experience with the development and implementation of integrated transportation systems with health care, education, employment and social support programs;
- Capacity for maintaining management information systems;
- Experience in implementation of consumer directed services;
- Capacity and experience in building coordination and collaboration between public and private sector, as well as critical pathways which include linkages with intermediary organizations such as employment and training agencies, hospital discharge planners, private pay insurance, special education transition programs, rehabilitation agencies, various social service and transportation system networks.
- Experience and demonstrated capacity to facilitate large and small group processes regarding policy development, resource allocation, systems change, administrative processes, and capacity building;
- Experience and knowledge of consumer involvement and consumer directed models in program planning and implementation;
- Capacity for developing and managing a technical assistance network using multiple types of intervention strategies (*e.g.*, long distance, peer-to-peer, onsite, communities of practice, *etc.*);
- Capacity and experience in large scale systems change efforts;
- Capacity and experience for providing effective off-site technical assistance, including technical assistance by telephone and E-mail, moderated and unmoderated list-serves, Web-based seminars, topic-based conference calls, the internet (including the development of Web content), *etc.*;
- Understanding implementation of a range of transportation services including older driver, pedestrian access, fixed route, paratransit, assisted (door to door; hand to hand; escort) services, volunteer, taxi, and other types of transportation services provision;
- Capacity and experience for conducting face-to-face and Web-based training for consumers, human service providers, and transportation agencies.

IV. Proposal Content

Proposals shall be submitted in double-spaced format using Times New Roman 12 point font. The application must contain the following components:

1. Cover sheet (1 page): Includes entity submitting proposal, principal investigator, title, and contact information (*e.g.*, address, phone, fax, and E-mail). Name and contact information for the entity' key point of contact for all cooperative activities (if different from principle investigators).

2. Abstract (2 pages): Abstract shall include background, purpose, methodology, intended outcomes, and plan for evaluation.

3. Detailed budget proposal and budget narrative.

4. Project narrative (not to exceed 75 pages): Project narrative shall include the following information:

a. Staff qualifications, experience in providing technical assistance and implementing the other tasks outlined in the solicitation. The proposal shall also include the proposed staff members' knowledge of issues related to human service transportation. One page biographical sketches for staff members shall be included in the appendices section of the proposal;

b. Existing and future capacity of organization to address the issues outlined in the proposal and ability to implement tasks 1–6 outlined under Section I in this solicitation;

c. Methodology for addressing tasks 1–6 outlined under Section I in this solicitation. The proposal shall also include objectives, activities, deliverables, milestones, timeline and intended outcomes for achieving the goals outlined in the scope for the first year;

d. Plan to work with stakeholders and build partnerships at the national, State, and local levels;

5. Project Management Plan that includes well defined objectives, tasks, activities, timelines, deliverables, indicators, and outcomes.

6. Plan for evaluation of NRC activities and data collection.

7. Supplemental materials and letters of support can be included in an appendices section that is beyond the 75 page limit. In addition to the full proposal, entities have the option to submit supplemental material such as: Brochures, publications, products, etc. These materials shall be delivered to Bryna Helfer, Federal Transit Administration, 400 7th Street SW., Room 9114, Washington, DC 20590.

V. Application Review Information.

Interdisciplinary review panels, including those external to FTA will be convened to review each proposal. Project proposals will be evaluated based on the following criteria and scoring system:

1. Staff qualifications, which includes experience in delivering technical assistance and training, knowledge of human service transportation, demonstrated process skills in assessment, strategic planning, facilitation, and other key areas associated with identified tasks. The entity shall also address a plan for knowledge retention. (15%).

2. Existing capacity of the organization, which includes clearinghouse functions, Web development and maintenance, technical assistance, training, long distance and on-site intervention strategies, and other identified tasks. (15%).

3. Understanding and reasonability of proposed goals, objectives,

methodologies, activities, timelines, deliverables, and budget. (40%).

4. Plan to collaborate with stakeholders and establish effective partnerships to implement tasks. (20%).

5. Plan for evaluation and data collection. (10%).

VI. Award Administration Information

The anticipated notification date for the award of this cooperative agreement is the fall of 2006, with an anticipated start date for the successful applicant by late fall 2006. The Federal Transit Administrator's (FTA) will notify the successful entity. Following receipt of the FTA Administrator's notification letter, the successful entity will be required to submit its proposal through the FTA Transportation Electronic Award Management (TEAM) system Web site. FTA will manage the cooperative agreement through the TEAM system Web site. Before FTA may award Federal financial assistance through a Federal cooperative agreement, the entity must submit all certifications and assurances pertaining to itself and its project as required by Federal laws and regulations. Since Federal fiscal year 1995, FTA has been consolidating the various certifications and assurances that may be required of its awardees and the projects into a single document published in the **Federal Register**. The fiscal year 2006 Annual List of Certifications and Assurances for FTA Cooperative Agreements and Cooperative Agreements and Guidelines will be published in the **Federal Register** and posted on the FTA Web site at *http://www.fta.dot.gov*.

Issued on: August 24, 2006.

James S. Simpson,

Administrator.

[FR Doc. 06–7231 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–57–M

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2005–22657]

RIN 2132–AA85

Charter Service Negotiated Rulemaking Advisory Committee

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of meeting location and time of the meeting.

SUMMARY: This notice lists the location and time of the next Charter Bus Negotiated Rulemaking Advisory Committee (CBNRAC) meeting.

DATES: August 29, 2006.

FOR FURTHER INFORMATION CONTACT: Elizabeth Martineau, Attorney-Advisor, Office of the Chief Counsel, Federal Transit Administration, 202–366–1936 (*elizabeth.martineau@dot.gov*). Her mailing address at the Federal Transit Administration is 400 Seventh Street, SW., Room 9316, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Meeting Location

The Radisson Hotel, 2020 Jefferson Davis Highway, Arlington, VA 22202 (Crystal City).

Meeting Time

September 12, 9 a.m.–4:30 p.m.

September 13, 8:30 a.m.–4 p.m.

Issued this 23rd day of August, 2006, in Washington DC,

James S. Simpson,

Administrator.

[FR Doc. 06–7213 Filed 8–28–06; 8:45am]

BILLING CODE 4911–57–M

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Notice of Limitation on Claims Against Proposed Public Transportation Projects; Correction

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice; correction.

SUMMARY: The Federal Transit Administration (FTA) published a notice in the **Federal Register** of August 17, 2006, concerning limitations on claims for certain specified public transportation projects. The notice contained an incorrect date.

FOR FURTHER INFORMATION CONTACT: Joseph Ossi, Environmental Protection Specialist, Office of Planning and Environment, 202–366–1613. FTA is located at 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 9 a.m. to 5:30 p.m., e.t., Monday through Friday, except Federal holidays.

Correction

In the **Federal Register** of August 17, 2006, in FR Doc. E6–13533, on page 47561, in the third column, correct the **DATES** caption to read:

Dates: By this notice, FTA is advising the public of final agency actions subject to Title 23 United States Code (USC) § 139(l). A claim seeking judicial review of the FTA actions announced herein for the listed public transportation projects will be barred unless the claim is filed on or before February 26, 2007.

Dated: August 23, 2006.

David B. Simpson,

Acting Associate Administrator for Planning and Environment.

[FR Doc. E6–14314 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–57–P

Federal Register

Tuesday,
August 29, 2006

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 20, 201, 207, et al.

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 330, 514, 515, 601, 607, 610, and 1271

[Docket No. 2005N–0403]

RIN 0910–AA49

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing drug establishment registration and drug listing. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products (including vaccines and allergenic products), and/or human cells, tissues, and cellular and tissue-based products (HCT/Ps), and animal drugs. The proposal describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally would require the electronic submission of all registration and most listing information. We (FDA) rely on establishment registration and drug listing information for administering many of our programs, such as postmarketing surveillance (including FDA inspections), bioterrorism, drug shortages and availability, and user fee assessments. We are taking this action to use the latest technology to improve our registration and listing system, which would further our goal of protecting the public health. We also believe that the conversion to an electronic system would make the registration and listing processes more efficient and effective for industry and us. We are also taking this action to support the implementation of, for example, the electronic prescribing provisions of the Medicare Prescription Drug, Improvement, and Modernization Act, our rulemaking requiring a bar code on certain drug products, and the DailyMed initiative.

DATES: Submit written or electronic comments by November 27, 2006. Submit written comments on the information collection requirements by September 28, 2006 to OMB (see **ADDRESSES**). See section IX of this document for the proposed effective date and section X for the proposed compliance dates of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0403 and/RIN 0910–AA49, 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). and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: *For information concerning drugs regulated by the Center for Drug Evaluation and Research (CDER)*: Herbert Gerstenzang or John W. Gardner, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8920, *herbert.gerstenzang@fda.hhs.gov* or *john.gardner@fda.hhs.gov*.

For information concerning products regulated by the Center for Biologics Evaluation and Research (CBER): Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, *valerie.butler@fda.hhs.gov*.

For information concerning animal drugs: Lowell Fried (HFV–212) or Isabel W. Pocurull (HFV–226), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–7820 or 240–453–6853, *lowell.fried@fda.hhs.gov* or *isabel.pocurull@fda.hhs.gov*.

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I. Background

We originally published establishment registration regulations for human drugs, certain biological products, and animal drugs in the **Federal Register** of February 14, 1963 (28 FR 1457) (proposed rule) and April 3, 1963 (28 FR 3195) (final rule), and listing regulations for these drugs in the **Federal Register** of December 12, 1972 (37 FR 26431) (proposed rule) and March 7, 1973 (38 FR 6258) (final rule).

We currently maintain a database containing the establishment registration and drug listing information submitted on paper to us. We rely on complete and accurate registration and listing information to accomplish a number of our statutory and regulatory objectives. For example, we use registration and listing information to:

- Identify the manufacturers, repackers, relabelers, and drug product salvagers of marketed drugs;[1]
- Identify the manufacturers, repackers, or relabelers of a specific drug or ingredient when that drug or ingredient is in short supply or is needed for a national emergency. This information helps us facilitate prompt drug shipment to the place where it is needed. For example, during a bioterrorism incident, we could use drug listing information to identify manufacturers, repackers, and relabelers of drugs that would be helpful in preventing or counteracting the deadly effects of biological weapons. With this information, we could facilitate prompt shipment of the drugs as needed;
- Facilitate the recall of drugs marketed by manufacturers, repackers, and relabelers;
- Identify and catalogue marketed drugs;
- Administer our postmarketing surveillance programs for drugs, including the drug surveillance sampling program that monitors the quality of the national drug supply;
- Identify drugs marketed in violation of the law;
- Schedule and plan inspections of registered establishments pursuant to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374); and
- Determine which marketed drugs are identical, related, or similar to drugs reviewed for effectiveness under the Drug Efficacy Study Implementation (DESI) program.

We also rely on registration and listing information to help us comply with several other statutory provisions. We use the information to:

- Determine which entities are subject to establishment and product user fees under the prescription drug user fee program and the animal drug user fee program (21 U.S.C.379h and 379).
- Generate accurate estimates of the number of manufacturers, repackers, relabelers, and drug product salvagers and drugs that are affected by our rulemaking. These estimates help us assess the impact of our regulations on the regulated industry, which we are required to do under the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*), the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), Executive Order 12866 (September 30, 1993), and the Congressional Review Act (section 251 of Public Law 104–121).

Registration and listing information will continue to be used for all of the important public health purposes outlined above. Moreover, recent technological advances would allow us to enhance the usefulness of registration and listing information. Specifically, we are proposing that registration and listing information be submitted to us by using the electronic drug registration and listing system that we intend to develop. In addition to making the registration and listing process more efficient for industry, the electronic submission of registration and listing information would allow us to review and use such information more quickly and effectively in carrying out all of the

[1] ''Drug'' or ''drugs'' refers to human drugs, including drugs that are regulated under a biologics license application, and animal drugs (including Type A medicated articles), unless otherwise specifically stated. ''Drugs'' is defined in proposed § 207.1 and discussed in section IV.A.5 of this document. Biological products subject to proposed part 207 are described in proposed § 207.9(c).

activities described above. Electronic submission of this information would also allow us to fully support the implementation of the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (Public Law 108–173) (Medicare Modernization Act), specifically the electronic prescribing provisions. In addition, electronic submission of registration and listing information would further the purpose of several statutes:

- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (Bioterrorism Act) amended section 510(i) of the act (21 U.S.C. 360(i)) to require that foreign establishments submit, among other things, registration information electronically.
- The Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) also amended section 510 of the act (at section 510(p)) to explicitly give the Secretary of Health and Human Services (the Secretary) discretion to require the electronic submission of registration information, upon a finding that electronic receipt of such registration information is feasible, unless the Secretary grants a request for a waiver.
- The Government Paperwork Elimination Act of 1998 (Public Law 105–277, Title XVII) (GPEA) requires Federal agencies to give persons who are required to maintain, submit, or disclose information the option of doing so electronically when practicable as a substitute for paper, and to use electronic authentication (electronic signature) methods to verify the identity of the sender and the integrity of the electronic content.

We believe that conversion to the electronic submission of registration and listing information will further the purpose of these laws and make the registration and listing processes more efficient and effective for industry and us.

II. Summary of Current Registration and Listing Requirements

A. Summary of Section 510 of the Act

Section 510(c) of the act requires every person upon first engaging in the ''manufacture, preparation, propagation, compounding, or processing'' of a drug in any establishment that he owns or operates in any State to immediately register his name and place of business and such establishment. Under section 510(a)(1) of the act, the term ''manufacture, preparation, propagation, compounding, or processing'' must include ''repackaging or otherwise changing the container, wrapper, or labeling of any drug package * * * in furtherance of the distribution of the drug * * * from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.'' Section 510(a)(2) of the act mandates that the term ''name'' include, among other things, the name of each partner of a partnership, and the name of each corporate officer and director of a corporation. An owner or operator of a registered establishment must also immediately register any additional establishment that he owns or operates in any State and in which he begins the ''manufacture, preparation, propagation, compounding, or processing'' of a drug (section 510(d) of the act). An owner or operator of any establishment that engages in these activities must register its establishment on or before December 31 of each year (section 510(b) of the act). Section 510(i) of the act contains certain registration requirements pertaining to foreign establishments (e.g., submission of the name of each importer of a drug in the United States that is known to the establishment, submission of the name of each person who imports or offers for import a drug into the United States for purposes of importation). Section 510(g) of the act provides for certain exemptions from the registration requirements. In addition, section 510(p) of the act gives the Secretary discretion to require the electronic submission of registration information, upon a finding that electronic receipt of such registration information is feasible, unless the Secretary grants a request for a waiver.

Section 510(j)(1) of the act requires that every person, at the time of registration, submit a list of all drugs that are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and that have not been previously listed by him. This information must be submitted in the form and manner prescribed by the Secretary (section 510(j)(1) of the act). This listing information must be accompanied by, among other things, a copy of certain labeling and, in some cases, advertising for certain categories of drugs. Section 510(j)(2) of the act requires certain changes in listing information to be reported every June and December, including any material changes in information previously submitted under the listing provisions.

Section 510(e) of the act permits the Secretary to assign a registration number to any person or any establishments registered under section 510 and a listing number to each drug or class of drugs listed under section 510(j) as long as the listing number is the same as that assigned pursuant to the National Drug Code. The disclosure provision in section 510(f) of the act requires the Secretary to make available for inspection any registration filed under section 510. Section 510(f) also provides that certain listing information must be exempt from disclosure unless the Secretary finds that such exemption would be inconsistent with protection of the public health.

B. Summary of Current Registration and Listing Regulations

1. Who Must Register and List Under Current Regulations?

Under current part 207 (21 CFR part 207), with certain exceptions, owners or operators of establishments that engage in the manufacturing or processing of a drug or drugs must, in addition to other requirements, register their establishments and submit listing information for each of their drugs in commercial distribution.[2] Notwithstanding certain exceptions, foreign drug establishments that manufacture, repack, or relabel a drug that is imported or offered for import into the United States must also comply with the registration and listing requirements. As explained in section IV.E of this document, all registration and listing information must currently be submitted to us using paper forms specified by us.

2. What Are the Current Registration Requirements?

Current requirements for registration include, among other things, the following provisions:

- Owners or operators of establishments entering into the manufacturing or processing of a drug or drugs must register their establishments within 5 days after beginning the manufacturing or processing of drugs at the establishments (§ 207.21(a)).
- If owners or operators of the establishments have not previously entered into such operations, then those owners or operators must register within 5 days after the submission of a new drug application (NDA), abbreviated new drug application (ANDA), new animal drug application (NADA), abbreviated new animal drug application (ANADA), medicated feed mill license application, or biologics license application (BLA) (§ 207.21(a)).

[2] ''Drug or drugs'' includes drugs regulated under a BLA. For a description of biological products covered under proposed part 207, see proposed § 207.9(c).

• Owners or operators of establishments that are required to register must renew their registration annually in accordance with the specified schedule (§ 207.21(a)). Changes in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as amendments to registration within 5 days of such changes (§ 207.26).

• We assign a permanent registration number to each registered establishment (§ 207.35).

• Private label distributors that do not otherwise manufacture or process drugs are not required to register; however, they must submit specified information to us to obtain a labeler code (§ 207.20(b)). Private label distributors are owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment.

3. What Are the Current Listing Requirements?

Current requirements for listing include, among other things, the following provisions:

• Owners or operators of establishments must, at the time of registration, submit a list of every drug being manufactured or processed in commercial distribution at that time (§ 207.21(a)).

• Private label distributors that do not otherwise manufacture or process drugs are not required to list, but may elect to submit listing information directly to us (§ 207.20(b)). Currently, private label distributors that elect to submit listing information directly to us assume full responsibility for compliance with the requirements of part 207 (§ 207.20(b)). Owners or operators of establishments that are required to register and list must submit listing information to us on behalf of private label distributors that do not elect to submit listing information directly to us (§ 207.20(b)).

• Drugs that may be subject to current listing requirements include bulk drug substances; finished dosage forms, whether prescription or over-the-counter (OTC) drugs; and Type A medicated articles (§ 207.25(b)).

• The required listing information submitted to us includes, but is not limited to:

—The application number, if applicable,

—Copies of current labeling as specified in current § 207.25(b) and, in some cases, a representative sampling of advertisements,

—A quantitative listing of the active ingredient(s) (in some cases),

—The NDC number, and

—Any imprinting information (§ 207.25(b)).

• Owners or operators of establishments that are required to register must update their listing information every June and December or, at the discretion of the owner or operator, when the change occurs. Updated information must include, but is not limited to:

—A list of each drug introduced by the registrant for commercial distribution that has not been included in any previously submitted list,

—A list of all previously listed drugs for which commercial distribution has been discontinued,

—A list of all drugs for which a notice of discontinuance was submitted and for which commercial distribution has resumed, and

—Any material change, as defined under current § 207.3(a)(3), in any information previously submitted (§ 207.30(a)).

4. What Are the Current Requirements Associated With the Use of the NDC Number?

The NDC system is used, among other things, to assign a drug listing number to each drug or class of drugs.

• The NDC number currently consists of the labeler code, product code, and package code. We assign the labeler code, and, as stated in current regulations, ''establishments'' assign the product code and package code within certain parameters specified by us (§ 207.35).

• Currently, we request, but not require, that the NDC number appear on all drug labels and labeling (§ 201.2 (21 CFR 201.2), § 207.35(b)(3)). However, drug products described in current § 201.25(b) (21 CFR 201.25(b)) must have on the label a bar code that contains, at a minimum, the appropriate NDC number in a linear bar code that meets specified standards (§ 201.25).

• The current regulations specify both format and placement of the NDC number if the NDC number is included on drug labels and labeling (§ 207.35(b)(3)).

5. Who Is Exempt From Registration and Listing Under Current Regulations and Who Is Not Covered by the Current Registration and Listing Requirements in 21 CFR Part 207?

Under current regulations, certain establishments are exempt from the registration and listing requirements. For example, practitioners who are licensed by law to prescribe or administer drugs and who manufacture or process drugs solely for use in their professional practice, and persons who manufacture or process drugs not for sale but solely for use in research, teaching, or chemical analysis are exempt from registration and listing requirements. Many of the exemptions in current § 207.10 are also listed in section 510(g) of the act.

The current regulations also describe those establishments that are not covered under part 207. Owners and operators of human blood and blood product establishments must register and list their products in accordance with part 607 (21 CFR part 607). However, such owners and operators who also manufacture or process other drug products at the same establishment must also register and list those drugs in accordance with part 207 (§ 207.7). Owners and operators of establishments that solely engage in the manufacture or processing of medical devices are not covered under part 207. However, such owners and operators must register and list their products in accordance with part 807.

6. Do Current Regulations Permit the Disclosure of Registration and Listing Information?

The current regulations specify the registration and listing information submitted to us that is available for public disclosure (§ 207.37).

III. Highlights of the Proposed Rule

This proposal would reorganize, consolidate, and modify the current registration and listing requirements. It would also assist us in promoting other important electronic health initiatives.

A. Proposed Changes to the Current Registration and Listing Requirements

We are proposing many changes to the current registration and listing requirements. In section IV of this document, we discuss in detail these changes and the reasons for the changes. The most significant proposed changes to the current requirements are as follows:

• All registration information and most listing information would be provided to us electronically using the electronic drug registration and listing system that we intend to develop. (Currently, the information is submitted to us on paper forms.)

• The appropriate NDC number would be required, with certain exceptions, to appear on drug labels. The appropriate NDC number is the NDC number belonging to the manufacturer, repacker, or relabeler, that corresponds to the particular drug;

a repacker or relabeler would not be permitted to place an NDC number that corresponds to an original manufacturer on a repackaged or relabeled drug. Although the NDC number would not be required to appear on other drug labeling (that is, the prescription drug labeling or the package insert), the NDC number would need to accompany the submission of the other drug labeling. (Currently, we only request that the NDC number appear on drug labels and labeling. However, certain drug products must have on the label a bar code that contains, at a minimum, the appropriate NDC number (see § 201.25).)

- All three sections of the NDC number—that is, the labeler code, product code, and package code—would be assigned prospectively by us to drugs that have not previously been assigned NDC numbers by a manufacturer, repacker, or relabeler. (Currently, we assign the labeler code, and the registered establishment or private label distributor assigns the product code and package code within certain parameters specified by us.) The labeler code assigned prospectively by us would be the same as the labeler code (or one of the labeler codes) used by the manufacturer, repacker, or relabeler on its currently marketed drugs.
- The NDC numbers currently assigned to drugs prior to the effective date of the rule would remain unchanged, provided those NDC numbers comply with the new regulations as finalized. FDA intends to validate that current NDC numbers comply with the new regulations as finalized. Manufacturers, repackers, and relabelers should review the information that they submitted to our registration and listing database to obtain an NDC number and update the information if necessary. They should complete their reviews and updates within 9 months after a final rule's effective date. If, after the effective date of the final rule, there is a change in a drug (in accordance with proposed § 207.33(f)), we would assign a new product code and package code to the newly changed drug, but the drug would keep the labeler code. If, after the effective date of the final rule, there is a change in a drug's packaging, we would assign a new package code to the drug, but the drug would keep the labeler code and the product code. (Currently, the registered establishment or private label distributor may assign the product and package codes within certain parameters specified by us.)
- Private label distributors would not be permitted to register or list under the proposed rule. (Currently, private label distributors submit certain information to request a labeler code and may list drugs. If the private label distributor elects not to submit drug listing information directly to us and to obtain a labeler code, the registered establishment must submit the drug listing information.) Manufacturers, repackers, relabelers, or drug product salvagers must submit drug listing information for those drugs they manufacture, repack, relabel, or salvage for a private label distributor.
- Drug product salvagers would, in addition to registering, be required to list the drugs they salvage, even if they do not repack or relabel the drugs. (Currently, drug product salvagers are required to register but not list.)
- The ''content of labeling'' as defined in proposed § 207.1 would be electronically submitted at the time of listing in a format that we can process, review, and archive. (Currently, all labeling required for listing is submitted in paper form.)

B. Promotion of the Department of Health and Human Services (DHHS) Federal Health Information Technology Initiatives

The proposal would allow us to provide important support for the full implementation of the electronic prescription provisions of the Medicare Modernization Act. The proposal would also support other initiatives, described in section IV.C.2 of this document, including DHHS Federal Health Information Technology initiatives. The proposal would result in an up-to-date NDC number system, in which we assign the NDC number, providing for accurate, unique, and unambiguous NDC numbers for each drug. This would allow electronic systems to reliably and consistently link the NDC number to the appropriate drug labeling through another DHHS health information technology initiative, Structured Product Labeling (SPL). The drug labeling would supply the drug ingredient and other information necessary to support the development of the standards for medication terminology necessary for electronic prescribing. Other initiatives supported by this proposal, including bar coding for drugs, are discussed in section IV.C.2 of this document.

IV. Description of the Proposed Rule

We are proposing to reorganize, consolidate, clarify, and modify the regulations in part 207. As a result, we have revised and recodified some provisions, added new provisions, and eliminated others. The following description of the proposed rule describes both new provisions and changes to existing regulations.

A. General

1. What Is the Purpose of Proposed Part 207?

We are proposing to add new § 207.5 to explicitly state the purpose of part 207, as set forth in the legislative history of the Drug Amendments of 1962 and the Drug Listing Act of 1972.

- Establishment registration information helps us to identify who is manufacturing, repacking, relabeling, or salvaging drugs and where those operations are being performed. As explained in Senate Report No. 1744, ''drugs should not be on the market unless [FDA] knows who is making them, and where they are being made. This will help stop illicit and substandard manufacturers who do not follow the methods or establish the controls called for by good manufacturing practice'' (1962 U.S.C.C.A.N. 2884, 2889). Knowing where drugs are being made is even more important today because it would increase the Nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies.
- Drug listing information gives us a current inventory of marketed drugs. As stated in Senate Report No. 92–924, ''[t]he effective enforcement of the drug provisions of the [a]ct requires the ready availability of a current inventory of all marketed drugs'' (1972 U.S.C.C.A.N. 2963, 2964). Moreover, the intent of drug listing is to provide us ''with an effective means of surveillance'' (Id. at 2965). Both establishment registration and drug listing information facilitate our implementation and enforcement of the act and are used for many important public health purposes. In addition, this information will help us better respond to emergencies (for example, we will be in a better position to effectively facilitate recalls should there be such a need).

2. Who Would Part 207 Cover?

We are proposing to add new § 207.9 to explain that part 207 would apply to the following.

- Domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers, unless they are exempt under section 510(g) of the act or proposed § 207.13. The terms ''domestic manufacturers,'' ''domestic repackers,'' ''domestic relabelers,'' and ''domestic drug product salvagers'' are defined in proposed § 207.1 and are explained in section IV.A.5 of this document. Proposed § 207.9 does not

change the scope of current part 207. Domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers would be covered under proposed part 207 whether or not the drugs they manufacture, repack, relabel, or salvage enter interstate commerce. Section 510(b) and (c) of the act refer to an establishment ''in any State.'' Congress's intention for section 510 of the act to apply to drugs both in interstate and intrastate commerce is stated in section 301 of Public Law 82–781, in part, as follows: ''[T]he products of all [establishments in which drugs are manufactured, prepared, propagated, compounded, or processed] are likely to enter the channels of interstate commerce and directly affect such commerce; and * * * the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.''[3] Accordingly, we are proposing to add to proposed § 207.9 the clause ''regardless of whether their drugs enter interstate commerce'' to reflect this congressional finding. The phrase ''Drug products * * * must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce'' is already included in current § 207.20(a).

- Foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers, unless they are exempt under proposed § 207.13(c) through (h). Foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers are currently required to register, and foreign manufacturers, foreign repackers, and foreign relabelers are currently required to submit listing information in accordance with section 510 of the act and § 207.40. The terms ''foreign manufacturers,'' ''foreign repackers,'' ''foreign relabelers,'' and ''foreign drug product salvagers'' are defined in proposed § 207.1 and explained in section IV.A.5 of this document.

An increased number of foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers may be required to comply with registration and/or listing requirements because we are proposing, as explained in section IV.A.4 of this document, to revoke certain provisions of current § 207.40(a) and (b). We are proposing to revoke the exemption in current § 207.40(a) relating to foreign establishments whose drugs enter a foreign trade zone and are re-exported from the foreign trade zone without having entered U.S. commerce. We are also proposing to revoke, in part, current § 207.40(b), which allows for a component of a drug imported under section 801(d)(3) of the act (21 U.S.C. 381(d)(3)) to be imported or offered for import into the United States even if the component is not listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. We are proposing to eliminate these two exemptions in current § 207.40(a) and (b) from the registration and listing requirements in light of certain statutory changes that have occurred since the publication of the final rule on foreign establishment registration and listing. Those changes include enactment of the Bioterrorism Act, which reflects Congress' desire to increase the Nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies.

- Manufacturers of drugs regulated under a BLA, as follows:

Manufacturers of drugs regulated under a BLA including, but not limited to: (1) Plasma derivatives such as albumin, Immune Globulin, Factor VIII and Factor IX, and recombinant versions of plasma derivatives or animal derived plasma derivatives; (2) vaccines; (3) allergenic products; (4) bulk product substances such as fractionation intermediates or pastes; and (5) therapeutic biological products.

Establishments solely engaged in the manufacture, as defined in § 1271.3(e) (21 CFR 1271.3(e)), of HCT/Ps, as defined in § 1271.3(d), that, under § 1271.20, are also drugs regulated under section 351 of the Public Health Service Act (PHS Act) or section 505 of the act. Proposed § 207.9(c)(2) would direct these establishments to register and list those HCT/Ps with CBER by following the procedures described in subpart B of part 1271 (21 CFR part 1271) instead of the procedures for registration and listing described in part 207. Proposed § 207.9(c)(2) is similar to current § 207.20(f), which we propose to revoke and replace with proposed § 207.9(c)(2).

We are also explaining the relationship between the requirements for HCT/Ps in part 207 and part 1271 of this chapter. We have implemented, in part 1271, a comprehensive, risk-based regulatory approach for HCT/Ps. Under this approach, some HCT/Ps are regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1271; other HCT/Ps are also subject to regulation as drugs or devices under the act and to premarket application or notification requirements (submissions may include BLAs, NDAs, or device PMAs, product development protocols, or 510(k) applications).

Current § 207.20(f) also states that the additional listing information requirements in current § 207.31 are applicable to HCT/Ps registered in accordance with the procedures in part 1271, subpart B if they are also drugs regulated under a BLA and/or the act. We are proposing to revoke current § 207.31 and move several of its requirements to other sections of the proposed rule (see discussion in sections IV.C and IV.D of this document). Consistent with the provisions in current § 207.20(f), the requirements will continue to apply to HCT/Ps that, under § 1271.20, are also drugs regulated under a BLA or section 505 of the act.

In addition, proposed § 207.9(c)(2) would require the submission of information not currently required for HCT/Ps under part 207, although the submission of such information has been required for drug products that are not HCT/Ps. For example, proposed § 207.9(c)(2) would require establishments to submit the NDC number, as described in proposed §§ 207.49(a), 207.53(a), and 207.54(b)(1), and the route of administration, as described in proposed § 207.49(b). Under these provisions, such HCT/P establishments would not be required to register and list with both CBER and CDER. Rather, we envision that establishments will register with CBER, and then will be asked to provide additional information as required under part 207. We will manage our databases so that both CBER and CDER have use of the registration and listing information provided. The concept is that there will be a link in place when the establishment electronically accesses the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm* for tissue registration. This will allow access to the drug database fields to fill in the additional information such as the NDC number. If the establishment enters that it manufactures a licensed biologic, this will trigger the link. At the current time, there is only one such product.

3. Who Would Not Be Subject to Part 207?

Proposed § 207.9 also describes two categories of establishments that would not be subject to part 207:

- Owners and operators of human blood and blood product

[3] See footnote 1 of section 510 of the act.

establishments. This proposed rule does not apply to owners and operators of human blood and blood product establishments unless they manufacture any of the products listed in proposed § 207.9(c)(1)(i) and (c)(1)(iv). If the owners and operators of human blood and blood product establishments manufacture any of those products, then they must register and list under part 207. Establishments that collect or process whole blood and blood products as well as establishments involved in the testing of whole blood and blood products would register and list under part 607. For purposes of this proposal, blood and blood products consist of human whole blood, plasma, or serum or any product derived from human whole blood, plasma, or serum, and the term includes biological products regulated as licensed devices. Manufacturers of licensed devices and manufacturers of licensed biological components used in a licensed device would register and list under part 607. This exclusion is consistent with current § 207.7(a) and would not apply to owners and operators of human blood and blood product establishments who also manufacture other drugs.

- Establishments that solely manufacture, prepare, propagate, compound, assemble, or process medical devices. Establishment registration and device listing regulations for such establishments and initial importers of devices, including in vitro diagnostic products, are codified in part 807. Establishments that manufacture, prepare, propagate, compound, assemble, or process medical devices, and also manufacture, prepare, propagate, compound, or process drugs, are subject to part 207 for drugs and part 807 for devices.

As a result of these proposed revisions clarifying the scope of part 207, proposed § 207.9 includes the provisions in current § 207.7 that explain the applicability of part 207 to human blood and blood products and medical devices. We are also proposing to revoke related provisions that set forth addresses in the Center for Devices and Radiological Health (CDRH) and CBER for submitting registration and listing information, and provisions that specify the appropriate forms for submitting such information.

4. Who Would Be Exempt From Registration and Listing?

Section 510(g) of the act and current § 207.10 provide for exemptions from registration and drug listing requirements. Proposed § 207.13 contains certain changes to some of the exemptions in current § 207.10, as discussed in the first part of this section. Proposed § 207.13 also incorporates without change some exemptions from current § 207.10, as discussed at the end of this section.

The introductory paragraph of proposed § 207.13, largely consistent with current § 207.10, states that, except as provided in proposed § 207.13(i), the classes of persons listed in proposed § 207.13 are exempt from registration and drug listing under section 510(g) of the act, or because we have found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. We are proposing to add the phrase ''except as provided in proposed § 207.13(i)'' to indicate that even though the classes of persons identified in paragraphs (a) through (h) are exempt from registration and drug listing, if such persons engage in activities as set forth in paragraph (i), the exemption does not apply and they are required nonetheless to register and list. We are also proposing to include in the introductory paragraph a sentence clarifying that the exemption under proposed § 207.13 would not provide exemptions from other provisions of the act or regulations. For example, persons that do not have to register establishments and list drugs are still subject to the adulteration and misbranding provisions under sections 501 and 502 of the act (21 U.S.C. 351 and 352) and also may be subject to the new drug approval requirements under section 505 of the act (21 U.S.C. 355) or new animal drug approval requirements under section 512 of the act (21 U.S.C. 360b). We may inspect their establishments in accordance with section 704 of the act and the current good manufacturing practice requirements. We are proposing to add the clarifying sentence because in the past some manufacturers, repackers, relabelers, and drug product salvagers that were exempt from registration and listing requirements incorrectly believed these provisions provided exemptions from other provisions of the act and regulations. Accordingly, we are proposing to add this sentence to remedy any confusion on this point.

a. *Pharmacies*—The current exemption for pharmacies is codified at § 207.10(a). The proposed rule would revise and clarify the exemption, and would move it to § 207.13(a). Except as noted in the discussion below, proposed § 207.13(a) is generally consistent with current § 207.10(a).

Under proposed § 207.13(a), pharmacies would be exempt from the registration and listing requirements if they: Operate in conformance with all applicable local laws regulating the practice of pharmacy, including all applicable local laws regulating the dispensing of prescription drugs; regularly engage in dispensing prescription drugs upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care; and do not manufacture (as defined in proposed § 207.1), repack, or relabel drugs for sale other than in the regular course of the practice of pharmacy, including dispensing and selling drugs at retail.

Additional language has been added to proposed § 207.13(a)(1)(i) and (a)(1)(ii) to more closely track the language in section 510(g)(1) of the act. In addition, proposed § 207.13(a) does not include language that is in current § 207.10(a) that provides that the supplying of prescription drugs to a practitioner licensed to administer the drugs for use in the course of the practitioner's professional practice or to other pharmacies to meet temporary inventory shortages are not acts that require pharmacies to register. We are deleting this language because it is not necessary. Pharmacies that engage in such activities would be exempt from registration if they fulfill the following requirements: Operate in conformance with all applicable local laws regulating the practice of pharmacy, including all applicable local laws regulating dispensing of prescription drugs (proposed § 207.13(a)(1)(i)); regularly engage in dispensing prescription drugs upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care (proposed § 207.13(a)(1)(ii)); and do not manufacture (as defined in § 207.1), repack, or relabel drugs for sale other than in the regular course of the practice of pharmacy, including dispensing and selling drugs at retail (proposed § 207.13(a)(1)(iii)).

Proposed § 207.13(a)(2) clarifies that pharmacies may potentially qualify for the exemption in proposed § 207.13(a) only if they are located in any State as defined in section 201(a)(l) of the act (21 U.S.C. 321) (that is, any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico). This proposed provision is currently located in the introductory paragraph in current § 207.10. We believe it would be more clear to place this provision in proposed § 207.13(a)(2). This aspect of the proposed provision is consistent with current §§ 207.10 and 207.40.

b. *Hospitals, clinics, other health care entities, and public health agencies*—The current exemption for hospitals, clinics, and public health agencies is

codified at § 207.10(b). The proposed exemption is generally consistent with current § 207.10(b), except for the addition of ''other health care entities'' and other mostly minor revisions and clarifications, as described below. The proposed exemption would move to § 207.13(b).

Hospitals, clinics, other health care entities, and public health agencies are exempt, under proposed § 207.13(b), from the registration and listing requirements if they: Operate establishments in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs; regularly engage in dispensing prescription drugs, other than human blood or blood products, upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care; and do not manufacture (as defined in proposed § 207.1), repack, or relabel drugs other than in the regular course of the practice of pharmacy, including dispensing.

The exemption in proposed § 207.13(b) would be limited to hospitals, clinics, other health care entities, and public health agencies located in any State as defined in section 201(a)(1) of the act. The proposed provision requiring that such facilities be located in any State is currently located in the introductory paragraph in current § 207.10. We believe it would be more clear to place this provision in proposed § 207.13(b)(2). This proposed provision (except with respect to BLA holders and the clarification with respect to positron emission tomography (PET) drugs) is generally consistent with current §§ 207.10 and 207.40.

We are proposing to add ''other health care entities'' to this exemption because we are aware that other health care entities besides hospitals, clinics, and public health agencies (such as skilled nursing facilities) lawfully provide medical care and dispense drugs and logically are similarly situated to hospitals, clinics, and public health agencies for purposes of exempting them from registration and listing, if they meet the statutory and regulatory requirements.

We are also proposing to add language to proposed § 207.13(b) to make the exemption more consistent with the pharmacy exemption in proposed § 207.13(a). For example, we are proposing to add language to proposed § 207.13(b)(1)(i) so that this exemption also specifically requires compliance with all applicable laws regulating dispensing of prescription drugs, as is required by proposed § 207.13(a)(1)(i). We are similarly proposing to add § 207.13(b)(1)(iii) to be consistent with proposed § 207.13(a)(1)(iii), although in proposed § 207.13(b)(1)(iii) we have not included the terms ''for sale'' or ''selling drugs at retail'' since this language is appropriate for retail pharmacies relying on the exemption provided by proposed § 207.13(a), but not for hospitals, clinics, other health care entities, and public health agencies relying on the exemption provided by proposed § 207.13(b).

We believe that the exemption for hospitals, clinics, other health care entities, and public health agencies provided in proposed § 207.13(b)(2) should be relied upon by pharmacies within these health care entities that dispense drugs to patients receiving care in the health care entities and that meet the requirements of the exemption, but should not be relied upon by retail pharmacies located within these health care entities. Retail pharmacies should rely upon the exemption in proposed § 207.13(a) if they meet the requirements of that proposed provision.

c. *Persons who manufacture, repack, relabel, or salvage certain medicated feeds*—Although we are proposing to reorganize and clarify the exemption for persons who manufacture, repack, relabel, or salvage certain medicated feeds, we are not proposing to change the substance of the exemption. Under proposed § 207.13(f), persons who manufacture, repack, relabel, or salvage Type B or Type C medicated feeds, except for manufacturers, repackers, relabelers, or drug product salvagers of Type B or Type C medicated feeds made from Category II, Type A medicated articles, are exempt from registration. This exemption would not apply to persons who would otherwise be required to register (such as manufacturers, repackers, relabelers, or drug product salvagers of certain free-choice feeds, as defined in 21 CFR 510.455, or certain liquid feeds, as defined in 21 CFR 558.5, where the specifications and/or formulas are not published and a feed mill license is required). Proposed § 207.13(f) also clarifies that all manufacturers, repackers, relabelers, or drug product salvagers of Type B or Type C medicated feeds would be exempt from listing.

d. *The current exemptions for foreign trade zones and drugs imported under section 801(d)(3) of the act would be revoked*—In 2001, we issued a final rule on foreign establishment registration and listing (66 FR 59138, November 27, 2001). The regulation created two exemptions in § 207.40:

- Under current § 207.40(a), a foreign establishment is not required to comply with the registration and listing requirements if its drug enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U.S. commerce. We created this exemption as part of the final rule on foreign establishment registration and listing because registering such foreign establishments or listing drugs that were confined to a foreign trade zone—and were therefore not introduced into domestic commerce—was not considered necessary for the protection of the public health (see 66 FR 59138 at 59139 and 59140).
- Current § 207.40(b), which states that no drug may be imported or offered for import into the United States unless the drug is listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment, also states that this prohibition does not apply to components of drugs imported under section 801(d)(3) of the act. Section 801(d)(3) of the act, as it existed before June 2002, allowed persons to import unapproved or otherwise noncompliant articles (such as drug components) provided that the imported articles were further processed or incorporated into products and exported or, if not used, the imported articles were destroyed or exported. The provision in § 207.40(b) reflected the fact that, at the time, section 801(d)(3) of the act imposed very few restrictions on the admission of drug components that are imported into the United States for further processing or incorporation into a product that will be exported from the United States (66 FR 59138 at 59148).

Given the additional level of import restrictions imposed by the Bioterrorism Act, and the underlying security concerns that led to the Bioterrorism Act's adoption, we are proposing to eliminate these two exemptions in current § 207.40(a) and (b) from the registration and listing requirements. In particular, sections 321 and 322 of the Bioterrorism Act, which affected foreign establishment registration by amending sections 510 and 801 (among other provisions) of the act, suggest that Congress intended the information requirements for foreign establishments and imported products to be comprehensive, and that Congress regarded the information it was requiring to be important to its goal in increasing the Nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies. This, in turn, suggests to

FDA that the exceptions from the registration and listing requirements are therefore no longer appropriate.

The Bioterrorism Act affected foreign establishment registration, in relevant part, by amending sections 510(i) and 801 of the act:

- To require, as part of an establishment's registration, the name of each importer of the drug that is known to the establishment and the name of each person who imports or offers to import the drug into the United States; and
- To provide that we may refuse admission of a product and, if the product is refused admission, that the product shall be held at the port of entry until a statement regarding the foreign establishment's registration is submitted to us.

The amendment to section 510(i) of the act reflects a determination on the part of Congress that a foreign establishment shipping drugs to the United States should provide additional information in its registration (that is, information about importers and persons who import or offer for import). FDA is concerned that if a foreign establishment is not subject to this establishment registration requirement—either by virtue of importing into a foreign trade zone or by importing components under section 801(d)(3) of the act—it would allow some importers and persons who import or offer for import to go undetected, thereby creating an unnecessary vulnerability in Congress' system of requiring this information.

The amendment to section 801(o) of the act reflects a determination that establishment registration and drug listing information is important enough that, if it is lacking at the time the article is offered for import, the article may be refused admission (and, if refused, shall be held at the port of entry). FDA is concerned that if a foreign establishment is exempt from the registration and listing requirements—either by virtue of importing into a foreign trade zone or by importing components under section 801(d)(3) of the act—FDA would be unable to rely on amended sections 510(i) and 801 of the act to require that imported products be held at the port of entry to the United States or to prevent such product's delivery to the importer or consignee. This situation would stand in the way of implementing Congress' apparent intent that this information be a prerequisite for entry of the imported product into the United States.

We believe that removing the exception to the registration and listing requirements for products entering foreign trade zones and for products imported under section 801(d)(3) of the act is consistent with Congress' desire to increase the Nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies by requiring foreign establishments to provide more, rather than less, information for imported products.

The Bioterrorism Act also revised section 801(d)(3) of the act, in part, by:

- Requiring importers to identify the manufacturers of the imported drug component, and each processor, packer, distributor, or other entity that had possession of the article from the manufacturer to the importer;
- Requiring certificates of analysis to accompany most imported articles; and
- Giving us the ability to refuse admission to the United States if we determine there is credible evidence or information indicating that the article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee into a drug, biological product, or other product specified in section 801(d)(3) of the act that will be exported from the United States.

These statutory changes also indicate a congressional desire to know more, rather than less, about the articles entering the United States under section 801(d)(3) of the act and to prevent potentially dangerous articles from entering the United States. The legislative history supports this belief, as the conference report for the Bioterrorism Act explained: ''Refusal of entry should not involve shipments between known shippers and known recipients unless the Secretary has received credible evidence or information that suggests such shipments may not be legitimate. The Managers intend to permit the Secretary to refuse admission of articles if the Secretary determines there is credible evidence or information that the articles may be used as instruments of terror. Such evidence might include highly toxic or otherwise exceptionally dangerous products going to recipients unknown to the Secretary or to recipients believed to lack the capability to further process such dangerous articles * * *.'' (See H. Rept. 107–481, l07th Cong. (2002), ''Joint Explanatory Statement of the Committee of Conference,'' ''Subtitle B—Protection of Drug Supply'' (discussing section 322).) The legislative history's references to ''known'' shippers, ''known'' recipients, and recipients who may lack the ability to further process an article, combined with the new statutory provision on refusing admission even if the article is imported under section 801(d)(3) of the act, strongly support our proposal to require that all drugs imported or offered for import into the United States be listed and manufactured at a registered foreign establishment. Failure to register such foreign establishments could compromise our ability to refuse admission of a dangerous article.

Therefore, the proposed rule would eliminate the exemption from the establishment registration and drug listing requirements for foreign establishments whose drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U.S. commerce. In addition, the proposal would require that all drugs imported or offered for import into the United States be listed and manufactured at a registered foreign drug establishment, even if the drug is imported under section 801(d)(3) of the act.

e. *Other exemptions*—As described in current § 207.10, the following remain exempt from registration and drug listing (proposed § 207.13):

- Practitioners who are licensed by law to prescribe or administer drugs and who manufacture, repack, relabel, or salvage drugs solely for use in their professional practice (current § 207.10(c); proposed § 207.13(c)).
- Manufacturers, repackers, relabelers, or drug product salvagers of drugs solely for use in research, teaching, or chemical analysis and not for sale (current § 207.10(d); proposed § 207.13(d)). Under proposed § 207.13(d), manufacturers, repackers, relabelers, or drug product salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale are exempt from registration requirements. Proposed § 207.13(d) would be consistent with the exemption in section 510(g)(3) of the act, except the language would be modified to take into account the proposed rule's uses of the terms ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' ''manufacture,'' ''repack,'' ''relabel,'' and ''salvage.'' We want to take the opportunity to remind interested persons that while the exemption from registration would apply to a sponsor that manufactures its own drug for use in its clinical trial of the drug, the exemption would not apply, for example, to a firm that manufactures a drug with the purpose of selling the drug to a sponsor for use in a clinical trial. In the latter situation, the manufacturer of the drug would be required to register.
- Manufacturers, repackers, relabelers, and drug product salvagers of

harmless inactive ingredients (current § 207.10(e); proposed § 207.13(e)). We considered proposing to revoke this exemption because of concerns related to potential contamination of those inactive ingredients. However, we concluded that submitting and maintaining in the database all excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs could be burdensome for industry. In proposing to maintain this exemption, we note that current regulations governing the manufacture of finished drug products require all manufacturers to perform quality control testing to ensure that components meet established specifications (see generally, part 211 (21 CFR part 211)).

- Manufacturers, repackers, relabelers, and drug product salvagers of animal viruses, serums, toxins, or analogous products (current § 207.10(g); proposed § 207.13(g)).
- Carriers (current § 207.10(h); proposed § 207.13(h)).

f. *Limits on exemptions*—Proposed § 207.13(i) would clarify that any of the persons who otherwise would qualify for an exemption under § 207.13(a) through (h) are not exempt from registration or listing if they: (1) Manufacture (as defined in proposed § 207.1),[4] repack, relabel, or salvage compounded positron emission tomography (PET) drugs as defined in section 201(ii) of the act; (2) manufacture (as defined in § 600.3(u)) a biological product subject to licensing under section 351 of the Public Health Service (PHS) Act; (3) manufacture (as defined in § 1271.3(e)) an HCT/P that, under § 1271.20, are also drugs regulated under section 351 of the PHS Act or section 505 of the act; or (4) engage in activities that would otherwise require them to register under this part.

Thus, any person identified in proposed § 207.13(a) through (h), such as pharmacies, hospitals, clinics, other health care entities, public health agencies, or practitioners, if they manufacture, repack, relabel, or salvage compounded PET drugs, as defined in section 201(ii) of the act (21 U.S.C. 321(ii)), would fall outside the scope of the exemptions provided in proposed § 207.13(a) through (h). Manufacturers, repackers, relabelers, or drug product salvagers of compounded PET drugs are not included among the persons that are exempt from registration under proposed § 207.13 because exempting manufacturers of compounded PET drugs from registration would be inconsistent with section 121 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105–115), which addresses the regulation of PET drug products. Section 121 of the Modernization Act directs us to develop appropriate procedures for the approval of PET drugs under section 505 of the act and appropriate CGMP requirements for such drugs. It also requires the submission of NDAs or ANDAs for PET drugs either 4 years after the date of enactment or 2 years after the date on which we establish approval procedures and CGMPs, whichever is longer. We published proposed CGMPs for PET drugs on September 20, 2005 (70 FR 55038). If Congress had intended to exempt manufacturers, repackers, relabelers, or drug product salvagers of PET drugs from registration requirements, it would have done so. Given that PET manufacturers will be expected to comply with CGMP requirements and FDA will need to inspect them to determine compliance, it is reasonable to require PET manufacturers, repackers, relabelers, or drug product salvagers to register so we can identify PET manufacturers, repackers, relabelers, or drug product salvagers and the drugs they manufacture, repack, relabel, or salvage for inspection purposes. Therefore, the proposed rule would require compounded PET drug manufacturers, repackers, relabelers, or drug product salvagers to register with us and list their drugs in accordance with section 510(j) of the act and proposed part 207.

Likewise, any person identified in § 207.13(a) through (h) who would otherwise qualify for an exemption would not qualify for an exemption if it manufactures (as defined in § 600.3(u)) a biological product subject to licensing under section 351 of the PHS Act.

We note that to the extent a person manufactures, repacks, relabels, or salvages PET drugs as set forth in proposed § 207.13(i)(1) or manufactures a biological product subject to licensing as set forth in proposed § 207.13(i)(2), the obligation to register and list would only apply to the extent that that person engages in the activities identified in proposed § 207.13(i)(1) or (i)(2). For example, a hospital dispensing and administering drugs and that also manufactures compounded PET drugs would list only the PET drugs it manufactures, assuming none of its other activities would subject it to registration or listing requirements. Likewise, a public health agency dispensing and administering drugs that holds a biologics license application would list only the biological drugs it manufactures, assuming none of its other activities would subject it to registration or listing requirements.

Proposed paragraph (i) also states that the exemptions provided in proposed § 207.13(a) through (h) do not apply to such persons if they engage in activities that would otherwise require them to register. This concept appeared in current § 207.10(e). We are proposing to apply this concept to all the exemptions in proposed § 207.13 to reiterate that if a person qualifies for an exemption from the activities stated in proposed § 207.13(a) through (h), that person may still need to register if that person engaged in activities that would otherwise require registration.

5. What Definitions and Interpretations of Terms Would Apply to Part 207?

In proposed § 207.1, we set forth new definitions and interpretations of terms for part 207 and revise or revoke certain definitions in current § 207.3(a).

Current § 207.3(b) states that the definitions and interpretations of terms in sections 201, 502(e), and 510 of the act apply to the terms used in part 207. We are proposing to revoke this sentence because it is unnecessary and has caused confusion in the past. For purposes of proposed part 207, the following definitions and interpretations of terms would apply to proposed part 207:

Act. This term, as used in proposed § 207.1, remains the same as current § 207.3(a)(1). ''Act'' means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301 *et seq.*)), except as otherwise provided.

Active pharmaceutical ingredient. We are proposing to replace the term ''bulk drug substance,'' as defined in current § 207.3(a)(4), with the term ''active pharmaceutical ingredient.'' We believe that the term ''bulk drug substance'' may be confused with the term ''bulk drug.'' The term ''bulk drug,'' as commonly used in the pharmaceutical industry, means an active ingredient, inactive ingredient, or finished dosage form, packaged in a large container (for example, a drum). To prevent confusion, we are proposing to replace the term ''bulk drug substance'' with the more descriptive term ''active pharmaceutical ingredient.''

We are also proposing to revise the definition of the current term ''bulk

[4]The term ''manufacture'' is defined in proposed § 207.1 and is used here for brevity to refer to the activities that trigger registration requirements (that is, ''manufacture, preparation, propagation, compounding, or processing'' of drugs). Although many PET facilities do not consider themselves to be ''manufacturing'' drugs, but rather preparing or compounding drugs, we are nonetheless using the term ''manufacture'' for brevity.

drug substance'' (changed to ''active pharmaceutical ingredient'' in the proposal) to make it consistent with the definition of ''drug substance'' in current § 314.3 (21 CFR 314.3). Current § 207.3(a)(4) states, in part, that a ''bulk drug substance * * * becomes an active ingredient,'' but does not explain what it means for an ingredient to be ''active.'' We believe that the definition of ''drug substance'' in current § 314.3 is more descriptive; that definition explains, in part, that ''drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the * * * body.'' Consistent with the language of current § 314.3, we are proposing to define ''active pharmaceutical ingredient'' in proposed § 207.1 as any substance that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Consistent with both current § 314.3 and current § 207.3(a)(4), the term would not include intermediates used in the synthesis of the substance. As proposed, the term would include both an active pharmaceutical ingredient marketed alone and as part of a finished dosage form.

Advertising and *labeling*. We are proposing to delete current § 207.3(a)(2), which explains that the terms ''advertising'' and ''labeling,'' as used in current part 207, include the promotional material described in current § 202.1(l)(1) and (l)(2) (21 CFR 202.1(l)(1) and (l)(2)), respectively. We believe that this information is more appropriately included in the definitions of ''representative sampling of advertisements'' and ''representative sampling of any other labeling.'' As a result, we are proposing to revise the definitions of those terms accordingly and delete current § 207.3(a)(2).

Commercial distribution. We are not proposing to substantively change the definition of ''commercial distribution'' from that set forth in current § 207.3(a)(5). The term would still mean any distribution of a human drug, except for investigational use under 21 CFR part 312, and any distribution of an animal drug or an animal feed bearing or containing an animal drug for non-investigational uses. The term would not include internal or interplant transfer of an active pharmaceutical ingredient between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign manufacturers, foreign repackers, foreign relabelers, foreign drug product salvagers, foreign private label distributors, and foreign establishments, the term ''commercial distribution'' would have the same meaning except that it does not include distribution of any drug that is neither imported nor offered for import by it into the United States. We are proposing to change the term ''bulk drug substance'' in the current definition to ''active pharmaceutical ingredient'' because the proposal replaces the definition of ''bulk drug substance'' with the definition of ''active pharmaceutical ingredient.'' Defining ''commercial distribution'' is important because, under proposed part 207, listing information must be provided to us for any drug that is being manufactured, repacked, relabeled, or salvaged for commercial distribution.

Content of labeling. We are proposing to add a new term, ''content of labeling,'' to part 207. The proposed definition of the term describes the labeling material that would be required to be electronically submitted at the time of listing under proposed §§ 207.49(g) and 207.61(a)(2). The proposed requirement to electronically submit the ''content of labeling'' would be in addition to the current listing requirement that formatted copies of certain labeling be submitted. We are proposing to define ''content of labeling'' because, as explained in section IV.E.4 of this document, the electronic submission of the ''content of labeling'' would be required for drug listing to permit us to electronically review, compare, and extract data from the labeling.

- For human prescription drugs that the manufacturer regards as subject to section 505 of the act or section 351 of the PHS Act, we are proposing to define ''content of labeling'' as the content of the prescription drug labeling, as specified in §§ 201.56, 201.57, and 201.80 (21 CFR 201.56, 201.57, and 201.80), including all text, tables, and figures.[5]

This proposed definition is consistent with how the term ''content of labeling'' is used in the final rule entitled ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format,'' (electronic labeling final rule), which published in the **Federal Register** of December 11, 2003 (68 FR 69009). Under the electronic labeling final rule, applicants are required to electronically submit, in a format that we can process, review, and archive, the ''content of labeling'' for human prescription drugs in NDAs, certain BLAs, ANDAs, supplements, and annual reports.[6] The electronic labeling final rule, including the use of the term ''content of labeling,'' only applies to this subset of drugs. Under the proposal, however, as set forth in proposed § 207.49(g), the ''content of labeling'' would be provided for drugs subject to the listing requirements of proposed part 207.

Proposed part 207 would also differ in one other respect from the way ''content of labeling'' is used in the electronic labeling final rule. The electronic labeling final rule states that the ''content of labeling'' that must be submitted electronically is commonly referred to as the content of the package insert or professional labeling. We are proposing to use the term ''prescription drug labeling'' instead of the term package insert or professional labeling. ''Prescription drug labeling'' is used in the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' published in the **Federal Register** of January 24, 2006 (71 FR 3922). In that final rule, ''prescription drug labeling'' is used to mean labeling for approved prescription drug products described in §§ 201.56, 201.57, and 201.80, which is commonly described using a variety of terms including ''professional labeling,'' ''package insert,'' ''direction circular,'' or ''package circular.'' We are proposing that the term ''content of labeling'' for human prescription drugs, as defined in proposed § 207.1 and required under proposed § 207.49(g), would be the content of the ''prescription drug labeling.''

- For human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the PHS Act, we are proposing to define ''content of labeling'' as the labeling equivalent to the content of the prescription drug labeling, as specified in §§ 201.56, 201.57, and 201.80, including all text, tables, and figures.
- For human OTC drugs, we are proposing to define ''content of labeling'' as the content of the drug facts labeling required by § 201.66 (21 CFR

[5]The use of the language ''that the manufacturer regards as subject to section 505 of the act or section 351 of the PHS Act,'' is explained in detail in section IV.D.7 of this document.

[6]For additional information, also see the guidance ''Providing Regulatory Submissions in Electronic Format—Content of Labeling'' (April 2005) (available at *http://www.fda.gov/cder/guidance/index.htm*), which discusses issues related to the submission of the content of labeling in electronic format in marketing applications for human drug and biological products. This guidance reflects our current thinking on providing in electronic format the content of labeling required in 21 CFR parts 314 and 601.

201.66) (format and content requirements for OTC drug product labeling), including all text, tables, and figures. Under § 201.66(b)(10), drug facts labeling means the title, headings, subheadings, and information required under or described in § 201.66(c) (content requirements).

- For animal drugs (including, but not limited to, drugs that the manufacturer regards as subject to section 512 of the act), we are proposing to define ''content of labeling'' as the content of the labeling that accompanies the drug that is necessary to enable safe and proper administration of the drug (for example, the labeling specified in §§ 201.1 and 201.5 (21 CFR 201.1 and 201.5)), including all text, tables, and figures.

Domestic. For the purposes of registration and listing under this proposal, and when used to modify the term ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' ''private label distributor,'' or ''establishment,'' we are proposing to use the term ''domestic'' to refer to a manufacturer, repacker, relabeler, drug product salvager, private label distributor, or establishment within any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. The terms ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' ''private label distributor,'' and ''establishment'' are defined in proposed § 207.1, and these definitions are discussed elsewhere in this section of the preamble. We are proposing to define the term ''domestic'' separately rather than repeat the meaning of the term under separate definitions for domestic manufacturer, domestic repacker, domestic relabeler, domestic drug product salvager, domestic private label distributor, and domestic establishment. The definition of ''foreign,'' as it would modify manufacturer, repacker, relabeler, drug product salvager, private label distributor, and establishment, is discussed elsewhere in this section of the preamble.

Drug(s). We are proposing to use the term ''drug(s),'' for purposes of proposed part 207, to mean the same as the definition of ''drug'' in section 201(g)(1) of the act. Section 201(g)(1) of the act defines ''drug'' to include, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals. ''Drug(s)'' under proposed § 207.1 would include drugs intended for use in humans, including the biologics described in proposed § 207.9(c), and animal drugs, including Type A medicated articles, and also includes articles ''intended for use as a component'' of any drug. The proposed term includes active pharmaceutical ingredients and finished dosage forms (prescription and OTC).

Drug product salvager, drug product salvaging. We are proposing to use the term ''drug product salvaging'' to mean applying manufacturing controls such as those required by current good manufacturing practice in parts 210 (21 CFR part 210) and part 211 to drug products and segregating out those drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products to the marketplace. We note, however, that drug product salvaging, like all manufacturing, must be conducted in accordance with current good manufacturing practice. We are proposing to use the term ''drug product salvager'' to mean a person who owns or operates an establishment that engages in drug product salvaging. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, the term would include both domestic drug product salvagers and foreign drug product salvagers.

Under current § 207.3(a)(6), drug product salvaging means the act of segregating drug products that may have been subjected to improper storage conditions, such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation, for the purpose of returning some or all of the products to the marketplace. We are proposing to revise the current definition of drug product salvaging to include ''applying manufacturing controls such as those required by current good manufacturing practice in part 210 and part 211 to drug products.'' We are not proposing to change the meaning of drug product salvaging but to clarify the current definition by explaining that the term also includes applying manufacturing controls to drug products. Drug product salvagers apply manufacturing controls to drug products so that they can determine whether the drug products may have been subjected to improper storage conditions. As discussed further in sections IV.B.1 and IV.D.1 of this document, ''applying manufacturing controls to drug products and segregating drug products'' would be covered under the scope of manufacturing, preparing, propagating, compounding, or processing, and repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user (section 510(a)(1) of the act). This activity would trigger the requirement to register under the act. In addition, under the proposal, drug product salvagers would also be subject to the drug listing requirements in section 510(j)(1) of the act because their activities involve conducting one of the aforementioned activities with respect to a given drug for the purpose of commercial distribution. As discussed in section IV.D.1 of this document, we are requesting comments specifically on whether drug product salvagers should be subject to the drug listing requirements because the drug products are being salvaged for commercial distribution.

Establishment. We are proposing to revise the definition of ''establishment'' at current § 207.3(a)(7) to mean, for purposes of registration and drug listing, a place of business under one management at one geographic location. Under the proposed definition, one geographic location may include separate buildings within the same city if their activities are closely related to the same business enterprise and are under the supervision of the same local management. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, the term would include both domestic establishments and foreign establishments. We are proposing to define the term ''establishment'' because, under proposed part 207, manufacturers, repackers, relabelers, and drug product salvagers must register each establishment, providing to us such information as the name and address of the establishment and type of operation performed at the establishment.

The proposed definition of ''establishment'' would clarify the phrase ''at one general physical location'' in the current definition by revising the phrase to read ''one geographic location'' and stating that this may include separate buildings within the same city if their activities are closely related to the same business enterprise and are under the supervision of the same local management.

The proposed definition of ''establishment'' is intended to simplify the current definition. The current definition defines establishment as a

place of business under one management at one general physical location, and includes, among others, independent laboratories that engage in control activities for a registered drug establishment (for example, consulting laboratories), manufacturers of medicated feeds and vitamin products that are drugs in accordance with section 201(g) of the act, human blood donor centers, animal facilities used for the production or control testing of licensed biologics, and establishments engaged in drug product salvaging. For brevity, the proposed definition of establishment does not restate the examples of establishments stated in the current definition. Some of these establishments would be covered under other definitions set forth in proposed § 207.1 and explained in section IV.A.5 of this document. For example, ''independent laboratories that engage in control activities for a registered drug establishment'' would be covered under the proposed definition of ''manufacturer.'' ''Establishments engaged in drug product salvaging'' would be covered under the proposed definition of ''drug product salvager.''

Establishment registration number. We are proposing to define ''establishment registration number'' as the number assigned by FDA to the establishment during the establishment registration process required in this part. The establishment registration number is assigned to each establishment of each manufacturer, repacker, relabeler, or drug product salvager inspected by our district office. The establishment registration number is assigned when the manufacturer, repacker, relabeler, or drug product salvager begins manufacturing, repacking, relabeling, or salvaging drugs subject to part 207. The establishment registration number would identify, among other things, where the drug is manufactured, repacked, relabeled, or salvaged. Currently, the FDA Establishment Identifier (FEI) will be the number we assign as the establishment registration number. In the future, however, we may use a different number as the establishment registration number.

Foreign. For the purposes of registration and listing under this proposal, and when used to modify the term ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' or ''private label distributor,'' we are proposing to use the term ''foreign'' to refer to a manufacturer, repacker, relabeler, drug product salvager, or private label distributor who is located in a foreign country and who manufactures, repacks, relabels, salvages, or distributes a drug that is imported or offered for import into the United States. When used to modify the term ''establishment,'' we are proposing to use the term ''foreign'' to refer to an establishment that is located in a foreign country and is the site where a drug that is imported or offered for import into the United States was manufactured, repacked, relabeled, salvaged or distributed. The terms ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' ''private label distributor,'' and ''establishment'' are defined in proposed § 207.1, and these definitions are discussed elsewhere in this section of the preamble. We are proposing to define the term ''foreign'' separately rather than repeat the meaning of the term under separate definitions for foreign manufacturer, foreign repacker, foreign relabeler, foreign drug product salvager, foreign private label distributor, and foreign establishment. The definition of ''domestic,'' as it would modify manufacturer, repacker, relabeler, drug product salvager, private label distributor, and establishment, is discussed elsewhere in this section of the preamble.

Importer. We are proposing to define ''importer'' to mean a company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States. We recognize that a foreign establishment may have more than one ''importer'' and we are proposing to include in this term any owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's drug that is imported into the United States. Under this proposal, the recipient of the drug would not include the consumer or patient who ultimately purchases, receives, or is administered the drug, unless the foreign establishment ships the drug directly to the consumer or patient. As described in section IV.B.3 of this document, this proposal would require foreign establishments to provide, for drugs manufactured, repacked, relabeled, or salvaged at the establishment, the name of each importer known to the establishment of such drug into the United States. Therefore, the establishment would need to provide the name of each owner, consignee, or recipient of the foreign establishment's drug imported into the United States that was known to the establishment. We describe more fully what we mean by ''known to the establishment'' in section IV.B.3 of this document. We invite comments on our definition of importer, including the scope of the entities included in the definition.

Manufacture, manufacturer. We are proposing to use the term ''manufacture'' for purposes of this part to mean each step in the manufacture, preparation, propagation, compounding, or processing of a drug. Manufacture includes the making by chemical, physical, biological, or other procedures or manipulations of a drug, including control procedures applied to the final product or to any part of the process. Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs, for another registered establishment's drug.

We are proposing to use the term ''manufacturer'' for purposes of this part to mean a person who owns or operates an establishment that manufactures a drug. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, ''manufacturer'' would include both domestic manufacturers and foreign manufacturers.

Under section 510(a)(1) of the act, the term ''manufacture, preparation, propagation, compounding, or processing'' includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. Accordingly, section 510(a)(1) of the act sets up a shorthand way of referring to all the activities that trigger registration requirements by using the specified phrase ''manufacture, preparation, propagation, compounding, or processing'' throughout section 510 of the act. However, for purposes of proposed part 207, the term ''manufacture'' would refer to the manufacture, preparation, propagation, compounding, or processing of a drug, as set forth in the proposed definition.

The term ''manufacturer'' would include, among others, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug, as defined in proposed § 207.1 and discussed in section IV.A.5 of this document. A ''control laboratory'' and a ''contract laboratory'' include independent establishments that manipulate, sample, test, or perform other quality control functions for another registered establishment's drug, including, for example, analytical

testing of drugs. A ''contract manufacturer'' is sometimes employed by other manufacturers to manufacture the drug. Similarly, a manufacturer may sometimes subcontract part of the manufacturing process such as packing or labeling to a ''contract packer'' or a ''contract labeler.'' The term ''manufacturer'' would include control laboratories, contract laboratories, contract manufacturers, and other entities that manufacture a drug because their activities include the making of drugs by chemical, physical, biological, or other procedures, including the manipulation, sampling, testing, or control procedures applied to the final drug product or to a part of the process. Such activities would fall under the scope of activities (that is, manufacture, prepare, propagate, compound, or process) in section 510(a)(1) of the act that trigger registration requirements.

The proposed definition of ''manufacture'' also explains that, for purposes of proposed part 207, the term manufacture is defined and used separately from the terms relabel, repack, and drug product salvage. Although we explain that repacking, relabeling, and drug product salvaging are activities that trigger registration (because the term ''manufacture, preparation, propagation, compounding, or processing,'' under section 510 of the act includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user), we believe that it is clearer to use four separate terms for the different activities for purposes of proposed part 207. We use separate terms so that we can clarify and differentiate the responsibilities of the four types of parties engaged in the separate activities of: ((1) Manufacturing that does not include repacking, relabeling, or drug product salvaging; (2) repacking; (3) relabeling; and (4) drug product salvaging).

Similarly, the proposed definition of ''manufacturer'' explains that the term manufacturer is defined and used separately from the terms relabeler, repacker, and drug product salvager. We explain that repackers, relabelers, and drug product salvagers are ''manufacturers'' (as that entity is contemplated in section 510 of the act), but we believe that, for purposes of proposed part 207, it is clearer to use four separate terms for the different entities: (1) Manufacturers (that are not also repackers, relabelers, or drug product salvagers); (2) repackers; (3) relabelers; and (4) drug product salvagers. Repackers, relabelers, and drug product salvagers would be subject to the provisions of part 207 that are applicable to repackers, relabelers, and drug product salvagers, respectively, but would not be subject to the provisions of part 207 that are applicable to ''manufacturers,'' as that term is defined in this proposal. For example, if a repacker, relabeler, or a drug product salvager supplies us with the manufacturer's NDC number, we would not require the repacker, relabeler, or drug product salvager to provide all of the information that the manufacturer provides to list a drug or, for the repacker or relabeler, to obtain an NDC number. We would already have much of the information in the database linked to the manufacturer's NDC number, and it would be an unnecessary burden to require that the information be provided again.

We are proposing to delete the definition of ''manufacturing or processing'' at current § 207.3(a)(8) and incorporate parts of the definition elsewhere in the proposed definitions. For example, the phrase ''control procedures applied to the final product or to any part of the process'' in the proposed definition of ''manufacture'' is part of the current definition of ''manufacturing or processing.''

Material change. We are proposing to revise the definition of ''any material change'' in current § 207.3(a)(3). The current definition includes, but is not limited to: (1) Any change in the name of the drug; (2) any change in the identity or quantity of the active ingredient(s); (3) any change in the identity or quantity of the inactive ingredient(s) where quantitative listing of all ingredients is required by current § 207.31(a)(2); (4) any significant change in the labeling of a prescription drug; and (5) any significant change in the label or package insert of an OTC drug. Changes that are not significant currently include changes in arrangement or printing or changes of an editorial nature. The proposed definition would continue to exclude labeling changes in arrangement or printing or labeling changes of an editorial nature. The inclusion of a bar code or NDC number on the label would not be considered a material change because it would be too burdensome to require the resubmission of labeling if the only change was to include a bar code or an NDC number. We are, however, proposing to rename the term ''material change'' and to more precisely identify all of the changes that would be considered ''material'' in the current definition. With respect to manufacturers, repackers, and relabelers, and drug product salvagers, a change in any information provided under proposed §§ 207.49, 207.53, 207.54, 207.55, or 207.57 would be considered a material change.

All listing information required under the proposal is needed to identify the drug. Under the broader definition of material change, as proposed, we would be better informed of changes to marketed drugs. This would result in more accurate and up-to-date drug listing information. Under proposed § 207.57 and section 510(j)(2)(D) of the act, the June and December updates of listing information must include reports of ''material changes'' in listing information previously submitted. The proposed definition of ''material change'' has been revised to more precisely identify which changes must be reported under proposed § 207.57.

Person who imports or offers for import. We are proposing to define a ''person who imports or offers for import'' as an agent, broker, or other entity that the foreign establishment uses to facilitate the import of its drug into the United States. As described in section IV.B.3 of this document, this proposal would require foreign establishments to provide, for drugs manufactured, repacked, relabeled, or salvaged at the establishment, the name of each person known to the establishment who imports or offers for import such drug into the United States. Therefore, the establishment would need to provide the name of each agent, broker, or other entity that the foreign registrant uses to facilitate the import of its drug into the United States. We describe more fully what we mean by ''known to the establishment'' in section IV.B.3 of this document. The term ''person who imports or offers to import'' would not include carriers, consistent with the legislative history of the Bioterrorism Act. The legislative history shows that although the House provision originally would have required registration information for importers and carriers, the conference substitute changed the language. The conference substitute deleted the term ''carriers,'' replacing it with ''persons who import or offer for import,'' clarifying that foreign manufacturers are not required to include information on carriers with annual registration. (See H. Rept. 107–481, 107th Cong., 2d sess., p. 140, 2002, Conf. Rept. to accompany H.R. 3448) We invite comments on our proposed definition of ''persons who import or offer for import.''

We also invite comment on our use of the word ''facilitate'' in the proposed definition. We recognize that the term

could be interpreted to include middlemen or other entities that may be viewed as assisting with or promoting the importation of a drug into the United States. For example, we are aware that ''buyer's clubs'' could be captured in the definition if ''facilitate'' were to be interpreted broadly. Buyer's clubs are groups that consolidate orders for drugs purchased from foreign establishments and then, once those drugs are imported into the United States, send them to the individuals or other entities who ordered the drugs through the clubs. It is also possible that ''facilitate'' could be interpreted to include organizations that may promote the awareness and sale of products through advertisements on the internet, for example. We recognize that, under this proposal, foreign establishments would only be required to give us information for persons who import or offer for import that are known to the establishments. Although the knowledge requirement in this proposed rule would include information that the foreign establishment, and persons in the foreign establishment, has reason to know of, we believe it is likely that foreign establishments generally would not know about most of the ''middlemen'' described previously. Therefore, even though the term ''facilitate'' in the proposed definition would be interpreted broadly to include middlemen, if the foreign establishment did not know of, or have reason to know of, the middlemen, the foreign establishment would not be required to report information about the middlemen under this proposal.

We also note that the terms ''broker'' or ''agent'' include ''customhouse brokers'' who facilitate importation by filing documents with the U.S. Customs Service, as well as FDA and other Federal agencies responsible for the regulation of imported products. We specifically invite comment on our use of the term ''facilitate'' in this proposal. We invite comment on whether we should interpret the term ''facilitate'' broadly to include middlemen as described previously. We also invite comment on whether foreign establishments would know about such middlemen and, if so, what effect a requirement to report information about those middlemen would have on foreign establishments. We also invite comment on whether there are benefits associated with such a reporting requirement, and, if so, what they are.

Private label distributor. We are proposing to define ''private label distributor'' to mean a person who owns or operates an establishment that commercially distributes, under its own label or trade name, any drug manufactured, repacked, relabeled, or salvaged by a registered establishment. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, the term would include both domestic private label distributors and foreign private label distributors.

Private label distributors are not considered to be manufacturers, repackers, relabelers, or drug product salvagers because they do not conduct any of the activities covered in section 510(a)(1) of the act with respect to the products they commercially distribute. Private label distributors only distribute drugs under their own label or trade name. The proposed definition is consistent with current § 207.20(b) and the description of private label distributors set forth in the 1973 final rule on drug listing requirements (38 FR 6258 at 6259). We are proposing to define this term to clarify its meaning and to distinguish private label distributors from manufacturers, repackers, relabelers, and drug product salvagers. Under the proposed definition, a private label distributor does not engage in any activities performed by a manufacturer, repacker, relabeler, or drug product salvager for the drug it distributes. As discussed in section IV.D.1 of this document, private label distributors currently may elect to submit listing information to us for the drugs they distribute. Under the proposal, private label distributors would not be permitted to list, and manufacturers, repackers, relabelers, and drug product salvagers would be required to provide listing information to us for drugs being manufactured, repacked, relabeled, or salvaged for private label distributors. However, if a private label distributor is a manufacturer with respect to a particular drug or drugs, for example, the private label distributor is subject to the registration and listing requirements for manufacturers in proposed part 207 with respect to that drug or drugs.

Relabel, relabeler. We are proposing to use the term ''relabel'' to mean changing the label or labels on a drug or drug package, or adding to the labeling for a drug or drug package, without repacking the drug or drug package. We remind interested persons that those activities must be conducted in accordance with the act and FDA regulations. We are proposing to use the term ''relabeler'' to mean a person who owns or operates an establishment that relabels a drug. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, the term would include both domestic relabelers and foreign relabelers.

Under the proposal, relabelers must provide registration and listing information. Under section 510(a)(1) of the act, the term ''manufacture, preparation, propagation, compounding, or processing'' includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. As discussed previously, we use the term ''relabeler'' separately from the term ''manufacturer'' because, although the relabeler's registration and listing responsibilities in general are the same as those for manufacturers under the act, the proposal would modify some of these requirements. For example, as described under the definition of ''manufacturer'' in section IV.A.5 of this document, if a relabeler supplies us with the manufacturer's NDC number, we would not require the relabeler to provide all of the information that the manufacturer provides to obtain an NDC number and to list a drug. We would already have much of the information in the database linked to the manufacturer's NDC number, and it would be an unnecessary burden to require that the information be provided again. Under the proposed definition, a relabeler does not engage in any other activity performed by a manufacturer for the drugs they relabel.

Repack, repacker. We are proposing to use the term ''repack'' to mean repack or repackage or otherwise change the container or wrapper of a drug or drug package. We are proposing to use both the terms ''repack'' and ''repackage'' in the definition because these terms are often used interchangeably with respect to drugs and, whether such activities are characterized as repacking or repackaging, they are subject to the requirements of this part. Although the term ''repackaging'' is used in section 510(a)(1) of the act, the terms ''repacking,'' ''repack,'' and ''repacker'' are more commonly used by industry when referring to this activity, and, therefore, we are using these terms throughout the proposal. We are proposing to use the term ''repacker'' to mean a person who owns or operates an establishment that repacks a drug or drug package. When not modified by ''domestic'' or ''foreign,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, the term would include both domestic repackers and foreign repackers.

Under the proposal, repackers must provide registration and listing information. Under section 510(a)(1) of the act, the term ''manufacture, preparation, propagation, compounding, or processing'' includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. We use the term ''repacker'' separately from the term ''manufacturer'' because, although the repacker's registration and listing responsibilities in general are the same as those for manufacturers under the act, the proposal would modify some of these requirements. For example, as described under the definition of ''manufacturer'' in section IV.A.5 of this document, if a repacker supplies us with the manufacturer's NDC number, we would not require the repacker to provide all of the information that the manufacturer provides to obtain an NDC number and to list a drug. We would already have much of the information in the database linked to the manufacturer's NDC number, and it would be an unnecessary burden to require that the information be provided again. Under the proposed definition, a repacker does not engage in any other activity performed by a manufacturer for the drugs they repack.

Representative sampling of advertisements. We are proposing to revise the definition of ''representative sampling of advertisements.'' Currently, § 207.3(a)(2) explains that the term ''advertising'' as used in part 207 includes the promotional material described in § 202.1(l). However, current § 207.3(a)(9) expressly excludes such material from the definition of ''representative sampling of advertisements.'' We believe that the inconsistency between the two provisions was an unintended result of certain editorial amendments made to part 207. We are proposing to revise the definition of ''representative sampling of advertisements'' to resolve the inconsistency. Specifically, we believe that the content of current § 207.3(a)(2) should be incorporated into the definition of ''representative sampling of advertisements'' to clarify that the term includes the promotional material described in § 202.1(l)(1).

We are proposing to define ''representative sampling of advertisements'' as typical advertising material (including the promotional material described in § 202.1(l)(1), but excluding labeling as determined in § 202.1(l)(2)), that gives a balanced picture of the promotional claims used for the drug. In addition to resolving the inconsistency described previously, the proposed definition would delete the example currently provided in § 207.3(a)(9) (that is, if more than one medical journal advertisement is used but the promotional content is essentially identical, only one needs to be submitted). We believe that this example is unnecessary and are proposing to simplify the definition by deleting it.

Representative sampling of any other labeling. We are proposing to revise the definition of ''representative sampling of any other labeling.'' We are proposing to delete current § 207.3(a)(2), which explains that the term ''labeling'' as used in part 207 includes the promotional material described in § 202.1(l)(2). We believe that this information would be more appropriately included in the definition of ''representative sampling of any other labeling.''

We are proposing to define ''representative sampling of any other labeling'' as typical labeling material (including the promotional material described in § 202.1(l)(2), but excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug. In addition to incorporating the relevant content of current § 207.3(a)(2), the proposed definition would delete the example currently provided in current § 207.3(a)(10) (that is, if more than one brochure is used but the promotional content is essentially identical, only one needs to be submitted). We believe that this example is unnecessary and are proposing to simplify the definition by deleting it.

United States agent. We are proposing to remove the definition of ''United States agent'' in current § 207.3(a)(11). Proposed § 207.69 would incorporate many of the provisions of the current definition of United States agent and current § 207.40 (registration and listing requirements for foreign establishments). The same requirements in the current definition appear at proposed § 207.69(b)(1), (b)(2), and (b)(3).

B. Registration

1. Who Would Be Required to Register?

Proposed § 207.17(a) would require manufacturers, repackers, relabelers, and drug product salvagers to register each establishment. This provision would replace the requirement at current § 207.20(a) that owners or operators of all drug establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug must register. The terms ''manufacturer,'' ''repacker,'' ''relabeler,'' and ''drug product salvager,'' as defined in proposed § 207.1 and discussed in section IV.A.5 of this document, more clearly indicate who must register.

Manufacturers, repackers, relabelers, and drug product salvagers would be required to register because the activities they perform fall within the scope of activities that trigger registration requirements in section 510(a)(1) of the act. Section 510(a)(1) states that the phrase ''manufacture, preparation, propagation, compounding, or processing'' includes repacking or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

We are proposing to use the terms ''repacker,'' ''relabeler,'' and ''drug product salvager'' separately from the term ''manufacturer'' in the proposal because, although the repacker, relabeler, and drug product salvager's listing responsibilities in general are similar to those for manufacturers under the act, the proposal would modify some of these requirements. In particular, if a repacker, relabeler, or drug product salvager supplies us with the manufacturer's NDC number, we would not require the repacker, relabeler, or drug product salvager to provide all of the information that the manufacturer provides to list a drug. Similarly, we would not require repackers and relabelers to submit all of the information that the manufacturer submits to obtain an NDC number.

Proposed § 207.17(a) would enable us to identify who is making drugs and where they are being made. Being able to accurately identify who makes drugs and where they are made is very important. Certain marketed drugs may need to be quickly identified and used to help counteract the effects of a bioterrorism attack. Registration information also assists us in scheduling and planning inspections of registered establishments pursuant to section 704 of the act.

Proposed § 207.17(a) also provides that registration information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. This provision would also apply when operations are

conducted at both domestic and foreign establishments and there exists joint ownership and control among all the establishments. This provision is consistent with current § 207.20(a).

We are proposing to revoke the requirement in current § 207.20(a) that no owner or operator may register an establishment if any part of that establishment is registered by another owner or operator. The requirement has caused uncertainty about who must register and which establishment must be registered. Under proposed § 207.17(a), manufacturers, repackers, relabelers, and drug product salvagers must register each establishment unless they are otherwise exempt under section 510(g) of the act or proposed § 207.13.

Under proposed § 207.17(b), private label distributors would not register with us unless they also manufacture, repack, relabel, or salvage drugs and are required to register under the act or proposed § 207.17(a). Private label distributors are not considered to be manufacturers, repackers, relabelers, or drug product salvagers because they do not conduct any of the activities covered under section 510(a)(1) of the act with respect to the drugs they commercially distribute. Private label distributors only distribute drugs under their own label or trade name. Proposed § 207.17(b) would revise the provision in current § 207.20(b) that owners or operators of establishments that distribute under their own label or trade name a drug manufactured or processed (as defined in current § 207.3(a)(8)) by a registered establishment may elect to obtain a labeler code from us and submit listing information directly to us. Under current regulations, if a private label distributor does not elect to submit drug listing information to us, the registered establishment must submit the drug listing information. As explained in section IV.D.1 of this document, we are proposing to revise current § 207.20(b) and not permit private label distributors to register or list. Manufacturers, repackers, relabelers, and drug product salvagers must submit drug listing information for those drugs they manufacture, repack, relabel, or salvage for commercial distribution for a private label distributor.

2. When Would Initial Registration Information Be Provided?

Under proposed § 207.21, a domestic manufacturer, domestic repacker, domestic relabeler, and domestic drug product salvager must register each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. The proposed timeframe ''no later than 5 calendar days'' is consistent with current § 207.21(a) in that the current registration requirement also provides for a 5-day registration timeframe for owners or operators of establishments entering into the ''manufacturing or processing'' of a drug (as defined in current § 207.3(a)(8)). The proposed timeframe is also consistent with the requirement in section 510(c) of the act to register each establishment ''immediately'' and ''upon first engaging in the manufacture, preparation, propagation, compounding, or processing'' of a drug.

Under proposed § 207.21, a foreign manufacturer, foreign repacker, foreign relabeler, and foreign drug product salvager must register each establishment before a drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States. This is consistent with current § 207.40(b), which states that no drug may be imported or offered for import into the United States unless it is listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment. In addition, section 510(i) of the act states that any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall register with the Secretary.

Proposed § 207.21 uses the term ''each establishment'' to emphasize that the requirement to register would apply even if the manufacturer, repacker, relabeler, or drug product salvager has previously registered one or more other establishments. This proposed requirement is consistent with two provisions of section 510 of the act. Section 510(d) of the act requires registration of any additional establishment immediately upon beginning the manufacture, preparation, propagation, compounding, or processing of a drug at that establishment. Section 510(i)(1) of the act states that any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States must register with the Secretary.

We are proposing to specify ''calendar'' days to be consistent with the terminology and timeframes used in the international pharmaceutical regulatory guidances of the International Conference on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (*http://www.ich.org*) and the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS) (*http://www.cioms.ch*).

We are proposing to revoke the requirement in current § 207.21(a) to register within 5 days after submitting certain marketing applications if the owner or operator has not previously entered into the manufacture or processing of a drug (as defined in current § 207.3(a)(8)). We are also proposing to revoke the requirement in current § 207.20(c) that, before beginning the manufacture or processing of a drug subject to certain marketing applications, an owner or operator of an establishment must register before the application is approved. We are proposing to revoke these requirements because, under proposed § 207.21 and consistent with section 510(c) and (d) of the act, registration of each establishment must occur no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug at the establishment. This provision would govern when to register an establishment rather than the date a marketing application is submitted or approved. We believe that this proposed requirement would provide us with sufficient notice as to who is manufacturing, repacking, relabeling, or salvaging drugs and where those activities are taking place. In addition, marketing application approval is linked to registration elsewhere in our regulations. Under current § 314.125(b)(11) (21 CFR 314.125(b)(11)), we may refuse to approve an application if the drug will be manufactured or processed in an establishment that is not registered. For consistency with current § 314.125(b)(11), we are proposing to revise § 514.111(a)(12) (21 CFR 514.111(a)(12)) for NADAs to state that we will refuse to approve an application if ''the drug will be manufactured in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and part 207.'' For licensed human biological products, current 21 CFR 601.4(b) includes a provision that we must deny a BLA if the establishment or product does not meet ''requirements established in Title 21, Chapter I'' (this would include the registration and listing provisions).

3. What Information Would Be Required for Registration?

Under proposed § 207.25, all manufacturers, repackers, relabelers,

and drug product salvagers must provide the following information to register each of their establishments:

- Name of the owner or operator of each establishment; if a partnership, the name of each partner would be submitted; if a corporation, the name of each corporate officer and director and the place of incorporation would be submitted (proposed § 207.25(a)). This provision is consistent with section 510(a)(2) of the act, which states that ''the term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.'' The proposal would replace ''State of incorporation'' with ''place of incorporation'' to include foreign corporations. Proposed § 207.25(a) is also consistent with section 510(c) of the act, which states that ''Every person * * * shall immediately register with the Secretary his name, place of business, and such establishment.'' The proposal would use ''owner or operator'' for consistency with current § 207.25(a), which provides that the information required for registration includes the name of the owner or operator of the establishment. Current § 207.25(a) provides that the term ''name of the owner or operator'' includes, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporate officer and director and the name of the State of incorporation. The proposal would revoke the requirement to include the title of each corporate officer and director because we have determined that it is not necessary for registration purposes. Current § 207.25(a) also requires the submission of the ''kind of ownership or operation (that is, individually owned, partnership, or corporation).'' The proposal would replace this requirement because the kind of ownership or operation would be captured under the requirement to provide, if applicable, the name of each partner, and corporate officer and director, and the place of incorporation in proposed § 207.25(a).
- Name, trade name(s), and address of each establishment (proposed § 207.25(b), (c), and (d)). This provision is consistent with section 510(c) of the act and current § 207.25(a). The proposal would continue the requirement in current § 207.25(a) to submit all trade names used by the establishment, but rephrase current § 207.25(a) to clarify that, for purposes of this subsection, we want the trade name(s) of the establishment, names under which the establishment conducts business, and additional names by which the establishment is known. We are not seeking under this section the trade name(s) of the drugs of the establishment. Although we are interested in the trade names of the drugs, we can obtain that information through the drug listing requirements.
- Registration number of each establishment, if previously assigned to the establishment by us (proposed § 207.25(e)). If not previously assigned by us, we would assign a registration number after we receive the registration information (proposed § 207.25(e)). Under section 510(e) of the act, we may assign a registration number to any person or establishment registered and, under current § 207.35(a), we will assign a permanent registration number to each establishment that registers. The ''establishment registration number'' is defined in proposed § 207.1 to mean the number assigned by FDA to the establishment during the establishment registration process. (Currently, the FEI will be the number we assign as the establishment registration number.) We are proposing to require the submission of the registration number because each establishment is identified by its registration number for registration and inspection purposes and to enable us to identify all registered establishments. The registration number is currently submitted on Form FDA 2656.
- Type of operations(s) performed at each establishment—for example, manufacturing, repacking, relabeling, or salvaging (proposed §207.25(f)). We are proposing to require this information because it is important for identifying, prior to an inspection, which operation the establishment engages in so that our investigators can be better prepared before inspection. Currently, the ''business type'' (for example, manufacturer, repacker, relabeler) must be submitted on Form FDA 2656.
- Name, address, telephone and fax numbers, and e-mail address of the official contact, as provided in proposed § 207.69(a), for each establishment (proposed § 207.25(g)). We are proposing to require this information because we need a contact person to facilitate discussion with the manufacturer, repacker, relabeler, and drug product salvager. This information needs to be current and, under proposed § 207.29(a)(3), any change in this information must be provided to us within 30 calendar days. This information is not required under current part 207. The requirements for the official contact are discussed in section IV.F.1 of this document.
- Information for foreign establishments only (proposed § 207.25(h)). With respect to foreign establishments only, for drugs manufactured, repacked, relabeled, or salvaged at the establishment, the name, address, telephone and fax numbers, and e-mail address must also be provided for: (1) The United States agent, as provided in proposed § 207.69(b), (2) each importer of such drug in the United States that is known to the establishment, and (3) each person who imports or offers for import such drug to the United States. The requirements for the United States agent are discussed in section IV.F.1 of this document. The name, address, and phone number of the United States agent is required to be submitted under current § 207.40(c). The information on importers and persons who import is not required to be submitted under current part 207. We are proposing to require the submission of the information on importers and persons who import because the Bioterrorism Act requires foreign establishments to submit, among other things, the name of each importer of each drug that is known to the manufacturer, repacker, relabeler, and drug product salvager and the name of each person who imports or offers for import each drug to the United States for purposes of importation. We want to make clear that the term ''known to'' would include any importer that is known to the foreign establishment as well as any importer that the foreign establishment has reason to know of. We therefore expect that the person responsible for completing the required registration forms on behalf of the foreign establishment would undertake appropriate due diligence in completing those forms, including to find out and report importers that others in his or her establishment know of or have reason to know of. In addition to the name, the proposal would require that the address, telephone and fax numbers, and e-mail address of each importer and of each person who imports or offers for import be provided to enable us to contact these persons.

All information required under proposed § 207.25 must be submitted for the establishment to be considered registered. As explained in section IV.B.l of this document, establishment registration would enable us to identify who is making drugs and where they are being made. Being able to accurately identify who makes drugs and where they are made is very important for protecting the public health. Among other things, registration information would enable us to become aware of and take action to stop manufacturers,

repackers, relabelers, and drug product salvagers who do not follow the requirements set forth in the act and in our regulations.

4. What Are the Proposed Requirements for Reviewing and Updating Registration Information?

The proposal would modify and streamline the requirements associated with updating registration information. Currently, manufacturers, repackers, relabelers, and drug product salvagers must enter new or revised registration information on Form FDA 2656 and return the form to us annually. Under the proposal, manufacturers, repackers, relabelers, and drug product salvagers would access the electronic drug registration and listing system and review their current registration information online, making any changes where needed. Updating registration information would be less time consuming under the proposal because the manufacturer's, repacker's, relabeler's, and drug product salvager's information would be easily accessible at any time and only changes to the information already in the system would need to be entered in the fields provided.

The following sections provide a description of the proposed requirements for reviewing and updating registration information and how they modify or reduce the burden of the current requirements.

a. *Expedited updates of registration information*. Manufacturers, repackers, relabelers, and drug product salvagers would report, under proposed § 207.29(a), the following changes as expedited updates no later than 30 calendar days after the change:

- The close or sale of an establishment;
- Any change in the name or address of an establishment; and
- Any change in the name, address, telephone and fax numbers, or e-mail address of the official contact or the United States agent.

We are proposing to require that these changes be reported as expedited updates because we need to know as soon as possible when a business has closed or has been sold and when the establishment's name or address has changed. This information is especially important for scheduling inspections. We also need current information for contacting the official contact or United States agent. As previously mentioned, it is increasingly important for us to be able to identify where drugs are being made and when drugs are no longer available. The expedited receipt of this information will help promote the efficient enforcement of the act.

Manufacturers, repackers, relabelers, and drug product salvagers are encouraged to provide expedited updates as soon as possible but no later than 30 calendar days after the change occurs. Our electronic drug registration and listing system will be easily accessible all the time to make changes.

The close or sale of an establishment, and a change in the name or address of an establishment, are currently reported annually on Form FDA 2656.

Proposed § 207.29(a) would revise current §§ 207.26 and 207.40(c)(3). Current § 207.26 requires the submission of certain amendments to registration information within 5 days of the change, and as noted previously, § 207.40(c)(3) requires the submission of any changes to the United States agent's name, address, or phone number within 10 business days of the change. As explained below, the proposal would lengthen the time period for reporting the changes in current § 207.40(c)(3). The proposal also would lengthen the time period for reporting some of the changes in current § 207.26 and revoke some of the reporting requirements in current § 207.26:

- A change in location would no longer be submitted as an amendment to registration within 5 days of the change, but would be reported under proposed § 207.29(a)(2) as an expedited update no later than 30 calendar days after the change (''address'' of an establishment is used in the proposal instead of location). We have determined that notification no later than 30 calendar days would be sufficient and would be consistent with the proposed timeframe for the other expedited updates.
- A change in ''drug-handling activity'' would no longer be submitted as an amendment to registration within 5 days of the change. A change in this information would only be reported during the annual review and update under proposed § 207.29(b). (The term ''type of operations'' is used in proposed § 207.25(f) instead of ''drug-handling activity.'') We have determined that annual notification of this change would be sufficient.
- Changes in ''individual ownership'' and ''corporate or partnership structure,'' in current § 207.26, would no longer be reported as amendments to registration because the proposal would revoke the corresponding provision for registration in current § 207.25(a) (the ''kind of ownership or operation (that is, individually owned, partnership or corporation)''). As explained in section IV.B.3 of this document, the kind of ownership or operation would no longer be submitted for registration because the information would be captured under the requirement to provide, if applicable, the name of the partner, corporate officer and director, and the place of incorporation in proposed § 207.25(a). This information would be reviewed and updated annually under proposed § 207.29(b). This proposed requirement is consistent with current § 207.26, which specifies that changes in the names of officers and directors of the corporation do not require an amendment and must be submitted at the time of annual registration.
- Under current § 207.26, a change in a registered establishment's firm name within 6 months of the registration of the establishment must be supported by a signed statement of the establishment's owner or operator that the change was not made for the purpose of changing the name of the manufacturer of a drug product under current § 201.1. This verification would no longer be required to be submitted as an amendment to registration. A change in the name of an establishment would be reported under proposed § 207.29(a)(2) no later than 30 calendar days after the change.

Proposed § 207.29(a)(3) would revise current § 207.40(c)(3), which provides that a foreign drug establishment or United States agent must report to us, within 10 business days, any changes to the United States agent's name, address, or phone number. The proposal would make the following revisions:

- The changes to the information about the United States agent would be revised to include not only the name, address, and telephone number, but also the fax number and e-mail address. This provision would be consistent with the information required to be submitted for the United States agent for registration under proposed § 207.25(h).
- The time period for reporting the changes would be lengthened to no later than 30 calendar days for consistency with the time period for the other expedited reports in proposed § 207.29(a).
- Changes in the name, address, telephone and fax numbers, and e-mail address of the official contact would also be reported under proposed § 207.29(a)(3) within 30 calendar days. This provision would be consistent with the information required to be submitted for the official contact for registration under proposed § 207.25(g).
- Under proposed § 207.29(a)(3), the manufacturer, repacker, relabeler, and drug product salvager, official contact, or United States agent may notify us about a change of information for the designated official contact or United

States agent. This provision would make the updates easier than the requirement in current § 207.40(c)(3) because it would enable the official contact and the United States agent (in addition to the manufacturer, repacker, relabeler, and drug product salvager) to update their own or each other's registration information.

- Under proposed § 207.29(a)(3), only a manufacturer, repacker, relabeler, or drug product salvager may designate a new official contact or United States agent. This proposed requirement is necessary because the manufacturer, repacker, relabeler, and drug product salvager is ultimately responsible for the actions of the official contact and the United States agent.

The requirements for the official contact and the United States agent are discussed in section IV.F.1 of this document.

b. *Annual review and update of registration information.* Proposed § 207.29(b) would require that the registration information provided under proposed § 207.25 be reviewed and updated annually. This timeframe is consistent with the requirement in section 510(b) of the act that owners or operators register on or before December 31 of each year and with the requirement in current § 207.21(a) that owners or operators renew their registration information annually. Proposed § 207.29(b) uses the term ''review and update'' to stress the importance of first reviewing all registration information to determine if any changes have occurred and then updating the information where needed. Proposed § 207.29(b)(1) specifies that the first review and update must occur no later than 1 year after the date of the initial registration of each establishment and that subsequent reviews and updates must occur no later than annually thereafter from the date of initial registration. Proposed § 207.29(b)(2) provides that the updates must reflect all changes that have occurred since the last annual review and update.

The proposal would add a new requirement for updating registration information. Under proposed § 207.29(b)(3), if none of the registration information has changed since the last annual registration (accomplished through the review and update of registration information), manufacturers, repackers, relabelers, and drug product salvagers must certify electronically that no changes have occurred. This is consistent with section 510(b) of the act, which requires manufacturers to register on or before December 31 of each year. If manufacturers, repackers, relabelers, and drug product salvagers certify that no changes have occurred, this certification would be the equivalent of resubmitting registration information, thereby satisfying the annual registration requirement. We are proposing to require that manufacturers, repackers, relabelers, and drug product salvagers certify annually that no changes have occurred because many manufacturers, repackers, relabelers, and drug product salvagers have not reviewed or updated this information on a regular basis. It has been difficult for us to determine whether failure to register annually is the result of no changes in information or noncompliance. The proposed requirement is intended to reduce these instances and improve the accuracy of our registration database. To increase the nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies, it is increasingly important for manufacturers, repackers, relabelers, and drug product salvagers to comply with registration requirements. With accurate information, we can identify where drugs are being made and better ensure that drugs are promptly available when needed. Furthermore, taking steps to increase compliance is consistent with section 301(p) of the act (21 U.S.C 331(p)), which makes it a prohibited act to fail to register under section 510 of act.

C. The National Drug Code (NDC) Number: What is It? How is It Used? What Changes Are We Proposing?

1. What Is the NDC Number?

The NDC number is a widely used identifier for drugs. It is a unique 10-digit number consisting of 3 segments: The labeler code, the product code, and the package code. Currently, the labeler code consists of four or five digits, the product code consists of either three or four digits, and the package code consists of either one or two digits. We assign the labeler code to the manufacturer, repacker, or relabeler after it has registered with us. For private label distributors, currently we provide a labeler code to the private label distributor if the private label distributor submits the required information to us. Alternatively, we provide a labeler code for a private label distributor to the manufacturer, repacker, or relabeler who is manufacturing, repacking, or relabeling the drug for the private label distributor after the manufacturer, repacker, or relabeler provides the required registration information pertaining to the private label distributor. The manufacturer, repacker, relabeler, or private label distributor then assigns the product code and package code to each drug within certain parameters that we have established.

2. How Did NDC Numbers Originate? How Are They Used?

Created in 1969, NDC numbers were originally intended to ''provide an identification system in computer language to permit automated processing of drug data by Government agencies, drug manufacturers and distributors, hospitals, and insurance companies'' (see 34 FR 11157, July 2, 1969). Participation in the NDC system was voluntary initially, and the program covered ''firms which manufacture and label or which repackage and label drugs'' (id.). In 1971, the NDC system expanded to include ''distributors who are marketing drug products in interstate commerce, under their own name (label), and through multiple wholesale outlets and/or five or more retail outlets'' (see 36 FR 27, January 1, 1971).

The enactment of the Drug Listing Act of 1972 (Public Law 92–387, 86 Stat. 559) changed the NDC number system even further. The Drug Listing Act required registered establishments to list all drugs that the establishment manufactures, prepares, propagates, compounds, or processes for commercial distribution and authorized us to assign a ''listing number'' to each drug or class of drugs that was listed. The Drug Listing Act declared that, ''Any number assigned * * * shall be the same as that assigned pursuant to the National Drug Code.'' Thus, by linking drug listings to the NDC numbers, the Drug Listing Act, in essence, authorized us to make participation in the NDC number system mandatory. In addition, by referring to the word, ''drug,'' the Drug Listing Act extended the NDC number system to over-the-counter drugs and animal drugs (because both are ''drugs'' under the act and are listed under section 510(j) of the act).

Today, NDC numbers continue to be an important, standardized, identification system for drug products used in data or claims processing, as well as in applications other than data or claims processing. For example, consumers may use NDC numbers to identify drugs that are the subject of a recall. Health care professionals submitting MedWatch reports (concerning possible adverse drug events) use NDC numbers to identify the drug at issue. Our investigators sometimes use NDC numbers to

determine a drug's compliance status by linking the NDC number to our registration and listing database to verify whether the manufacturer has registered and listed a particular drug. We compile the NDC numbers in the National Drug Code Directory, and the directory is accessible online at *http://www.fda.gov/cder/ndc/database*.

In addition, several new or future public health programs or initiatives rely or will rely on NDC numbers. For example:

- On February 26, 2004 (69 FR 9120), we published in the **Federal Register** a final rule to require certain human drug and biological products to have bar codes (see 69 FR 9120). The bar code must contain, at a minimum, the drug's NDC number. This rule is designed to reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being administered to the right patient at the right time.
- The electronic prescription drug program established by the Medicare Modernization Act promotes uniform standards that permit (among other things) electronic exchange of drug labeling and drug listing information maintained by us and by the National Library of Medicine (see 42 U.S.C. 1860D–4(e)(3)(C)(iii)). The goal behind the program is to reduce transcription and dispensing errors (which, in turn, lead to medication errors) and to prevent adverse drug interactions. As we stated previously in this document, drug listing numbers are, under the Drug Listing Act of 1972, to be the same as NDC numbers.
- The Health Insurance Portability and Accountability Act (Public Law 104–191) required, among other things, adoption of code set standards to facilitate electronic transactions. The standard code set for drugs is the NDC (see final rule on ''Health Insurance Reform: Standards for Electronic Transactions'' (65 FR 50312, August 17, 2000), 45 CFR 162.1002(c); amended February 20, 2003: ''Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets'' (68 FR 8381), 45 CFR 162.1002(a)(3) and (b)(2)).
- We are working with the National Library of Medicine, manufacturers, repackers, relabelers, and health care information suppliers to improve patient safety by better access to medication information through the DailyMed initiative. The DailyMed is an up-to-date, computerized repository of medication information including product labeling. The changes we are proposing to the NDC number would complement the DailyMed initiative by providing a link to product labeling made available through the DailyMed. The product labeling in this repository would be in the form of SPL. SPL is a standardized computer readable product labeling that links the NDC number to the product information.

To illustrate how this would work, someone could simply scan a bar code encoded with the NDC number or type into the DailyMed search program the NDC number on the carton label to access the most current information in the product labeling available from the DailyMed. This capability would enable DailyMed users to have the most up-to-date information for a drug, which could be an important public health benefit for consumers and health care professionals. For example, assume that a manufacturer modified its labeling to reflect a new adverse drug experience. If a consumer, pharmacist, or health care provider received a drug whose labeling had been printed earlier, the consumer, pharmacist, or health care provider would not be alerted to the new adverse drug experience. By using the DailyMed, the consumer, pharmacist, or health care provider would be able to access the new drug labeling and would, therefore, learn about the new adverse drug experience and possibly be able to avoid it. The consumer, pharmacist, or health care provider would also be better able to assess the risks and benefits of the drug and, therefore, would be able to make more informed decisions about using the drug. The DailyMed would be a publicly accessible repository of drug information that could be used in many ways by various parties, such as by those who could add value to the information, such as pricing information, and make it available to other parties.

Unfortunately, despite the widespread and growing use and reliance on NDC numbers, the existing NDC number system has several shortcomings. For example, manufacturers, repackers, and relabelers can assign NDC numbers, and the current regulations at § 207.35(b)(4)(ii) permit them to re-use the product codes under certain circumstances (such as taking the NDC number assigned to drug X and then, after drug X has been discontinued, later assign the same NDC number to drug Z). Also, under current regulations, it is difficult for FDA to control the practice of a manufacturer, repacker, or relabeler making changes to a drug but continuing to use the same NDC number despite those changes.

The manufacturer, repacker, and relabeler's ability to assign the product code and package code themselves has also resulted in problems that affect the National Drug Code Directory and its reliability. Product and package codes are not always assigned appropriately, and industry practices for assigning codes are inconsistent. In addition, manufacturers, repackers, and relabelers currently do not tell us what codes they have assigned until they list drugs with us; this means that the National Drug Code Directory is not always complete or comprehensive. Moreover, manufacturers, repackers, and relabelers may never list a product or may sometimes omit information or submit incorrect information to us; this often prevents us from including the correct information in the National Drug Code Directory and forces us to devote resources to obtaining, sometimes unsuccessfully, the correct information.

Furthermore, because NDC code segments can vary in length (such as a NDC having a four-digit labeler code, a four-digit product code, and a two-digit package code while another NDC has a five-digit labeler code, a three-digit product code, and a two-digit package code), electronic systems that view the NDC as a single number might interpret two different NDC numbers as being the same number. For example, one manufacturer, repacker, or relabeler's drug might have a NDC number that reads as 12345–678–90 while another could have a drug whose NDC number reads as 1234–5678–90. If a database omits the hyphens, the result would be a misleading impression that both drugs have identical NDC numbers (i.e., 1234567890), although they are made by different manufacturers and may be entirely different products.

We have also found that some manufacturers, repackers, and relabelers have assigned NDC numbers to products that are not drugs, such as dietary supplements and medical devices; such actions can confuse drug databases or lead to inappropriate reimbursements.

Consequently, to address these shortcomings and to create an accurate, up-to-date NDC number system, we propose to revise the NDC number system. In brief, we believe that to ensure that the numbers are unique and unambiguous, we need to take on the responsibility of assigning the NDC numbers prospectively to drugs that have not previously been assigned NDC numbers by a manufacturer, repacker, or relabeler. The NDC numbers currently assigned to drugs prior to the effective date of the rule would remain unchanged, provided those NDC numbers comply with the new

regulations as finalized. FDA intends to validate that current NDC numbers comply with the new regulations as finalized. We believe that the NDC number structure can remain very similar to what exists today, as we describe below, and still allow for unique and unambiguous NDC numbers if we assign the NDC numbers.

The proposal would also delete obsolete or unnecessary requirements. For example, current § 207.35 refers to the National Health Related Items Code (NHRIC) system as another code system; the proposal would omit references to the NHRIC system because we no longer maintain the NHRIC database (see 42 FR 52808 at 52810, September 30, 1977)).

We describe the proposed changes in more detail in the next section.

3. What Changes Are We Proposing?

a. *Proposed § 201.2—Drugs; National Drug Code (NDC) Number.* Currently, § 201.2 states that NDC numbers are requested, but not required, to appear on all drug labels and in all drug labeling, ''including the label of any prescription drug container furnished to a consumer.'' Section 201.2 also states that if the NDC number appears on the drug label, it must be displayed as required by current § 207.35(b)(3).

The proposal would revise § 201.2 to explain:

- What drugs must have an NDC number, in human-readable form, on the label;
- What an appropriate NDC number is;
- Whether any other NDC number may appear on a label;
- What prefix must be used to identify the NDC number on the label; and
- Where the NDC number goes on the label.

Specifically, proposed § 201.2(a) would require the appropriate NDC number, in human-readable form, to appear on the labels of drugs subject to the drug listing requirements. In this case, the word ''drugs'' should be interpreted in light of proposed § 207.1 and encompasses human drugs, including the drugs regulated under a BLA, as described in proposed § 207.9(c), and animal drugs, including Type A medicated articles. These drugs may be active pharmaceutical ingredients or finished dosage forms, whether prescription or OTC. The drugs regulated under a BLA, as described in proposed § 207.9(c) include, but are not limited to: (1) Plasma derivatives such as albumin, Immune Globulin, Factor VIII and Factor IX, and recombinant versions of plasma derivatives or animal derived plasma derivatives; (2) Vaccines; (3) Allergenic products; (4) Bulk product substances such as fractionation intermediates or pastes; and (5) Therapeutic biological products.

We propose to require human-readable NDC numbers to appear on drug labels because various individuals and databases use and rely on NDC numbers, and those individuals or databases might not have the technology or means to read an automatic identification technology such as a bar code that is required under § 201.25. In addition, for those who are able to read bar codes, a human-readable NDC number may serve as a ''backup'' in case the bar code is damaged, cannot be read, or is otherwise illegible.

Proposed § 201.2(b) would explain that an ''appropriate NDC number'' is the NDC number that we have assigned (under proposed §§ 207.33 or 207.37, which we discuss later in this part) to the last manufacturer, repacker or relabeler (including a drug product salvager who repacks or relabels the drug), or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer. For example, assume that a manufacturer makes a drug and sells that drug to a wholesaler or retailer. Under proposed § 201.2(b), the manufacturer is the last person responsible for the drug immediately before it reached the wholesaler or retailer, so the appropriate NDC number would be the manufacturer's NDC number that we have assigned to that drug. If, however, the manufacturer sold the drug to a repacker, who then repackages the drug and sells the repackaged drug to a retailer, the repacker is the last person responsible for the drug immediately before it reached the retailer, so the appropriate NDC number would be the repacker's NDC number that we have assigned and not the manufacturer's NDC number.

Identifying the last person responsible for a drug may be important in situations where the drug's quality, purity, labeling, or packaging may be at issue; for example, if a drug appeared to be contaminated, knowing who the last person was who manufactured, repacked, or relabeled the drug could help focus an investigation to determine how the contamination occurred. It also allows linking to the correct product information in the DailyMed. In addition, requiring the NDC number of the last manufacturer, repacker, relabeler, or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer would enable us to accurately and quickly identify the original manufacturer by connecting the NDC number on the label to the information in the electronic drug registration and listing system.

The proposed approach of assigning NDC numbers would mean that repackers, for example, would have to use their own NDC number, rather than using the manufacturer's NDC number on drug labels. We recognize that some, but not all, repackers have been using the manufacturer's NDC number rather than their own on drug labels. We are aware that some repackers' practice of using the manufacturers' NDC numbers has led to some confusion among FDA, the Centers for Medicare & Medicaid Services (CMS), other Federal agencies, State agencies, and private insurance organizations that rely on NDC numbers for many purposes, including to identify a drug and a drug's source and for purposes of reimbursement and dispensing systems. It also has led to some confusion by practitioners and patients. There may be other reasons that this practice has posed difficulties or is cause for concern.

We are aware that the use of manufacturer's NDC numbers by some repackers may lead to inaccurate or improper reimbursement by Medicaid, Medicare, and private insurers. It also may result in misunderstanding as to which rebate agreement a particular drug is covered by or whether a particular drug is covered by any rebate agreement at all.

We are also aware that the use of manufacturer's NDC numbers by repackers may not always be accurate or consistent. For example, a repacker might use a manufacturer's NDC number for a particular drug and then continue to use that manufacturer's NDC number for generic equivalents to that drug. This may lead to confusion for caregivers and patients who may be dispensed medication based on the original manufacturer's NDC number, but receive a drug that is different in size, shape and/or color than the drug they are accustomed to using. Additionally, there could be reimbursement differences between one firm's product and another firm's product. Further, the NDC number of the wrong manufacturer on the drug's label (even if the drugs of both manufacturers are generic equivalents) may also be a problem when pharmacies rely on verification systems that include exact color images of drugs based on NDC numbers.

Recently, the National Association of Chain Drug Stores (NACDS) and the Healthcare Distribution Management Association (HDMA) asked us to exercise enforcement discretion concerning our recent bar code rule (see

21 CFR 201.25 (69 FR 9170, February 26, 2004)) so that repackers could continue using manufacturers' NDC numbers on retail-based repackaged drug products (Ref. 1). In brief, NACDS and HDMA assert that FDA has ''historically allowed the use of original manufacturer NDC numbers by repackagers on the product labels of retail-based repackaged drug products'' and that this practice is standard among repackers (Ref. 1, p. 2). NACDS and HDMA also stated that use of the repackers' NDC numbers ''is not necessary or desirable'' because repackers identify themselves on the drug labels and that procedures exist to allow recall of particular lots of repacked drugs (rather than all drugs made by a manufacturer). They also stated that mandatory use of the repackers' NDC numbers might affect patient safety adversely and create additional, excessive costs to patients, health care providers, and payers because databases use the manufacturers' NDC numbers and cannot be modified to accommodate repackers' NDC numbers (Ref. 1, pp. 4 through 9). For example, NACDS and HDMA said that requiring repackers to use their own NDC numbers could ''greatly increase the potential for medication errors'' because pharmacists would: ''be required to inefficiently and manually choose between multiple options of the same product, e.g., Motrin 800mg by [one manufacturer] or Motrin 800mg repackaged by 5 different repackagers. The more NDC numbers in use for the same product across the country, the greater the chance that data entry errors will occur across the many pharmacies that use repackaged products.'' (Ref. 1, p. 7.) In addition, NACDS and HDMA said that requiring repackers to use their own NDC numbers would oblige them to pay substantial rebate fees under Medicaid when Congress intended drug manufacturers, not repackers, to pay those rebates and would complicate Medicaid billing; they further stated that requiring repackers to use their own NDC numbers would lead to a ''sharp reduction or elimination of this type of repackaging'' (Ref. 1, p. 8).

On March 28, 2005, we issued a response to the letter from NACDS and HDMA. The response stated, among other things, that we intend to temporarily exercise our enforcement discretion and permit repackers to use manufacturers' NDC numbers in bar codes placed on their products. We said that there will be an opportunity to directly consider this issue when we issue our proposed rule on establishment registration and drug listing. The response stated that we will consider all information provided that documents the impact on repackers.

We lack sufficient information to assess whether requiring repackers to use their own NDC numbers would be as problematic and expensive as NACDS and HDMA suggest. We also do not know the extent to which databases that use NDC numbers cannot be modified to accommodate repackers' NDC numbers or to associate more than one NDC number with drugs made by the same manufacturer. Moreover, although repackers currently assign their own NDC numbers and report those numbers to us, we do not know whether databases ignore or omit repackers' NDC numbers that we make available through the National Drug Code Directory.

We believe that allowing repackers to use the manufacturers' NDC numbers would be contrary to the proposal's goal of making the NDC number unique and the system more accurate and reliable.

We are requesting additional information on this issue. We specifically invite comments on the proposed approach of requiring on the drug's label the NDC number of the last manufacturer, repacker or relabeler (including the drug product salvager who repacks or relabels the drug), or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer, which would result in prohibiting the use of manufacturer's NDC numbers by repackers. We are especially interested in: (1) Examples and discussions of dispensing errors or difficulties, confusion, reimbursement problems, or other difficulties that may have been caused or contributed to by the practice of some repackers using the manufacturer's NDC number; (2) The magnitude of the problems that may be attributed to the use of manufacturer's NDC numbers by repackers and of the problems that NACDS and HDMA have articulated that may result from mandating the use of repacker's NDC numbers by repackers; (3) the extent to which such problems do or are likely to occur; and (4) whether there are technological (that is, software) solutions or alternatives that could address the issues presented in the NACDS and HDMA letter, other issues identified in this preamble, or those raised in comments to this proposed rule.

By inviting comment, we are specifically giving NACDS and HDMA, and any other interested parties, the opportunity to comment on whether repackers should be able to use the manufacturers' NDC numbers on the repacked drugs' label.

Proposed § 201.2(c) states that only the appropriate NDC number required by proposed § 201.2(b) may appear on the label. This provision would complement proposed § 201.2(b) by requiring the drug's label to bear the appropriate NDC number.

Proposed § 201.2(d) would require the human-readable NDC number to be immediately preceded by the letters ''NDC.'' This provision would modify the current requirement at § 207.35(b)(3)(ii), which states that the NDC number must be preceded by the prefix ''NDC'' or ''N'' when used on a label or labeling. We decided to limit the prefix to ''NDC'' because, when compared to ''N'' alone, ''NDC'' is a clearer signal that the number following ''NDC'' is the NDC number.

Proposed § 201.2(e) would require that the appropriate NDC number appear clearly on the drug's label as defined by section 201(k) of the act. Section 201(k) of the act defines ''label'' as ''a display of written, printed, or graphic matter upon the immediate container of any article.'' Section 201(k) also states that ''a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.'' This proposed requirement would be a change from current § 207.35(b)(3)(i), which requires the NDC number to appear ''prominently in the top third of the principal display panel.'' We decided to remove the restriction on the NDC number's location because our bar code rule, which requires the bar code to encode the drug's NDC number, allows the bar code to appear anywhere on the drug's label. Consequently, some establishments may wish to place the human-readable NDC number next to the bar code, so we have decided against specifying the location of the human-readable NDC number.

We are also proposing to revise current § 201.25 because, as discussed in section IV.A.5 of this document (definition of ''drug(s)'') and in the February 26, 2004, bar code final rule, certain drugs that would be subject to proposed part 207 are not subject to current § 201.25. Under proposed § 201.25(e), a drug product that is subject to the drug listing requirements of proposed part 207 but is not subject to current § 201.25 may display a bar

code on the label only if the bar code meets the requirements of § 201.25(c). We are proposing this revision to help ensure consistency in the appearance, content, and placement of bar codes on drug labels. We are also proposing to revise current § 201.25 to further clarify what ''appropriate'' NDC number must appear in the bar code. Current § 201.25(c)(1) states that each drug product subject to current § 201.25 must have a bar code that contains, at a minimum, the appropriate NDC number. To clarify this requirement, we are proposing to amend current § 201.25(c)(1) to state that the ''appropriate NDC number,'' as used in current § 201.25(c)(1), is described in proposed § 201.2(b).

We note that when there is a change in the NDC number on a drug product label, or when an NDC number is added to a label, application holders must submit revised labeling to us with their annual reports under § 314.81(b)(2) for human drugs, § 514.80(b)(4) for animal drugs (''periodic reports'' are required instead of ''annual reports''), and § 601.12(f)(3) for biological drugs.

b. *Proposed § 207.33—What is the National Drug Code Number, who must obtain it, and what information must be submitted?* Proposed § 207.33 would describe the NDC number and the process for obtaining NDC numbers. The proposal would differ from the pre-existing NDC number system by having us assign the NDC number for newly listed drugs, by describing the changes that would require a manufacturer, repacker, or relabeler to obtain a new NDC number, and by describing when information must be submitted to us to obtain an NDC number. Under the proposal, all three sections of the NDC number would be assigned prospectively by us to drugs that have not previously been assigned NDC numbers by a manufacturer, repacker, or relabeler. The NDC numbers currently assigned to drugs prior to the effective date of the rule would remain unchanged, provided those NDC numbers comply with the new regulations as finalized. FDA intends to validate that current NDC numbers comply with the new regulations as finalized.

Currently, § 207.35(a) states that we will provide a validated copy of an establishment's registration form and assign a permanent registration number to each drug establishment in accordance with our regulations. Current § 207.35(b)(1) and (b)(2) state that we will assign a drug listing number to each drug or class of drugs and that the number of characters in that number may differ depending on whether the drug is already listed in the NDC system or the NHRIC system. For example, current § 207.35(b)(1) states that if a drug is already listed in the NDC system or NHRIC system, the drug listing number is the same as that assigned under those codes and that we will add a lead zero to the first three characters to create a four-character labeler code. Current § 207.35(b)(1) also states that manufacturers or distributors may retain alphanumeric characters that they already use in the product and package code segments and must inform us if they convert those code segments into numeric digits. Current § 207.35(b)(2) also explains how many characters may be in a labeler code, product code, and package code.

Given that this proposal would designate the responsibility of assigning the NDC number to FDA, the proposal would eliminate many of the provisions in current § 207.35, such as our need to provide to sponsors validated copies of registration forms as well as information on how to assign the product code and package code. Proposed § 207.33(a) explains that the NDC number is a unique 10-digit number composed of a labeler code, product code, and package code. Proposed § 207.33(a) also states that we would assign the complete NDC number (that would include the existing labeler code, if any) to each drug that is subject to the listing requirements in part 207. We would use the same configuration when assigning each segment of the NDC number: The labeler code would be either five or four digits, the product code would be either four or three digits, and the package code would be either two digits or one digit. When we assign a NDC number to a drug, we intend to leave a space between the segments of the NDC number so that the separate codes are distinguishable. Manufacturers, repackers, and relabelers may add symbols, such as hyphens or asterisks, between the segments of the human-readable NDC number if they want to visually distinguish the codes in such a manner. Under the proposal, manufacturers, repackers, and relabelers would keep the same labeler code that they use for currently marketed drugs. However, if more than one labeler code is currently used by a manufacturer, repacker, or relabeler, only one labeler code would be used for any new NDC numbers that we would assign under this rule prospectively. Also, as described below, the proposal would allow currently marketed drugs to keep the same NDC numbers in most cases.

Proposed § 207.33(b)(1) and (b)(2) would require that manufacturers, repackers, relabelers, and, in certain circumstances, drug product salvagers, obtain NDC numbers from us for each drug that is subject to the drug listing requirements. In the case of drug product salvagers, they would obtain an NDC number for each drug that is subject to the drug listing requirements only if they repack or relabel the salvaged drug. For private label distributors, proposed § 207.33(b)(3) states that the manufacturer, repacker, or relabeler who manufactures, repacks, or relabels the drug for the private label distributor is responsible for obtaining the NDC number from us for each drug that is subject to the drug listing requirements.

Proposed § 207.33(b) is intended to clarify who must obtain NDC numbers. For example, drug product salvagers ordinarily would not need to obtain NDC numbers because they merely salvage drugs. If a drug product salvager simply recovers the drug and sells it without repacking or relabeling the product, the drug product salvager would not need to obtain an NDC number for the salvaged drug. However, if the drug product salvager repacks or relabels the salvaged drug, then the drug product salvager is similar to a repacker or relabeler, and proposed § 207.33(b) would require the drug product salvager to obtain an NDC number from us for the repacked or relabeled drug. As another example, under the proposal, private label distributors would not be permitted to register or list and, consequently, they would not obtain NDC numbers for the drugs they distribute. Instead, the manufacturer, repacker, or relabeler who manufactures, repacks, or relabels the drug for the private label distributor would be responsible for obtaining the NDC number, including a labeler code appropriate for the private label distributor. This change ensures that more accurate information is provided to FDA about the drug distributed by the private label distributor because the manufacturer supplies the necessary drug information to FDA.

Under current § 207.35, manufacturers, repackers, and relabelers assign NDC numbers to the drugs they manufacture, repack, or relabel, and private label distributors assign NDC numbers to the drugs they distribute if they opt to list the drugs themselves. Drug product salvagers currently do not receive NDC numbers for the drugs they salvage, and under current § 207.20(a), they are not required to list the drugs they salvage.

As noted previously, even though we would assign NDC numbers under the proposal, an establishment's labeler code would remain the same in most

cases. For example, if a manufacturer's labeler code were 12345, we would assign NDC numbers for the manufacturer's drugs and still use 12345 as the manufacturer's labeler code. However, under the proposal, if a manufacturer, repacker, or relabeler uses more than one labeler code, we would prospectively assign NDC numbers that use only one labeler code for that manufacturer, repacker, or relabeler.

Note, too, that other components in an NDC number may remain unchanged under the proposal. For example, assume that a drug is already listed in the National Drug Code Directory and its manufacturer later decides to change its package size. In this situation, the labeler code and the product code would ordinarily remain the same, and, generally, we would assign a new package code for the changed drug.

Furthermore, if a drug already has an NDC number at the time of the effective date of a final rule, the drug would retain that NDC number provided that the manufacturer, repacker, or relabeler, within 9 months after the effective date of a final rule, reviews and updates, in accordance with proposed §§ 201.2, 207.33, 207.37, 610.60, and 610.61, the information in our database for the NDC number (see sections IV.C.4, IX, and X of this document for information on the proposed implementation and effective and compliance dates of this rulemaking). We also will work with manufacturers, repackers, and relabelers to address any problems with existing NDC numbers (such as duplicate or potentially duplicate NDC numbers) that might arise after a final rule becomes effective.

Using a 5-digit labeler code, we estimate that we have the capacity for NDC numbers for up to 100,000 registered establishments, each having a capacity for up to 100,000 product/package size combinations (using the 5 remaining digits). If a registered establishment requires more than 100,000 product/package size codes, we could issue that establishment an additional labeler code. We currently have about 25,000 active establishments in our registration database, utilizing less than half of the 5-digit labeler code capacity. We currently issue about 1,000 new labeler codes annually. If we reach NDC number capacity (possibly in 30 to 50 years), we could propose to either add alphanumeric capability or expand the number of numeric digits to 11 or 12 (current § 207.35(b)(2)(i) states that FDA will go from a 5- to 6-digit labeler code if needed). This change in NDC numbers will necessitate advances in current UPC technology (due to the need for bar code reading), which we anticipate will likely occur prior to our reaching the 10-digit NDC numeric capacity.

The proposal would also omit the references to Form FDA–2656 in current § 207.35(a) and (b)(2) because the proposal's electronic submission of registration and listing information would make it unnecessary for us to provide validated copies of forms. In addition, because we would assign NDC numbers, the proposal would eliminate the provision in current § 207.35(b)(1) that allows manufacturers and distributors to convert alphanumeric product codes and package codes they may have and report such changes to us. (If any establishment still has alphanumeric product or package codes for a drug, we will work with them to assign new NDC numbers.) The proposal would also omit references in current § 207.35(b)(1) and (b)(2) to the NHRIC system because we do not maintain a NHRIC database (see 42 FR 52808 at 52810).

Proposed § 207.33(c) and (d) describes the information that a manufacturer, repacker, or relabeler would be required to submit before we assign an NDC number to a drug. As discussed earlier in this section, if a drug product salvager simply recovers the drug and sells it without repacking or relabeling the drug, the drug product salvager would not need to obtain an NDC number for the salvaged drug. However, if the drug product salvager repacks or relabels the salvaged drug, then the drug product salvager is similar to a repacker or relabeler, and proposed § 207.33(b) would require the drug product salvager to obtain an NDC number from us for the repacked or relabeled drug. The following table illustrates the proposed requirements.

TABLE 1.—INFORMATION TO BE SUBMITTED TO OBTAIN AN NDC NUMBER, ARRANGED BY MANUFACTURER, REPACKER, OR RELABELER AND DRUG

Proposed Section	Type of Drug	Information to be Submitted
§ 207.33(c)(1) (Manufacturer)	Active pharmaceutical ingredient	• Manufacturer's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's established name and proprietary name (if any) • Package size and type • Drug Master File number or Veterinary Master File number, if any, assigned to the active pharmaceutical ingredient
§ 207.33(c)(2) (Manufacturer)	Drug other than an active pharmaceutical ingredient	• Manufacturer's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's established name and proprietary name (if any) • Name and quantity of each active pharmaceutical ingredient or the approved U.S. application number • Name of each inactive ingredient (or approved U.S. application number) for certain drugs, and whether you consider the name of the inactive ingredient to fall under § 20.61 (21 CFR 20.61) of this chapter or to be otherwise prohibited from disclosure and, if so, why • Dosage form • Package size and type, including immediate unit-of-use container • Marketing status (e.g., prescription or OTC) • Drug or drug product type (human drug or animal drug) • Imprinting information

TABLE 1.—INFORMATION TO BE SUBMITTED TO OBTAIN AN NDC NUMBER, ARRANGED BY MANUFACTURER, REPACKER, OR RELABELER AND DRUG—Continued

Proposed Section	Type of Drug	Information to be Submitted
§ 207.33(c)(3) (Manufacturer)	Active pharmaceutical ingredient for a private label distributor	• Manufacturer's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's established name and proprietary name (if any) • Package size and type • Drug Master File number or Veterinary Master File number, if any, assigned to the active pharmaceutical ingredient • Private label distributor's name, address, telephone number, fax number, e-mail address, labeler code • Drug's proprietary name (if any) as assigned by the private label distributor
§ 207.33(c)(3) (Manufacturer)	Drug other than an active pharmaceutical ingredient for a private label distributor	• Manufacturer's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's established name and proprietary name (if any) • Name and quantity of each active pharmaceutical ingredient or the approved U.S. application number • Name of each inactive ingredient (or approved U.S. application number) for certain drugs, and whether you consider the name of the inactive ingredient to fall under § 20.61 of this chapter or to be otherwise prohibited from disclosure and, if so, why • Dosage form • Package size and type, including immediate unit-of-use container • Marketing status (e.g., prescription or OTC) • Drug or drug product type (human drug or animal drug) • Imprinting information • Private label distributor's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's proprietary name (if any) as assigned by the private label distributor
§ 207.33(d)(1) (Repacker or relabeler)	Drug that is repacked or relabeled	• Repacker's or relabeler's name, address, telephone number, fax number, e-mail address, and labeler code • NDC number assigned to the drug immediately before its receipt by the repacker or relabeler • Type of operation performed for the drug (repacking or relabeling) • Drug's established name and proprietary name (if any) • Package size and type, including immediate unit-of-use container, if any (required for repackers only)
§ 207.33(d)(2) (Repacker or relabeler)	Drug that is repacked or relabeled for a private label distributor	• Repacker's or relabeler's name, address, telephone number, fax number, e-mail address, and labeler code • NDC number assigned to the drug immediately before its receipt by the repacker or relabeler • Type of operation performed for the drug (repacking or relabeling) • Drug's established name and proprietary name (if any) • Package size and type, including immediate unit-of-use container, if any (required for repackers only) • Private label distributor's name, address, telephone number, fax number, e-mail address, and labeler code • Drug's proprietary name (if any) assigned by the private label distributor

Proposed § 207.33(c) and (d) are intended to accomplish several goals:

1. The proposal would reduce redundant data submission and improve the accuracy of information that we receive. For example, under the current system, a manufacturer and a repacker may submit the same drug listing information for the same type of drug. However, the repacker might not have adequate information from the manufacturer or might describe the drug differently than the manufacturer; this would lead to data discrepancies and omissions. So, by requiring only manufacturers to provide descriptive information about the drugs they make, we would eliminate potential duplicate submissions, data discrepancies, and data omissions. Instead, the repacker, under the proposal, would simply tell us the NDC number of the drug that the repacker receives, and we could use the NDC number to link the drug back to its manufacturer.

2. By having manufacturers, repackers, relabelers, and drug product salvagers submit information on behalf of private label distributors, the proposal would eliminate the potential for redundant, incomplete, or inconsistent submissions by private label distributors. For example, under the current system, some manufacturers have submitted information for drugs that they manufactured for private label distributors, and the private label distributors also submitted information for the same drugs; if the manufacturers and private label distributors described the drugs differently to us, we then had different information for the same drugs.

3. By linking a repacker's or relabeler's drug to an NDC number, the proposal would eliminate a problem that some repackers and relabelers have encountered in the past. Under the current listing system, repackers and relabelers have sometimes found it difficult to obtain necessary information from manufacturers. This difficulty has

resulted in data errors and omissions and an incomplete or inaccurate National Drug Code Directory.

4. By separating the NDC number process from drug listing and creating an electronic drug registration and listing system, the proposal should make it easier for manufacturers, repackers, and relabelers (and drug product salvagers who obtain NDC numbers for private label distributors) to obtain their NDC numbers quickly and, as a result, prepare product labels and marketing plans earlier.

5. Under the proposal, the information submitted about the drug to obtain an NDC number would be retained in the electronic drug registration and listing system. Thus, when the manufacturer, repacker, or relabeler later lists the drug, they would need to provide only the additional information required for listing.

6. By assigning a unique NDC number to each drug, the proposal would ensure that the drug has an accurate identifier, allowing us to support the implementation of the electronic prescribing provisions of the Medicare Modernization Act. We would link the accurate NDC number to the product labeling that would be made available through the DailyMed initiative.

i. *Information to be submitted to receive an NDC number*. We describe the information that proposed § 207.33(c) and (d) would require and our reasons for proposing to require the information, as follows:

- Name, address, telephone and fax numbers, e-mail address, and labeler code. Proposed § 207.33(c) and (d) would require manufacturers, repackers, and relabelers to provide this information to enable us to identify and contact (if necessary) the appropriate manufacturer, repacker, or relabeler and identify their labeler code. In situations where a manufacturer, repacker, or relabeler manufactures, repacks, or relabels a drug for a private label distributor, the proposal would also require the manufacturer, repacker, or relabeler to provide comparable information for the private label distributor. This information would enable us to associate the manufacturer's, repacker's, or relabeler's drugs with a particular private label distributor and to contact that private label distributor if necessary.
- The drug's or active pharmaceutical ingredient's established name and proprietary name (if any). The established name (sometimes referred to as generic name) is ordinarily either the drug's compendial name or, if there is no compendial name, the drug's common or usual name. The proprietary name (sometimes referred to as trade name) is generally the drug's marketed or advertised name as designated by the manufacturer, repacker, relabeler, or private label distributor. Most consumers recognize a drug by its proprietary name rather than its established name. Proposed § 207.33(c) and (d) would require submission of these names because knowing a drug's established name would let us determine, for example, which companies market identical drugs and which drugs can be substituted in the event of drug shortages or recalls. Knowing a drug's proprietary name would enable us to identify a drug to the public during a recall or consumer alert. This information is currently required under § 207.25(b)(1) and is submitted on Form FDA 2657.
- The Drug Master File (DMF) number or Veterinary Master File (VMF) number, if any, assigned to the active pharmaceutical ingredient. Under proposed § 207.33(c)(1)(iv) (and, if applicable, proposed § 207.33(c)(3)), if a DMF number or VMF number is assigned to the active pharmaceutical ingredient, the manufacturer would identify for us the DMF number or the VMF number. The DMF or VMF may contain additional information about the active pharmaceutical ingredient that our electronic drug registration and listing system could associate with the active pharmaceutical ingredient at other points in the registration and listing process. This could reduce the burden on the manufacturer of submitting to us the information already contained in the DMF or VMF. This information is not currently provided to us under current part 207 or Form FDA 2657 or Form FDA 2658.
- Name and quantity of each active pharmaceutical ingredient in a drug. Proposed § 207.33(c)(2) and, if applicable, proposed § 207.33(c)(3), would require manufacturers to submit this information to us (unless the approved U.S. application number is provided). Knowing the name and quantity of a drug's active pharmaceutical ingredients would help us assign unique product codes and help ensure that the assigned NDC numbers are unique to different products. For example, assume that a manufacturer makes a drug in two different strengths, 100 milligrams (mg) and 500 mg. If we only required the manufacturer to identify the active pharmaceutical ingredient, we might assume, incorrectly, that the manufacturer made two versions of the same drug in the same strength and then assign the same product code to both drugs. Instead, by proposing to require information about the quantity of the drug's active pharmaceutical ingredient, we would be able to assign one product code to the 100 mg product and a different product code to the 500 mg product. As an alternative to providing the name and quantity of the drug's active pharmaceutical ingredient, proposed § 207.33(c)(2) would allow a manufacturer to give us the drug's approved U.S. application number; the approved U.S. application number would allow us to link the drug to a particular application and determine the name and quantity of the active pharmaceutical ingredients in that drug.

The proposed requirement is similar to the requirement regarding quantitative listing of active ingredients in current § 207.25(b). Current § 207.25(b)(6) requires a quantitative listing of a drug's active ingredient(s) for drugs that a registrant regards as not being subject to sections 505 or 512 of the act or section 351 of the PHS Act. Current 207.25(b)(2) requires, for each drug listed that the registrant regards as subject to section 505 or 512 of the act, the application number. The act, for purposes of certain drug listing requirements, appears to treat drugs differently depending on whether those drugs are subject to sections 505 or 512 of the act or not. Section 510(j)(1)(A) of the act mandates that the drug list be prepared in the form and manner prescribed by us. That drug list, for drugs subject to sections 505 or 512 of the act, must be accompanied by ''the authority for the marketing of such drug''. In contrast, section 510(j)(1)(C) of the act states that the drug list, for drugs that are not subject to either section 505 or 512 of the act, must be accompanied by a ''quantitative listing'' of the drug's active ingredient or ingredients and that we may require a quantitative listing of all ingredients with respect to a particular product if we find such submission is necessary to carry out the act's purposes.

We believe that these provisions, and others, give us sufficient authority to require the submission of active ingredient information for all drugs as part of the NDC number assignment process. We already have such information for drugs approved under sections 505 and 512 of the act because information concerning active ingredients is an essential part of the drug's marketing application. Thus, when a manufacturer gives us the approved U.S. application number (as proposed § 207.33(c)(2)(i) would require and as current § 207.25(b)(2) (pertaining to required drug listing information) requires), the manufacturer is, in essence, giving us a link to information

about the drug's active ingredients. As noted previously, section 510(j)(1)(A) of the act, for drugs subject to sections 505 or 512 of the act, requires the ''reference to the authority for the marketing of such drug.'' This reference would be the approved U.S. application number. The act, for drugs not subject to section 505 or 512, explicitly requires a quantitative listing of active ingredients. Proposed § 207.33(c)(2)(i) would, therefore, enable us to input the active ingredient information into an electronic database. This would enable us to link to certain information in the application, and would be more efficient than having to review individual marketing applications, identify each drug's active ingredients, and then enter that data into the database ourselves.

• Name of the inactive ingredient(s). Proposed § 207.33(c)(2), and, if applicable, (c)(3) would require manufacturers to give us the drug's approved U.S. application number or, in the alternative, the name of each inactive ingredient for each human and animal drug that the manufacturer regards as subject to section 505 or section 512 of the act or section 351 of the PHS Act, and for each human OTC drug that the manufacturer regards as not subject to section 505 of the act, and whether the name of an inactive ingredient falls under § 20.61 or is otherwise prohibited from disclosure and, if so, why. Proposed § 207.33(c)(3) describes the requirements of the manufacturer who is manufacturing a drug for a private label distributor. Such manufacturers would be required to give us the name of each inactive ingredient for certain drugs, as described previously, or the drug's U.S. approved application number for the drug it manufactures for a private label distributor. Proposed § 207.33(c)(2) and (c)(3) are authorized under section 510 of the act as well as other provisions. We are considering whether to require the name of each inactive ingredient to be submitted for other categories of drugs as well.

• Dosage form. Proposed § 207.33(c)(2) and (c)(3) would require manufacturers to identify a drug's dosage form. This information will also help us distinguish between drug products that contain the same active ingredient and, consequently, assign unique product codes to such drugs. For example, assume that a manufacturer makes drug X, in a 100 mg strength, in a tablet form and also in a gelatin capsule. If we did not know there were two dosage forms of drug X, we might mistakenly assign the same product code to the tablet and gelatin capsule. Thus, information about dosage forms will help us create an NDC system that ties unique NDC numbers to unique products. The drug's dosage form is currently submitted on Form FDA 2657.

• Package size and type. Proposed § 207.33(c)(1), (c)(2), (c)(3) (if applicable), (d)(1), and (d)(2) would require manufacturers and repackers respectively to provide information about package size and type. This information would obviously be relevant in helping us assign package codes to a particular drug. For example, a drug packaged in a glass container would have a different NDC number from the same drug packaged in a plastic container. The proposal would require that information about the drug's package size and type be provided for each package, including the immediate unit-of-use container. For example, a drug packaged in a box containing a card of 12 unit-of-use blisters would have a different NDC number than each individual blister (unit-of-use). In the latter example, the different NDC numbers would have a practical impact with respect to our bar code requirements. A database system computer reading the bar code for the individual unit-of-use blister would see that the health care professional is administering a single dose of a particular drug to a patient; if the NDC number for the box were the same as that used for each unit-of-use blister, then the computer might mistakenly believe that the health care professional was administering 12 doses to the patient. In these scenarios, distinct NDC numbers for each package level would enhance the bar code's accuracy and value. The drug's package size and type is currently submitted on Form FDA 2657.

• Marketing status. Proposed § 207.33(c)(2) and, if applicable, (c)(3), would require manufacturers to tell us whether the drug is available only by prescription or is available OTC. Having such information in our electronic database would enable us to determine quickly which drugs are available by prescription and which are OTC. In addition, some entities that rely on NDC numbers, such as CMS and health care insurance companies, might treat prescription drugs differently from OTC drugs. For example, an insurer might reimburse consumers for prescription drug expenses, but not for OTC drug expenses. The drug's marketing status—whether prescription or OTC—is currently submitted on Form FDA 2657.

• Drug or drug product type. Under proposed § 207.33(c)(2) and, if applicable, (c)(3), manufacturers would identify whether a drug is a human drug or animal drug. This information would enable us to refine our databases to distinguish quickly between human and animal drugs. Having such information readily available could help us determine the regulatory obligations for a particular drug. For example, the bar code requirement applies to human drugs only. Thus, if we could differentiate quickly between human and animal drugs based on NDC numbers alone and we received a report that a particular drug failed to have a bar code on its label, we would be able to determine, based on the NDC number alone, whether that drug was subject to the bar code requirement. This information is currently submitted under ''product type'' on Form FDA 2657.

• Imprinting information. For each drug product subject to the listing requirements and covered under § 206.1, including products that are exempted under § 206.7(b), manufacturers must provide the size, shape, color, and code imprint (if any) (proposed § 207.33(c)(2)(vii) and, if applicable, proposed § 207.33(c)(3)). This provision is similar to current § 207.25(c), except the current provision also requires that the name of the drug product, its active ingredient(s), dosage strength, NDC number, and the name of its manufacturer or distributor be submitted. Under the proposal, the name of the drug product, its active ingredient(s) (proposed § 207.33(c)(2) uses the term ''active pharmaceutical ingredient''), and dosage strength (proposed § 207.33(c)(2) uses the term ''dosage form'') would be submitted to us under proposed § 207.33(c) along with the imprinting information. The NDC number would be submitted under proposed § 207.49 for listing, the name of the private label distributor would be submitted under proposed §§ 207.33 and 207.49 for listing, and the name of the manufacturer would be submitted under proposed § 207.25 for registration. All of this information would be accessible via our electronic drug registration and listing system. The proposal would also delete the requirement in current § 207.25(c) that ''any other characteristic that identifies the drug product as unique'' must be submitted. We need to know the drug's size, shape, color, and code imprint, as well as the other information required under proposed § 207.33(c), to assign an NDC number to the manufacturer's drug. Imprinting information would enable us to investigate reports of medication errors and counterfeiting and to assist poison control centers in identifying drugs in overdose and accidental poisoning situations.

• NDC number assigned to the drug immediately before the repacker or relabeler received that drug. Proposed § 207.33(d) would require repackers and relabelers to give us the NDC number of the drug that they receive. This information would enable us to link that drug to a particular source and, as we said earlier in this part, eliminate the need for repackers and relabelers to obtain certain drug information from those sources to obtain an NDC number. For example, assume that relabeler Alpha received drug X from manufacturer Beta. If Alpha gives us the NDC number for drug X, we will then be able to link Alpha's relabeled drug to Beta. We would also eliminate any need for Alpha to ask Beta for information about drug X for purposes of getting an NDC number and eliminate the possibility that Alpha might report incorrect or contradictory information about drug X compared to the information given to us by Beta.

• Type of operation. Proposed § 207.33(d) would require repackers and relabelers to report the type of operation (that is, repacking or relabeling) performed for a drug. This information is comparable to the information we currently receive about an establishment's ''type of business'' on Form FDA 2657, except that proposed § 207.33(d) is limited to repackers and relabelers.

• Information regarding private label distributors. Proposed § 207.33(c)(3) and 207.33(d)(2) would require manufacturers, repackers, and relabelers who manufacture, repack, or relabel drugs for a private label distributor to tell us the private label distributor's name, address, telephone number, fax number, e-mail address, labeler code, and any proprietary name assigned by the private label distributor to the drug. This information will help us link the manufacturer's, repacker's, or relabeler's drug to a particular private label distributor and, as we stated earlier in this part, eliminate potential data duplication, omissions, and inaccuracies that would otherwise result if private label distributors were able to seek NDC numbers from us. Manufacturers, repackers, and relabelers should be able to obtain the necessary information from private label distributors. Listing information for private label distributors is currently submitted on Form FDA 2658.

ii. *How the information would be submitted*. Proposed § 207.33(e) would require manufacturers, repackers, and relabelers to submit information to us electronically, in accordance with proposed § 207.61 unless we grant a waiver under proposed § 207.65. We discuss proposed §§ 207.61 and 207.65 later in this document.

iii. *Types of changes that would require a new NDC number*. Proposed § 207.33(f) would describe the types of changes in information that would require a new NDC number. In brief, proposed § 207.33(f)(1) would require a new NDC number for any change of information that would be required under proposed § 207.33(c) and (d), except for the following contact information: Name; address; telephone and fax numbers; and e-mail address for the manufacturer, repacker, relabeler, or private label distributor. In addition, § 207.33(f)(2) requires manufacturers to obtain a new NDC number when there is a change in an inactive ingredient for each human prescription drug that the manufacturer regards as not subject to section 505 of the act and for each animal drug that the manufacturer regards as not subject to section 512 of the act. Although we are not proposing to require, at this time, that manufacturers submit the name of each inactive ingredient to us when they obtain an NDC number for these drugs, we are proposing to require that manufacturers notify us only of the fact that there has been a change in an inactive ingredient for these drugs. This would ensure that a unique NDC number is assigned to these drugs when the drug's inactive ingredient(s) has changed. It is important that marketed drugs have unique NDC numbers that are accurate because, as discussed in section IV.C.2 of this document, NDC numbers are an important, standardized, identification system for drug products and are used for many purposes. In addition, identifying marketed drugs in our electronic database for which inactive ingredients have changed would help us investigate, as discussed in section IV.C.3 of this document, incidents of allergic reactions in patients as well as possible drug contamination, counterfeiting, or adulteration. Although we are not proposing it at this time, we are considering requiring in the future that manufacturers submit the name of each inactive ingredient to obtain an NDC number for categories of drugs beyond those referenced in proposed § 207.33(c)(2)(ii) and 207.33(c)(3). We are specifically requesting comments on the feasibility of submitting these inactive ingredients. The proposed rule would be similar to current § 207.35(b)(4)(i), which requires a registrant to assign a new NDC number if any change occurs in a product's characteristics that clearly distinguishes one drug product version from another. However, proposed § 207.33(f) would differ from the current requirement in several important respects. First, proposed § 207.33(f) would require changes to be reported to us in accordance with proposed § 207.33(e) (which would require electronic submission of information) and § 207.33(g) (which describes timing requirements discussed later in this part). The current regulation has no comparable electronic reporting requirement. Second, proposed § 207.33(f) would not require us to publish a notice in the **Federal Register** announcing our determination as to whether a change requires assignment of a new product code. Because the proposed rule would create an electronic drug registration and listing system and have us assign NDC numbers quickly that would be accessible in the registration and listing database, we find it unnecessary and impractical to publish **Federal Register** notices regarding product code changes. Third, although current § 207.35(b)(4)(i) allows registrants to assign their own package codes for changes involving trade packages, proposed § 207.33(f) would eliminate this provision because we would assign the new NDC number ourselves to ensure that the NDC number is unique and that our NDC number database is accurate and up-to-date. Fourth, proposed § 207.33(f), in conjunction with proposed § 207.33(c) and (d), gives a more complete description of which changes would require a new NDC number, compared with current § 207.25(b)(4)(i) (which currently lists examples of changes). Because manufacturers, repackers, and relabelers currently have different practices with respect to assigning NDC numbers, this change would eliminate inconsistency and would introduce an element of certainty with respect to the assignment of new NDC numbers.

iv. *When the information would be provided*. Proposed § 207.33(g) would explain when a manufacturer, repacker, or relabeler must provide the information to obtain an NDC number. In brief, the proposal would require a manufacturer, repacker, or relabeler to provide the information described in proposed § 207.33(c), (d), and (f) either before or at the time drug listing information is required under proposed §§ 207.45 or 207.57. (We discuss proposed §§ 207.45 and 207.57 later in this document.) The proposed requirement differs slightly from current §§ 207.21(b), 207.22(b), and 207.25(b)(8), which allows manufacturers, repackers, and relabelers to give us NDC numbers as part of their

drug listing information, because the proposal would allow companies to give us information earlier than the drug listing process would be completed. This ability to seek NDC numbers throughout the year should help us keep the National Drug Code Directory current and, as a result, provide more accurate and useful NDC number information to entities that rely on or use NDC numbers. In addition, the proposed scheme would give manufacturers, repackers, and relabelers more flexibility to obtain an NDC number earlier for their own planning purposes. Furthermore, we will know which NDC number corresponds to a drug immediately because we will assign it, rather than the current system where manufacturers, repackers, and relabelers assign their own NDC numbers and only report those numbers to us as part of their drug listing information.

We considered assigning the NDC number as part of the drug listing process, but believe that allowing for earlier assignment would provide optimal flexibility for manufacturers, repackers, and relabelers. We note that the information submitted to have an NDC number assigned is a subset of the information submitted to list a drug. Therefore, if a manufacturer, repacker, or relabeler provides us the information early to get an NDC number, they will only need to provide the additional information needed when they later list the drug.

c. *Proposed § 207.37—What restrictions pertain to the use of NDC numbers?* Proposed § 207.37 would establish four restrictions on the use of NDC numbers insofar as FDA-regulated products or activities are concerned. The proposed restrictions reflect practical problems or difficulties that we have encountered when manufacturers, repackers, or relabelers assign their own NDC numbers.

Proposed § 207.37(a) would state that an NDC number must not be used to represent a different drug than the drug to which it was assigned. This restriction would prevent manufacturers, for example, from using the same NDC number for different drugs and thus prevent potential discrepancies among databases that rely on or use NDC numbers to distinguish between drugs. The restriction would prevent two different drugs from having the same NDC number and avoid medication errors that could result if the NDC number encoded in a bar code represented more than one drug. Use of an NDC number not assigned to a drug would also cause a drug to be misbranded under section 502(a) of the act because the drug's label would be misleading.

Proposed § 207.37(b) would state that a different NDC number must not be used if marketing is resumed for a drug that was discontinued earlier. If marketing is resumed for a drug, and no changes have been made to the drug that would require a new NDC number under § 207.33(f), the drug must have the same NDC number that was assigned to it earlier before marketing was discontinued. This would prevent two NDC numbers from being assigned to or used for the same drug. Consistent with this rationale, proposed § 207.37(b) would revoke current § 207.35(b)(4)(ii), which states that the product code of a discontinued product may be reassigned to another product 5 years after the expiration date of the discontinued product or, if there is no expiration date, 5 years after the last shipment of the discontinued product into commercial distribution.

Proposed § 207.37(c) would state that NDC numbers must not be used to denote FDA approval. This is similar to current § 207.39, which states, in part, that assignment of an NDC number does not in any way denote approval of a product. For drugs subject to sections 505 or 512 of the act, those drugs must be shown to be safe and effective for their intended uses to obtain FDA approval. Mere assignment of an NDC number by us is not equivalent to our determining whether a drug is safe and effective for its intended uses.

Proposed § 207.37(d) would state that NDC numbers must not be used on products that are not subject to the drug listing requirements of part 207, such as dietary supplements and medical devices. We are proposing this requirement because the fundamental purpose behind NDC numbers was to establish an identification system to help in the automated processing of drug data and claims. Use of NDC numbers on non-drug products could introduce misleading information in databases, lead to inappropriate claims processing, and undermine the accuracy and reliability of an NDC system. For example, some human dietary supplements bear an NDC number on their labels. FDA considers a human dietary supplement that bears an NDC number misbranded under 21 U.S.C. 343(a)(1), which provides that a food is misbranded if its labeling is false or misleading in any particular. A product labeled and marketed as a human dietary supplement is not a drug listed with FDA; thus, the presence of an NDC number on the label is a false representation about the nature of the product.

d. *Proposed §§ 610.60(a)(2) and 610.61(b)—Where would the NDC number be required for biological products?* Under proposed § 201.2(a), all drugs, including human biological drugs, subject to the drug listing requirements of part 207 must have labels that bear the appropriate NDC number in human-readable form, in accordance with the provisions in proposed § 201.2. Current § 610.60(a) (21 CFR 610.60(a)) specifies which items must appear on the label affixed to each container of a biological product capable of bearing a full label and current § 610.61 specifies which items must appear on the label affixed to each package containing a biological product. We are proposing to amend §§ 610.60(a)(2) and 610.61(b) (21 CFR 610.60(b)) to require that the NDC number appear, in accordance with proposed part 207, on these biological product labels. Many individuals and companies use NDC numbers and they may not have the technology or ability to read an automatic identification technology such as a bar code that is required under current § 207.25 or § 610.67. In addition, a human-readable NDC number may serve as a ''backup'' in case the bar code is damaged, cannot be read, or is otherwise illegible.

4. How Do We Intend to Implement the NDC Number Changes?

a. *When would we expect compliance with the NDC number requirements?* We are proposing that our electronic drug registration and listing system be used to enter and update all NDC number information, as well as all registration and listing information, no later than 9 months after the effective date of a final rule. If a drug already has an NDC number at the time of the effective date of a final rule, the drug would retain that NDC number provided that the manufacturer, repacker, or relabeler, within 9 months after the effective date of a final rule, reviews and updates, in accordance with proposed §§ 201.2, 207.33, 207.37, 610.60, and 610.61, the information in our database for the NDC number. To retain the NDC number, new information about the drug's characteristics may need to be provided to us. We will, if necessary, assign a new product code and/or package code, creating a new NDC number for the drug. If a manufacturer, repacker, or relabeler does not review or update its information within 9 months after a final rule's effective date, we may assign a new NDC number to the drug or take other appropriate steps.

As discussed in section IV.E.6 of this document, we intend to make available guidance on how to provide to us in

electronic format information required to receive an NDC number, as well as registration and listing information. We can assist manufacturers, repackers, and relabelers in determining whether their NDC numbers are accurate and address any problems with existing NDC numbers (such as duplicate or potentially duplicate NDC numbers). We are available to work with manufacturers, repackers, and relabelers to resolve issues that might arise after a final rule becomes effective. Information on how to contact us for assistance will be specified in the guidance.

b. *When would we expect NDC numbers to appear on drug labels?* Although current regulations do not require NDC numbers on drug labels (other than NDC numbers encoded in a bar code, where such bar codes are required under current § 201.25), almost all human and animal prescription drugs already have NDC numbers on their labels because government agencies and third-party payers rely on NDC numbers for reimbursement and other purposes. Thus, when we issue a final rule requiring NDC numbers to appear on drug labels, such a requirement should have little impact on human and animal prescription drug labels.

We intend to phase-in the requirements for NDC number placement and appearance on human and animal prescription drug labels over a 3-year period, starting from the effective date of a final rule. This implementation scheme should lessen the impact on prescription drug labels (which might stem from changing the NDC number on the label or adding an NDC number, for example, for unit-of-use blisters).

As for human and animal OTC drugs, we estimate that approximately 30 percent of these drug labels currently have NDC numbers. (We discuss this issue further in section VI of this document.) We intend to phase-in the requirements for NDC number placement and appearance on OTC drug labels over a 7-year period, starting from the effective date of a final rule.

We are considering shortening the compliance dates by which the appropriate NDC number must appear on drug labels to 2 years after the effective date of a final rule for prescription drugs and 5 years after the effective date of a final rule for OTC drugs. We discuss this issue further in section VI of this document. We invite comment on whether a shorter implementation period would be preferable.

These implementation periods would permit manufacturers, repackers, and relabelers to incorporate the appropriate NDC number at minimal additional cost when redesigning their labels in the course of the normal relabeling cycle. We should note, however, that manufacturers, repackers, relabelers, and private label distributors who are subject to the bar code requirements at current § 201.25 might find it easier to put human-readable NDC numbers on their labels when they revise those labels to accommodate the bar code. We remind readers that the bar code requirement became effective on April 26, 2004, and the compliance dates varied depending on when we approved a drug relative to the April 26, 2004, date. For example, for drugs approved on or after April 26, 2004, we expected compliance within 60 days of the drug's approval date. For drugs approved before April 26, 2004, we expect compliance within 2 years. So, for example, a manufacturer whose prescription drug is subject to the bar code requirement might find it easier to redesign its label once to add a human-readable NDC number and a bar code, rather than redesign its label twice.

We invite comments on the implementation scheme described here.

D. Listing

1. Who Would Be Required To List Drugs?

Proposed § 207.41(a) would require manufacturers, repackers, relabelers, and drug product salvagers who are subject to the registration requirements under proposed § 207.17 (and not exempt under proposed § 207.13) to list drugs being manufactured, repacked, relabeled, or salvaged by them for commercial distribution. Proposed § 207.41(a) is consistent with current § 207.20(a), which states that owners or operators of all drug establishments, not exempt under section 510(g) of the act or current § 207.10, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug submit a list of every drug in commercial distribution. Section 510(j)(1) of the act requires, among other things, that every person who registers with the Secretary must list drugs that are being manufactured, prepared, propagated, compounded, or processed for commercial distribution.

Under current § 207.20(a), such drugs must be listed whether or not they enter interstate commerce. This is consistent with Congress's intention for section 510 of the act to apply to drugs both in interstate and intrastate commerce as stated in section 301 of Public Law 82–781, in part, as follows: ''[T]he products of all [establishments in which drugs are manufactured, prepared, propagated, compounded, or processed] are likely to enter the channels of interstate commerce and directly affect such commerce; and * * * the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.''

Proposed § 207.41(a) also provides that when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments, listing information may be submitted by the parent, subsidiary, and/or affiliate company for drugs at all establishments. This provision would also apply when operations are conducted at both domestic and foreign establishments and there exists joint ownership and control among all the establishments. This provision is consistent with current § 207.20(a).

Under proposed § 207.41(a), drug product salvagers would be required to list. As discussed in sections IV.A.5 and IV.B.1 of this document, and consistent with current § 207.20(a), drug product salvagers would continue to be required to register because their activities include applying manufacturing controls to drug products and segregating drug products. This activity would be covered under the scope of manufacturing, preparing, propagating, compounding, or processing, and would trigger the requirement to register under the act. Because drug product salvagers are conducting one of these activities with respect to a given drug for the purpose of commercial distribution, this activity would also trigger the requirement to list under the act (section 510(j)(1) of the act). (Drug product salvagers sometimes repack/relabel drug products and would also have to register because of those activities.) Under current § 207.20(a), drug product salvagers are not required to list. Because drug product salvagers place the salvaged drug in commercial distribution, we are proposing to require that drug product salvagers submit listing information to us. We specifically invite comments on the scope of activities of drug product salvagers, that is, whether drug product salvagers salvage drug products for commercial distribution and whether these activities should trigger listing under the act.

Under proposed § 207.41(b), manufacturers, repackers, relabelers, and drug product salvagers who engage

in more than one activity for drugs would list each drug in accordance with the requirements for the activity engaged in for that drug. An example of a company that engages in more than one activity for drugs would be a company that manufactures Drug X and relabels Drug Y. The company would provide the listing information described in proposed § 207.49 for Drug X and the listing information described in proposed § 207.53 for Drug Y. We are proposing this requirement to clarify which listing information would be provided by manufacturers, repackers, relabelers, and drug product salvagers who engage in more than one activity for drugs. As discussed below, manufacturers, repackers and relabelers, and drug product salvagers would provide similar listing information to us (although some information would be provided by reference).

Under proposed § 207.41(c), manufacturers, repackers, relabelers, and drug product salvagers would, in addition to listing their own drugs, provide all listing information to us for drugs they manufacture, repack, relabel, or salvage for private label distributors. In general, private label distributors would not list drugs with us. However, private label distributors would be required to list a drug with us if they manufacture, repack, relabel, or salvage the drug for commercial distribution. Proposed § 207.41(c) would revise current § 207.20(b), which states that owners or operators of establishments, not otherwise required to register, that distribute under their own label or trade name a drug manufactured or processed (as defined in current § 207.3(a)(8)) by a registered establishment may elect to submit listing information directly to us and obtain a labeler code. Under current part 207, if a private label distributor does not elect to submit drug listing information to us, the registered establishment must submit the drug listing information. Currently, private label distributors that elect to submit listing information must include the registration number of the establishment that manufactured or processed (as defined in current § 207.3(a)(8)) each drug listed and must assume full responsibility for compliance with all the requirements of part 207. Private label distributors must currently certify to the registered establishment that the submission has been made by providing a signed copy of Form FDA 2656 to the registered establishment. Private label distributors must submit to us the original Form FDA 2656 showing this certification. A list showing the NDC number assigned to each drug must accompany the certification.

We are proposing to alter the arrangement permitted under current § 207.20(b). Although we recognize that this proposed shift in responsibility may alter current business practices, we believe that proposed § 207.41(c) will help to ensure that listing information is more accurate and complete. The current scheme has caused confusion and resulted in inaccurate and incomplete listing information. Some private label distributors that have elected to list their drugs have not had access to all the information needed to list the drugs accurately. Some private label distributors have claimed that manufacturers, repackers, and relabelers have been reluctant to provide certain information to them. In addition, in some instances, the parties have been uncertain about who is responsible for listing.

As discussed in section IV.B.1 of this document and previously, manufacturers, repackers, relabelers, and drug product salvagers would be required to register and list the drugs they manufacture, repack, relabel, or salvage. They would be required to do so even if they conduct such activities on behalf of private label distributors. This proposed requirement would be consistent with section 510(j)(1) of the act which requires every person who registers to submit listing information for drugs ''which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution'' (emphasis added). In addition, private label distributors would not be required (nor permitted) to register because their activities are not covered under the scope of manufacturing, preparing, propagating, compounding, or processing. Nor do private label distributors conduct one of these activities with respect to a given drug for the purpose of commercial distribution and, thus, would not be required (nor permitted) to list. Private label distributors only commercially distribute drugs under their own label or trade name. Manufacturers, repackers, relabelers, and drug product salvagers often manufacture, repack, relabel, or salvage drugs that are distributed by a private label distributor, and they have all the information about the drug that is necessary to list the drug distributed by the private label distributor. Under the proposal, to list a drug that is manufactured, repacked, relabeled, or salvaged for a private label distributor, manufacturers, repackers, relabelers, and drug product salvagers would have to obtain any existing NDC number from the private label distributor or would have to obtain the NDC number from FDA for a drug distributed by a private label distributor. Manufacturers, repackers, relabelers, and drug product salvagers would have to place the NDC number assigned to the private label distributor's drug on the label. We specifically invite comments on this proposed change in the listing responsibilities of manufacturers, repackers, relabelers, drug product salvagers, and private label distributors and its potential effect on business practices.

2. When Would Initial Listing Information Be Provided?

Under proposed § 207.45, manufacturers, repackers, relabelers, and drug product salvagers would list, at the time of initial registration of an establishment, any drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at that establishment. This provision is consistent with section 510(j)(1) of the act, which requires, among other things, that every person who registers with the Secretary under sections 510(b), (c), (d), or (i) of the act must list drugs that are being manufactured, prepared, propagated, compounded, or processed for commercial distribution. Proposed § 207.45 pertains to the submission of listing information for drugs at the time of the initial registration of an establishment. Reviewing and updating information for drugs already listed and providing listing information for drugs not previously listed are covered under proposed § 207.57. Proposed § 207.57 is discussed in section IV.D.8 of this document.

3. What Listing Information Would Be Required?

To list a drug, manufacturers would be required to provide the information in proposed § 207.49, repackers and relabelers would be required to provide the information in proposed § 207.53, and drug product salvagers who are not repackers or relabelers would be required to provide the information in proposed § 207.54. We are proposing different listing requirements for manufacturers, repackers and relabelers, and drug product salvagers because much of the information about a drug is submitted to us by the manufacturer to obtain an NDC number and to list the drug. When the repacker, relabeler, and drug product salvager provide, during listing, the required NDC number for the drug, we can incorporate by reference the information already submitted about the drug by the manufacturer. The information required to obtain an NDC

number is explained in section IV.C of this document, and the requirements for providing the NDC number during listing are explained in section IV.D.4.a of this document.

The following paragraphs summarize the information that would be required for listing from manufacturers, repackers, relabelers, and drug product salvagers. These summaries are followed by descriptions of each of the listing requirements (see section IV.D.4 of this document).

a. *Summary of proposed listing information for manufacturers.* Manufacturers would be required to submit to us the following listing information (if applicable to the drug being listed) under proposed § 207.49:

- NDC number;
- Route of administration;
- Approved U.S. application number or approved U.S. BLA number, if any;
- Registration number of each establishment where the manufacturing is performed for the drug;
- Schedule of the drug under section 202 of the Controlled Substances Act (21 U.S.C. 812);
- With respect to foreign establishments only, the name and contact information of each importer of the drug and of each person who imports or offers for import the drug;
- Labeling;
- Advertisements; and
- Information about the private label distributor, if any.

b. *Summary of proposed listing information for repackers and relabelers.* Repackers and relabelers would be required to submit to us the following listing information (if applicable to the drug being listed) under proposed § 207.53:

- NDC number;
- Registration number of each establishment where the repacking or relabeling is performed for the drug;
- With respect to foreign establishments only, the name and contact information of each importer of the drug and of each person who imports or offers for import the drug;
- Labeling;
- Advertisements; and
- Information about the private label distributor, if any.

c. *Summary of proposed listing information for drug product salvagers who are not repackers or relabelers.* Drug product salvagers who do not otherwise repack or relabel the drugs they salvage would be required to submit to us the following listing information (if applicable to the drug being listed) under proposed § 207.54:

- NDC number assigned to the drug immediately before the drug is received by the drug product salvager;
- Lot number and expiration date of the salvaged drug;
- Registration number of each establishment where the drug product salvager salvages the drug;
- With respect to foreign establishments only, the name and contact information of each importer and of each person who imports or offers for import the drug; and
- Information about the private label distributor, if any.

4. What Listing Information Would Be Required for Manufacturers?

Under proposed § 207.49, manufacturers would be required to provide to us the following listing information for each drug they list, including a drug manufactured for a private label distributor.

a. *NDC number.* For a drug to be considered listed, manufacturers and, as discussed below, repackers, relabelers, and drug product salvagers, must submit the NDC number for the drug as part of the drug's listing information.[7] The NDC number, including the information that would be submitted to us to obtain an NDC number, is explained under proposed § 207.33. Knowing the NDC number of the drug would enable us to incorporate by reference information about the drug submitted by the manufacturer, repacker, or relabeler to obtain an NDC number under proposed § 207.33(c) and (d), as well as information submitted by the manufacturer, repacker, or relabeler to list the drug. This would reduce the amount of information that must be provided to us by manufacturers, repackers, relabelers, and drug product salvagers for listing. Current § 207.25(b)(8) requires the submission of the NDC number for each drug listed, and this information is currently submitted on Form FDA 2657.

b. *Route of administration.* The route of administration would enable us to identify a specific formulation of a drug. For example, drugs having the same active ingredient may have different routes of administration. The route of administration is currently submitted on Form FDA 2657.

c. *Approved U.S. application number.* The approved U.S. application number or the approved U.S. BLA number,[8] if any, would enable us to link to the information about the drug that was already submitted to us for marketing approval. Section 510(j)(1)(A) of the act requires the submission of a reference to the authority for marketing a drug subject to section 505 or 512 of the act. In addition, current § 207.25(b)(2) requires the submission of the application number for each drug listed that the registrant regards as subject to section 505 or 512 of the act. The drug's application number is currently submitted on Form FDA 2657. As discussed in section IV.D.4.g of this document, if the approved U.S. application number is provided to us when a human prescription or OTC drug is listed, the manufacturer would not be required to re-submit the labeling for the approved drug. The application number would incorporate by reference the labeling for approved drugs. This would eliminate unnecessary duplication of effort and cost to industry. The application number may have already been provided under § 207.33(c)(2)(i) and (c)(2)(ii) instead of providing the names of the active pharmaceutical ingredient and the inactive ingredient. If so, it will already be in our database and would not need to be resubmitted.

d. *Registration number of each establishment.* The registration number of each establishment where the manufacturing is performed for the drug would enable us to identify the establishment where the drug is manufactured. This would help our investigators better prepare for inspections and collect postmarketing surveillance samples. Although this information would already be submitted for registration under proposed § 207.25(e), submitting it at listing would enable us to link this information to the drug being listed. Current § 207.25(b)(7) requires, for each drug listed, the submission of the registration number of each drug establishment at which the drug is manufactured or processed (within the meaning of current § 207.3(a)(8)). Current § 207.25(b)(3) requires the submission of the license number of the manufacturer of drugs subject to section 351 of the PHS Act. The ''establishment registration number'' is defined in proposed § 207.1 to mean the number assigned by FDA to the establishment during the establishment registration process. Currently, we plan to assign the FEI number as the establishment registration number. In the future, however, we may use a different

[7] The drug product salvager (that does not repack or relabel) would submit the NDC number assigned to the drug immediately before the drug is received by the drug product salvager; the manufacturer, repacker, and relabeler (and the drug product salvager that repacks or relabels) would submit the NDC number assigned to their drug under proposed § 207.33(c) and (d).

[8] Human drugs are approved by FDA under an NDA, ANDA, or a BLA. Part 314 (21 CFR part 314) for human drugs and part 601 (21 CFR part 601) for biologics set forth the approval requirements.

number as the establishment registration number. The establishment registration number is currently submitted on Form FDA 2657.

e. *Schedule of the drug.* The schedule of the drug under section 202 of the Controlled Substances Act would enable us to provide yearly estimates of medical, scientific, and reserve stock needs for Schedule I and II substances (21 CFR part 1303, 21 U.S.C. 826). Under section 302(a) of the PHS Act (42 U.S.C. 242(a)), the Secretary is responsible for providing to the Drug Enforcement Administration estimates of the quantities of controlled substances for which production quotas must be established that will be required to meet the legitimate medical, scientific, and reserve stock needs of the United States for the following calendar year. The schedule of the drug is currently submitted on Form FDA 2657.

f. *Information about each importer of the drug and each person who imports or offers for import the drug to the United States.* Foreign establishments only must provide the name, address, telephone and fax numbers, and e-mail address of each importer of such drug in the United States that is known to the establishment, and of each person who imports or offers for import such drug to the United States. As discussed under section IV.B.3 of this document, the term ''known to'' would mean any importer that is known to the foreign establishment as well as any importer that the foreign establishment has reason to know of. We therefore expect that the person responsible for completing the required registration forms on behalf of the foreign establishment would undertake appropriate due diligence in completing those forms, including to find out and report importers that others in his or her establishment know of or have reason to know of. Foreign establishments would provide this information for listing unless previously provided under proposed § 207.25(h) for registration. The Bioterrorism Act requires foreign establishments to submit, among other things, the name of each importer of each drug that is known to the establishment, and the name of each person who imports or offers for import each drug to the United States for purposes of importation. The Bioterrorism Act requires submission of such information as part of registration information and also specifically requires listing information to be submitted for each drug being manufactured for commercial distribution (see section IV.A.4.d of this document). We are proposing, under this part, to make the submission of information concerning importers of drugs and persons who import or offer for import drugs to the United States both a registration and a listing requirement. However, if the information has been previously provided by the foreign establishment at registration, the foreign establishment would not be required to re-enter that information into the database at listing. Our listing database will be populated automatically with the required information. This would reduce the amount of information that must be provided to us by the foreign establishment at listing. The information about each importer of the establishment's drug that is known to the establishment and each person who imports or offers for import the drug to the United States is not currently required to be submitted under current part 207 or on Form FDA 2656 or Form FDA 2657.

g. *Labeling.* Under proposed § 207.49(g), the following labeling would be provided to us for each drug listed:

- Human prescription drugs. If the manufacturer has not provided the drug's approved U.S. application number as part of the listing information under proposed § 207.49(c), the manufacturer would submit a copy of all current labeling, including the content of labeling, for each human prescription drug (proposed § 207.49(g)(1)).

Under proposed § 207.49(g)(1) and, as discussed below under proposed §§ 207.49(g)(2) and 207.49(g)(3), only one representative container or carton label would be submitted where differences exist only in the quantity of contents statement or the bar code. This proposed provision is consistent with current § 207.25(b)(2), although the proposal would add differences in the bar code to the provision. This provision would reduce the number of labels that must be submitted to us by the manufacturer.

If the manufacturer provides the drug's approved U.S. application number as part of the drug's listing information, the labeling required under proposed § 207.49(g)(1) and, as discussed below under proposed § 207.49(g)(2), would be deemed to accompany the listing information. Incorporating the labeling, including the content of labeling, by reference to the application number would eliminate unnecessary duplication of effort and cost to industry. This proposed exception would not apply to animal drugs approved under section 512 of the act because currently these application holders are not required to provide the content of labeling electronically with the application for those drugs.

The ''content of labeling'' would be provided to FDA under proposed § 207.49(g)(1) and, as discussed below, under proposed § 207.49(g)(2) and (g)(3). The ''content of labeling'' is defined in proposed § 207.1 and discussed in sections IV.A.5 and IV.E.4 of this document and would mean, for human prescription drugs that the manufacturer regards as subject to section 505 of the act or section 351 of the PHS Act, the content of the prescription drug labeling, including all text, tables, and figures. For human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the PHS Act, the ''content of labeling'' would mean the labeling equivalent to the content of the prescription drug labeling, including all text, tables, and figures. For human OTC drugs, the ''content of labeling'' would mean the content of the drug facts labeling required by § 201.66, including all text, tables, and figures. For animal drugs, the ''content of labeling'' would mean the content of the labeling that accompanies the drug that is necessary to enable the safe and proper administration of the drug, including all text, tables, and figures.

The labeling submission requirements in proposed § 207.49(g) are almost identical in substance to the labeling submission requirements of current § 207.25(b)(2) through (b)(5), except that manufacturers would also be required, as discussed previously, to submit electronically the ''content of labeling.'' In addition, the labeling submission requirements in proposed § 207.49(g) conform to the statutory requirements of section 510(j) of the act. The proposed requirement to submit labeling, including the content of labeling, for human prescription drugs and, as discussed below, for human OTC drugs and animal drugs, whether or not the drugs are subject to the pre-approval provisions of the act or the PHS Act, is consistent with the statutory requirements of section 510(j)(1)(A), 510(j)(1)(B)(i), and 510(j)(1)(B)(ii) of the act. Section 510(j)(1)(A) of the act requires, among other things, the submission of a copy of all labeling for drugs subject to section 505 or 512 of the act. Section 510(j)(1)(B)(i) requires, among other things, the submission of a copy of all labeling for prescription drugs not subject to section 505 or 512 of the act, and section 510(j)(1)(B)(ii) requires, among other things, the submission of the label, package insert, and representative sampling of any other labeling for OTC drugs not subject to section 505 or 512 of the act. We also

have the authority to require that labeling be submitted in this format under other sections of the act (e.g., sections 201, 301, 501, 502, 503, 505, 506, 506A, 506B, 506C, 513–516, 518–520, 701, 704, 721, 801 of the act) and the PHS Act.

- Human OTC drugs that manufacturers regard as subject to section 505 of the act or section 351 of the PHS Act. If the manufacturer has not provided the drug's approved U.S. application number as part of the listing information under proposed § 207.49(c), the manufacturer would submit a copy of all current labeling, including the content of labeling, for each human OTC drug that the manufacturer regards as subject to section 505 of the act or section 351 of the PHS Act (proposed § 207.49(g)(2)(i)).

Drugs subject to section 505 of the act or section 351 of the PHS Act must be approved by FDA under an NDA, ANDA, or a BLA. Part 314 for human drugs and part 601 for biological products set forth the approval requirements.

- Human OTC drugs that manufacturers regard as not subject to section 505 of the act or section 351 of the PHS Act. The manufacturer would submit a copy of the current label, the content of labeling, the package insert (if any), and a representative sampling of any other labeling for each human OTC drug that the manufacturer regards as not subject to section 505 of the act or section 351 of the PHS Act (proposed § 207.49(g)(2)(ii)).

The term ''label'' means the container label as defined at section 201(k) of the act. ''Content of labeling'' is defined at proposed § 207.1 (as discussed in section IV.A.5 of this document) and for OTC drugs refers to the content of the drug facts labeling as specified at § 201.66. Most OTC drugs do not have a package insert. However, for those that do, it is currently required to be submitted for drug listing under section 510(j)(1)(A) and (j)(1)(B)(ii) of the act and current § 207.25(b)(4) and (b)(5). We are proposing to retain that requirement in proposed § 207.49(g)(2)(i) and (g)(2)(ii). For OTC drugs marketed pursuant to an approved application, any package insert would be included within the requirement to submit ''all current labeling.'' The term ''representative sampling of any other labeling,'' as used in proposed § 207.49(g)(2)(ii) and, as discussed below, in proposed § 207.49(g)(3)(ii), is defined in proposed § 207.1 and discussed in section IV.A.5 of this document. Examples of OTC drugs that a manufacturer may regard as not subject to section 505 of the act or section 351 of the PHS Act would include human OTC drugs marketed under an OTC monograph and deemed generally recognized as safe and effective (see part 330 (21 CFR part 330)).

- Animal drugs that manufacturers regard as subject to section 512 of the act. The manufacturer would submit a copy of all current labeling, including the content of labeling, for each animal drug that the manufacturer regards as subject to section 512 of the act (proposed § 207.49(g)(3)(i)).
- Animal drugs that manufacturers regard as not subject to section 512 of the act. For all other animal drugs, the manufacturer would submit a copy of the current label, the package insert, the content of labeling, and a representative sampling of any other labeling, for each animal drug that the manufacturer regards as not subject to section 512 of the act (proposed § 207.49(g)(3)(ii)).

h. *Advertisements*. Under proposed § 207.49(h), and in accordance with section 505(j)(1)(B)(i) of the act, the following advertisements would be provided by the manufacturer for each drug listed:

- A representative sampling of advertisements for human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the PHS Act. Proposed § 207.49(h)(1) is consistent with section 510(j)(1)(B)(i) of the act and current § 207.25(b)(4). The term ''representative sampling of advertisements'' is defined in proposed § 207.1 and discussed in section IV.A.5 of this document.
- If we request it, for good cause, a copy of all advertisements for human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the PHS Act, including those advertisements described in § 202.1(l)(1), would be required to be submitted to FDA within 30 calendar days after our request. Proposed § 207.49(h)(2) is consistent with section 510(j)(1)(B)(i) of the act and current § 207.31(a)(1). Section 510(j)(1)(B)(i) of the act requires, among other things, the submission of a representative sampling of advertisements and, upon request for good cause, a copy of all advertisements for prescription drugs not subject to section 505 of the act. Current § 207.31(a)(1) requires, upon request, the submission of a copy of all advertisements for prescription drugs that the manufacturer regards as not subject to section 505 of the act.

i. *Private label distributor*. If the drug is manufactured for a private label distributor, the manufacturer would submit the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor. The manufacturer may obtain this information from the private label distributor or other sources. This information would indicate whose drug (the manufacturer's or the private label distributor's) is being listed and would identify and enable us, if needed, to contact the private label distributor. The information for a private label distributor is currently submitted on Form FDA 2658.

5. What Listing Information Would Be Required for Repackers and Relabelers?

Under proposed § 207.53, repackers and relabelers would be required to provide to us all of the following listing information for each drug they list, including a drug repacked or relabeled for a private label distributor.

a. *NDC number*. For a drug to be considered listed, repackers and relabelers would submit the NDC number for the drug being repacked or relabeled as part of the drug's listing information. This requirement is explained in section IV.D.4.a of this document.

b. *Registration number of each establishment*. The registration number of each establishment where the repacking or relabeling is performed for the drug would enable us to identify the establishment where the drug is repacked or relabeled. This requirement is explained in section IV.D.4.d of this document.

c. *Information about each importer of the drug and each person who imports, or offers for import, the drug to the United States*. This requirement is explained in section IV.D.4.f of this document.

d. *Labeling*. Under proposed § 207.53(d), the following labeling must be provided for each drug listed:

- Human prescription drugs. If the repacker or relabeler makes any change in the labeling of the drug repacked or relabeled, the repacker or relabeler would submit a copy of all changed labeling for each human prescription drug that is repacked or relabeled (proposed § 207.53(d)(1)). We would already have, as required under proposed § 207.49(g), the labeling for the drug provided by the manufacturer during listing, and the repacker or relabeler would not need to resubmit it to us unless they make changes to the labeling. Proposed § 207.53(d)(1) is consistent with section 510(j)(1)(A) and (j)(1)(B)(i) of the act and current § 207.25(b)(2) and (b)(4), except that repackers and relabelers would not need to resubmit labeling when no changes have been made.

• Human OTC drugs that manufacturers regard as subject to section 505 of the act or section 351 of the PHS Act. If the repacker or relabeler makes any changes, in accordance with the act and FDA regulations, in the labeling of the drug repacked or relabeled, the repacker or relabeler would submit a copy of all changed labeling for each human OTC drug that the manufacturer of the drug regards as subject to section 505 of the act or section 351 of the PHS Act (proposed § 207.53(d)(2)(i)). As stated previously, we would not need a copy of the unchanged labeling because we would already have the labeling for the drug provided by the manufacturer during listing. Proposed § 207.53(d)(2)(i) is consistent with section 510(j)(1)(B)(i) of the act and current § 207.25(b)(2), except that some of the information required under current § 207.25(b)(2) would not need to be provided by the repacker or relabeler under proposed § 207.53(d)(2)(i) if the repacker or relabeler provides the manufacturer's NDC number. The NDC number would provide a link to that information.

• Human OTC drugs that manufacturers regard as not subject to section 505 of the act or section 351 of the PHS Act. The repacker or relabeler would submit a copy of the current label, a copy of any changes made to the package insert, if there is one, and a representative sampling of any other labeling for each human OTC drug that the manufacturer of the drug regards as not subject to section 505 of the act or section 351 of the PHS Act (proposed § 207.53(d)(2)(ii)). The term ''representative sampling of any other labeling,'' as used in proposed § 207.53(d)(2)(ii) and, as discussed below, in § 207.53(d)(3), is defined in proposed § 207.1 and discussed in section IV.A.5 of this document. Examples of OTC drugs that a manufacturer may regard as not subject to section 505 of the act or section 351 of the PHS Act would include human OTC drugs marketed under an OTC monograph and deemed generally recognized as safe and effective (see part 330). Proposed § 207.53(d)(2)(ii) is consistent with section 510(j)(1)(B)(ii) of the act and current § 207.25(b)(5), except redundant information would not be submitted.

• Animal drugs. The repacker or relabeler would submit a copy of the current label, a copy of any changes made to each animal drug labeling, and a representative sampling of any other labeling for each animal drug (proposed §§ 207.53(d)(3)). Proposed § 207.53(d)(3) is consistent with section 510(j)(1)(B)(ii) of the act and current § 207.25(b)(2) and (b)(5), except redundant information would not be submitted.

e. *Advertisements*. Under proposed § 207.53(e), and in accordance with section 505(j)(1)(B)(i) of the act, the following advertisements would be provided by the repacker or relabeler for each drug listed:

• A representative sampling of advertisements for human prescription drugs that the repacker or relabeler regards as not subject to section 505 of the act or section 351 of the PHS Act. Proposed § 207.53(e)(1) is consistent with section 510(j)(1)(B)(i) of the act and current § 207.25(b)(4).

• If we request it, for good cause, a copy of all advertisements for human prescription drugs that the repacker or relabeler regards as not subject to section 505 of the act or section 351 of the PHS Act, including those advertisements described in § 202.1(l)(1), would be required within 30 calendar days after our request. Proposed § 207.53(e)(2) is consistent with section 510(j)(1)(B)(i) of the act and current § 207.31(a)(1).

f. *Private label distributor*. If the drug is repacked or relabeled for a private label distributor, the repacker or relabeler would submit the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor. The repacker or relabeler may obtain this information from the private label distributor or other sources. This information would indicate whose drug (the repacker's, relabeler's, or private label distributor's) is being listed and would identify and enable us, if needed, to contact the private label distributor. The information for a private label distributor is currently submitted on Form FDA 2658.

6. What Listing Information Would Be Required for Drug Product Salvagers Who Are Not Repackers or Relabelers?

Drug product salvagers who do not otherwise repack or relabel the drugs they salvage would be required to provide all of the following listing information to us for each drug they list, including a drug salvaged for a private label distributor. Drug product salvagers who also repack and relabel the drugs they salvage must list those drugs as a repacker or relabeler in accordance with § 207.53.

a. *NDC number*. For a drug to be considered listed, the drug product salvager would be required to provide the NDC number assigned to the drug immediately before the drug is received by the drug product salvager. Under the proposal, we would assign an NDC number to a manufacturer's, repacker's, or relabeler's drug (or to a drug manufactured, repacked, or relabeled for a private label distributor) after the information required under proposed § 207.33(c) or (d) is provided (see discussion in section IV.D.4.a of this document). The drug product salvager who is not also a repacker or a relabeler for the drug would provide to us the NDC number that is already on the salvaged drug's label (that is, the NDC number of the manufacturer, repacker, relabeler, or private label distributor). Knowing the NDC number of the drug would enable us to incorporate by reference information about the drug submitted by the manufacturer, repacker, or relabeler to obtain an NDC number under proposed § 207.33(c) and (d), as well as information submitted by the manufacturer, repacker, or relabeler to list the drug.

b. *Lot number and expiration date*. We need to know the lot number and expiration date to properly identify the drug because the drug product salvager who is not a repacker or relabeler for the drug would not be assigned an NDC number for the drug. The salvaged drug's lot number would enable us to specifically identify the salvaged drug and determine which batch of a manufacturer's drug has been processed by the drug product salvager. Lot number (or control number or batch number) is defined at current § 210.3(b)(11) as any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined. Knowing the drug's expiration date would indicate approximately how long the salvaged drug may be available for use by consumers. The expiration date would also allow us to identify the approximate date that the salvaged drug would no longer be marketed.

c. *Registration number of each establishment*. The registration number of each establishment where the drug product salvager salvages the drug would enable us to connect the salvaging activity to a particular drug and identify the specific location where the drug product salvaging is performed for the drug. This information would also be used in conducting our establishment inspections and for collecting postmarketing surveillance samples. Current § 207.25(b)(7) requires, for each drug listed, the submission of the registration number of each drug establishment at which the drug is manufactured or processed (within the meaning of current § 207.3(a)(8)), and

current § 207.25(b)(3) requires the submission of the license number of the manufacturer of drugs subject to section 351 of the PHS Act. The establishment registration number is currently submitted on Form FDA 2657.

d. *Information about each importer of the drug and each person who imports, or offers for import, the drug to the United States*. This requirement is explained under section IV.D.4.f of this document.

e. *Private label distributor*. If the drug is salvaged for a private label distributor, the drug product salvager would be required to submit the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor. The drug product salvager may obtain this information from the private label distributor or other sources. This information would identify the private label distributor and enable us, if needed, to contact the private label distributor. The information for a private label distributor is currently submitted on Form FDA 2658.

7. What Additional Drug Listing Information May Be Required?

Under proposed § 207.55, if we request it, the manufacturer, repacker, relabeler, or drug product salvager would be required to briefly state the basis for its belief that a particular drug product is not subject to section 505 or 512 of the act or section 351 of the PHS Act. This proposed provision, which is consistent with section 510(j)(1)(D) of the act and current § 207.31(a)(3), is needed because some manufacturers, repackers, and relabelers have mistakenly considered a drug not to be subject to section 505 or 512 of the act or section 351 of the PHS Act. Although in some cases manufacturers, repackers, and relabelers have correctly concluded that a drug is not subject to section 505 or 512 of the act or section 351 of the PHS Act, in other cases we may consider the drug to be subject to section 505 or 512 despite that conclusion.

The brief statement that would be requested under proposed § 207.55 may include, for example, the **Federal Register** citation for the applicable OTC monograph. We anticipate that our electronic drug registration and listing system will provide some options for brief statements, including **Federal Register** citations as described in the example above, from which manufacturers, repackers, relabelers, and drug product salvagers may select as the basis for their belief that a particular drug product is not subject to section 505 or 512 of the act or section 351 of the PHS Act.

We are also considering whether to require establishments to provide the number of batches and batch size for each drug subject to the listing requirements that they manufactured, repacked, or relabeled since the establishment last provided listing information. Typically, this information would be provided every 6 months, based on the obligation to review and update listing information in June and December of each year. We would consider ''batch size'' to mean, as a general matter, the batch size included in the master production and control records for each drug, as required by the regulations governing current good manufacturing practice for finished pharmaceuticals in part 211, including § 211.186(a) (master production and control records). Typically, ''batch size'' would be the number of unit dosage forms (such as for tablets) or, if the unit dosage form is not defined before primary packaging (such as for liquids), the total batch weight or volume before primary packaging.

We are considering this requirement because it would provide us with important data regarding a product's volume in the U.S. marketplace to assess the potential impact the product has on the public health, which, in turn, will enable us to use our limited resources more efficiently, particularly with regard to inspectional oversight. For example, we currently use data collected as a surrogate for production volume, among many other factors, in our risk-based model to prioritize routine inspections. This model is a systematic, objective, data-driven method to prioritize inspections. (See ''Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites—A Pilot Risk Ranking Model'' at *http://www.fda.gov/cder/gmp/gmp2004/risk_based_method.htm*.) However, better estimates of manufacturing volume would improve our ability to implement a more risk-based approach to manufacturing quality oversight activities. By requiring establishments to provide the number of batches and batch size for each drug subject to the listing requirements, we would have objective data regarding production volume and be better able to find and address CGMP violations that may have the most impact on public health. Actual production data would also give us the ability to more efficiently allocate our resources in other areas.

We specifically invite comments on whether we should require manufacturers, repackers, relabelers, and drug product salvagers to provide the number of batches and batch size for each drug subject to the listing requirements.

8. What Are the Proposed Requirements for Reviewing and Updating Listing Information?

Currently, manufacturers, repackers, and relabelers must enter new or revised listing information on Form FDA 2657 (Form FDA 2658 is used when manufacturers, repackers, and relabelers enter new or revised information for a private label distributor's drug) and return the form to FDA. Under the proposal, manufacturers, repackers, relabelers, and drug product salvagers would access our electronic drug registration and listing system and review their current listing information online, making any changes where needed. Updating listing information would be less time consuming under the proposal because the manufacturer, repacker, relabeler, and drug product salvager would be able to easily access their information at any time, and only changes to the information already in the system would need to be entered in the fields provided.

Under proposed § 207.57, manufacturers who are required to list under proposed § 207.41 would review and update all listing information provided under proposed §§ 207.49, 207.55, and 207.57; repackers and relabelers (including drug product salvagers who repack and/or relabel) who are required to list under proposed § 207.41 would review and update all listing information provided under proposed §§ 207.53, 207.55, and 207.57; and drug product salvagers (who are not repackers and/or relabelers) who are required to list under proposed § 207.41 would review and update all listing information provided under proposed §§ 207.54, 207.55, and 207.57. Proposed § 207.57 uses the term ''review and update'' to stress the importance of first reviewing all listing information to determine if any changes have occurred and then updating the information.

Under proposed § 207.57(a), during the annual review and update of registration information, manufacturers, repackers, relabelers, and drug product salvagers would provide listing information for any drug that has not been previously listed. Proposed § 207.57(a) is consistent with section 510(j)(1) of the act, which requires, among other things, that a list of all drugs must be provided at the time of annual registration.

Under proposed § 207.57(b), manufacturers, repackers, relabelers, and drug product salvagers would

review and update their listing information each June and December of every year. Proposed § 207.57(b) is consistent with the timeframes set forth in section 510(j)(2) of the act, which requires, among other things, that each person who registers must report certain listing information ''once during the month of June of each year and once during the month of December of each year.'' Under current § 207.21(b), an update of listing information must occur each June and December.

Under proposed § 207.57(b)(1) through (b)(5), manufacturers, repackers, relabelers, and drug product salvagers would, during the review and update, submit the following information:

- Listing information would be provided for any drug manufactured, repacked, relabeled, or salvaged for commercial distribution that has not been previously listed (proposed § 207.57(b)(1)). The information would be provided in accordance with proposed §§ 207.49, 207.53, 207.54, and 207.55. This information is currently required under section 510(j)(2)(A) of the act and current § 207.30(a)(1).
- The date that the manufacture, repacking, relabeling, or salvaging for commercial distribution of a listed drug has been discontinued would be provided (proposed § 207.57(b)(2)). The date of discontinuation is currently required under section 510(j)(2)(B) of the act and current § 207.30(a)(2). Section 510(j)(2)(B) of the act requires submission of a ''notice of discontinuance.'' We are proposing to also require that the expiration date of the last lot manufactured, repacked, relabeled, or salvaged be part of proposed § 207.57(b)(2). This information would enable us to know when a drug is no longer marketed and approximately how long the discontinued drug may be available for use by consumers.

We recognize that because of their business practices, drug product salvagers may discontinue commercial distribution of a listed drug almost immediately after they salvage the drug. Drug product salvagers may salvage a drug, put the drug into commercial distribution by selling it to a retailer or other party, and then discontinue salvaging the drug. In that case, we intend to minimize the reporting burden on drug product salvagers by allowing the drug product salvager to provide notice of discontinuation of the drug at the same time the drug product salvager lists the drug. We would not expect under proposed § 207.57(b)(2) that the drug product salvager inform us again, during the review and update of listing information in either June or December of the year, that the salvaged drug is discontinued. Under this proposal, we expect that our electronic drug registration and listing system would provide the opportunity for drug product salvagers to first list a drug, as required by proposed § 207.54, and then indicate that they are discontinuing the drug, as required by proposed § 207.57(b)(2). Because the drug product salvager would have provided the lot number and expiration date for the drug under proposed § 207.54(b)(2), we would not require that same information be submitted again under proposed § 207.57(b)(2).

- The date that the manufacture, repacking, or relabeling for commercial distribution of a previously discontinued drug has resumed and any other listing information not previously required or submitted for the drug would be provided (proposed § 207.57(b)(3)). This proposed provision is consistent with section 510(j)(2)(C) of the act, which requires, among other things, that if a registrant has resumed the manufacture, preparation, propagation, compounding, or processing of a discontinued drug for commercial distribution, the registrant must provide notice and the date of such resumption, the established name and proprietary name of the drug, and other listing information required under section 510(j)(1) of the act not previously provided. The established name and proprietary name would have previously been submitted at the time of listing. Because we would be able to reference that information in our listing database, manufacturers, repackers, and relabelers would not need to resubmit the established name and proprietary name. Current § 207.30(a)(3) requires, in addition to the date of resumption of commercial distribution, that the NDC number, the established name and proprietary name, and any other listing information not previously submitted must be provided. Under the proposal, this information would not need to be provided at this time because we would have access to it from the listing database.

We anticipate that drug product salvagers would not report information under proposed § 207.57(b)(3) because we are unaware of instances when drug product salvagers resume salvaging a drug that they have already salvaged and returned to the marketplace. Drug product salvagers salvage a drug and then put the drug into commercial distribution by selling it to a retailer or other party. This activity ends the drug product salvager's association with that drug. In contrast, manufacturers, repackers, and relabelers may resume the manufacture, repacking, or relabeling of a drug (usually a different lot of the drug) that they had previously listed but are currently not manufacturing, repacking, or relabeling. Thus, we anticipate that proposed § 207.57(b)(3) would not be applicable to drug product salvagers. We invite comment on whether drug product salvagers resume salvaging a drug that they have already salvaged and returned to the marketplace.

- The June and December review and update of listing information would include the submission of all material changes in any information previously submitted under § 207.49, § 207.53, § 207.54, § 207.55, or § 207.57 (proposed § 207.57(b)(4)). Current § 207.30(a)(4) requires that any material change in any information previously submitted must be reported every June and December or, at the discretion of the registrant, when the change occurs. Material changes are listed in the definition of ''any material change'' in current § 207.3(a)(3). As discussed in section IV.A.5 of this document, we are proposing to broaden this definition to mean any change in any listing information provided under proposed §§ 207.49, 207.53, 207.54, 207.55, and 207.57 (except for labeling changes in arrangement or printing or of an editorial nature, or the inclusion of a bar code or NDC number on the label). Under the proposed definition of ''material change,'' the number of changes in listing information that are considered ''material'' would include more than the five types of changes considered ''material'' in the current definition. We are proposing a broader definition of material change because, for the reasons explained in section IV.D of this document, the accuracy of all listing information is essential for us to maintain a reliable and current drug listing database. Proposed § 207.57(b)(4) is consistent with section 510(j)(2)(D) of the act, which requires that each person who registers shall report once during the month of June of each year and once during the month of December of each year any material change in any information previously submitted pursuant to section 510(j)(1) or section 510(j)(2) of the act. Section 510 of the act does not define ''material change.''
- If no changes have occurred since the last review and update of listing information, manufacturers, repackers, relabelers, and drug product salvagers would certify that no changes have occurred (proposed § 207.57(b)(5)). Proposed § 207.57(b)(5) also provides that if a drug is discontinued and we have received the information required under proposed § 207.57(b)(2)

concerning the discontinuation of a listed drug, no further certifications would be necessary for the discontinued drug. We are proposing to revoke current § 207.30(b), which states that no report is required when no changes have occurred since the previously submitted list.

FDA is proposing this certification to ensure that manufacturers, repackers, relabelers, and drug product salvagers have reviewed their listing information and have determined that there have been no changes. There have been many instances where manufacturers, repackers, and relabelers have not updated their listing information on a regular basis. It has been difficult for us to determine whether failure to update listing information is the result of no changes in information or noncompliance. The proposed requirement is intended to reduce these instances and improve the accuracy of our drug listing database. Furthermore, under section 301(p) of the act, it is a prohibited act to fail to submit drug listing information under section 510(j) of the act. Failure to submit drug listing information would also render a drug misbranded under section 502(o) of the act. In addition, the proposed requirement to certify is supported by the statutory provision in section 701(a) of the act (21 U.S.C. 371(a)) that the Secretary has the authority to promulgate regulations for the efficient enforcement of the act.

We specifically request comment on any burden that may result from this proposed requirement that manufacturers, repackers, relabelers, and drug product salvagers certify that no changes have occurred.

Current § 207.30(a) provides that the updates to listing information must be submitted during each June and December or, at the discretion of the registrant, when the change occurs. Although proposed § 207.57(b) would require that listing information be reviewed and updated only every June and December, we are requesting that manufacturers, repackers, relabelers, and drug product salvagers provide all updates to listing information within 30 calendar days of a change. We are requesting that this information be provided on an expedited basis because our listing database will be more accurate if listing information is submitted sooner.

E. Electronic Format

1. How Would Registration and Listing Information Be Provided To FDA?

Under proposed § 207.61(a)(1), the following information required under proposed part 207 would be provided to us using our electronic drug registration and listing system:

- Establishment registration information required in proposed §§ 207.25 and 207.29 (proposed § 207.61(a)(1)(i));
- Information required for an NDC number in proposed § 207.33 (proposed § 207.61(a)(1)(ii)); and
- Drug listing information required in proposed § 207.49 (except for labeling and advertising information in proposed § 207.49(g) and (h)), 207.53 (except proposed §§ 207.53(d) and (e)), 207.54, 207.55, and 207.57 (proposed § 207.61(a)(1)(iii)). As explained in section IV.E.7 of this document, the submission of establishment registration and drug listing information and information required for an NDC number would be made in accordance with 21 CFR part 11, except for the requirements under § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30.

Proposed § 207.61(a)(2) would require that the content of labeling defined in proposed § 207.1 and required under proposed § 207.49(g)(1) through (g)(3) be provided to us in electronic format. The NDC number would also be provided with[9] the content of labeling for each drug. As explained in section IV.E.7 of this document, the submission of the content of labeling would be made in accordance with 21 CFR part 11, except for the requirements under § 11.10(a), (c) through (h), and (k), and the corresponding requirements under § 11.30. As explained in section IV.E.4 of this document and stated in proposed § 207.49(g), the labeling, including the content of labeling, would not be required if the approved U.S. application number is provided by the manufacturer when the drug is listed.

In addition to the electronic submission of information under proposed § 207.61(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(2)), advertisements and labeling (other than the content of labeling) required under §§ 207.49(g) and (h) and 207.53(d) and (e) would be provided to us in either paper or electronic format (proposed § 207.61(a)(3)). The NDC number would also be provided with[10] the advertisements and labeling. As explained in section IV.E.7 of this document, the electronic submission of advertisements and labeling, other than the content of labeling, would be made in accordance with part 11 (21 CFR part 11), except for the requirements under § 11.10(a), (c) through (h), and (k), and the corresponding requirements under § 11.30.

Under proposed § 207.61(a)(4), electronic format submissions must be in a form that we can process, review, and archive. As explained in section IV.E.6 of this document, we may periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation and organization of files).

The electronic submission of the information covered under proposed § 207.61(a) would provide a number of advantages over the current submission of FDA paper forms:

- We would receive a greater quantity of accurate information in less time than it takes to receive information from paper submissions. The information received would also be more accurate because our electronic drug registration and listing system would eliminate errors associated with inputting paper-based data into an electronic system.
- The electronic transmission of the information would be easier and more efficient for both industry and us than the current use of paper forms. For example, you would receive on-screen feedback if the information submitted was not complete, reducing errors and the time and cost of communicating with us. Similarly, electronic transmission of the information would reduce significantly the time and cost associated with our processing paper forms and communicating with industry concerning errors on those forms.
- Information search and retrieval time would be reduced, allowing quicker access to the information in the database.

The requirement to provide listing information to us electronically is consistent with the requirement to list in section 510(j)(1) of the act: ''Every person who registers with the Secretary * * * shall * * * file with the Secretary a list of all drugs * * *. Such list shall be prepared in such form and manner as the Secretary may prescribe * * *.'' The requirement to provide registration information to us electronically is consistent with section 510(p) of the act: ''Registrations * * * (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible * * *.'' Persons who register are also required to list drugs which are being manufactured, prepared,

[9] As explained in section IV.E.4 of this document, the NDC number may accompany the content of labeling; it does not need to be in the content of labeling.

[10] See footnote 9.

propagated, compounded, or processed for commercial distribution (21 U.S.C. 510(j)(1)).

2. What Was the Electronic Submission Pilot Project?

In the **Federal Register** of January 9, 2001 (66 FR 1684), we requested volunteers to participate in a pilot project involving the electronic submission of registration and listing information. In a September 2001 meeting/teleconference with the pilot project volunteers, we provided information on the major functions of the electronic drug registration and listing system, including instructions on the installation, setup, and testing of the systems. The pilot test was held from October 19, 2001, through November 9, 2001, and approximately 28 industry representatives voluntarily participated.

As mentioned previously, our electronic drug registration and listing system is expected to be a Web-enabled, integrated system that provides controlled database access for you to register establishments and list drugs. A separate capability—an extranet—could be used that authenticates external users and controls their access to the our online registration and listing database. This system would allow you to create user accounts and manage additional users.

Industry representatives accessed the pilot test through our extranet to perform the following functions: (l) Initial company setup and establishment registration; (2) registration of additional establishments; (3) drug listing; (4) updates; and (5) system access, logoff, and exit. The pilot test included installation, setup, and operational testing of our electronic drug registration and listing system.

The pilot test was intended to get direct input from the pilot participants about the usability and functionality of the system. The pilot test provided feedback to us on:

- The pilot participants' experience in submitting and preparing registration and listing data.
- Web browsers used.
- Acceptability of proposed normal operating hours.
- Page layout and design.
- Ease of navigation within pages and between functions.
- Whether error messages provide sufficient information to resolve the error.
- The appropriateness of the style, content, and depth of detail of the onpage help.

The comments we received on our electronic drug registration and listing system were generally positive. Those who volunteered to participate in the pilot test were able to successfully access the system, set up a company account within the system, register establishments, and list drugs. Pilot participants encountered a few one-time difficulties that we will address, including minor password problems and difficulties completing the initial company setup and establishment registration process.

We are using information from the pilot program to develop our electronic system.

3. How Would the Electronic Drug Registration and Listing System Work?

Electronic format submissions of registration and listing information, as well as information required for an NDC number, would consist of the electronic transmission via the Internet of the required information from manufacturers, repackers, relabelers, and drug product salvagers into our electronic drug registration and listing system.

Our electronic drug registration and listing system would be made available using an Internet-based data collection system accessed through our FDA Internet site.

- To use the Web site, you would need access to the Internet using a browser.
- You could arrange for Internet access through one of many available Internet Service Providers (ISPs).
- You would need an e-mail address so we can send you confirmation of submissions and other related information.
- This e-mail service could be provided by the ISP or by other sources.

Prior to accepting registration and listing information from this online system, we would authenticate the source (that is, the manufacturer, repacker, relabeler, or drug product salvager) providing the data.

- We could, for example, authenticate entry into the electronic drug registration and listing system by establishing user accounts based on current registration information.
- We anticipate that we may contact manufacturers, repackers, relabelers, and drug product salvagers to obtain contact information to establish an administration account.

To register and list electronically, to provide updated registration and listing information, and to provide information to obtain an NDC number, you would go to our Web site and follow the prompts.

- You could sign onto the system by entering the account number, user name, and password obtained by following the procedures in the guidance we intend to issue on our electronic drug registration and listing system, as discussed in section IV.E.6 of this document.
- You would then be prompted to provide general information about your company and then specific information about each establishment and drug as required in proposed part 207.
- When all of the required information is provided, your official contact would receive confirmation electronically that the information has been received by us.
- If you provide information to obtain an NDC number, the number could be issued electronically.

4. What Are the Proposed Requirements for the Submission of Content of Labeling in Electronic Format?

Under proposed § 207.61(a)(2), the content of labeling would be provided to us in an electronic format. The electronic submission of the content of labeling would permit us to electronically review, compare, and extract data from the labeling.

The content of labeling would be submitted in electronic format for the following drugs:

- Human prescription drugs;
- Human OTC drugs, including those that the manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act as well as those regarded as not subject to sections 505 or 351; and
- Animal drugs, including those that the manufacturer regards as subject to section 512 of the act as well as those regarded as not subject to section 512.

The ''content of labeling'' is defined in proposed § 207.1 (and discussed in section IV.A.5 of this document) to mean:

- For human prescription drugs that the manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act: The content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.
- For human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act: The labeling equivalent to the content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.
- For human OTC drugs: The content of the drug facts labeling required by § 201.66 of this chapter, including all text, tables, and figures.

• For animal drugs (including, but not limited to, drugs that the manufacturer regards as subject to section 512 of the act): The content of the labeling that accompanies the drug that is necessary to enable the safe and proper administration of the drug (e.g., the labeling specified in §§ 201.1 and 201.5 of this chapter), including all text, tables, and figures.

The proposed requirement to provide the content of labeling electronically is consistent with (among other things) that part of the listing requirement in section 510(j)(1) of the act which states that ''Such list shall be prepared in such form and manner as the Secretary may prescribe.'' The proposed requirement to submit the content of labeling for human prescription drugs, human OTC drugs, and animal drugs is consistent with the statutory requirements of section 510(j)(1)(A), (j)(1)(B)(i), and (j)(1)(B)(ii) of the act. Section 510(j)(1)(A) of the act requires, among other things, the submission of a copy of all labeling for drugs subject to sections 505 or 512 of the act. Section 510(j)(1)(B)(i) requires, among other things, the submission of a copy of all labeling for prescription drugs not subject to section 505 or 512 of the act. Section 510(j)(1)(B)(ii) requires, among other things, the submission of the label, package insert, and representative sampling of any other labeling for OTC drugs not subject to section 505 or 512 of the act.

We are proposing that manufacturers provide the NDC number electronically with the content of labeling during listing so that we can more easily link the content of labeling to the listed drug and, thus, expedite the listing process. The NDC number may accompany the content of labeling by being referenced, for example, in the transmittal message to us that contains the content of labeling. The NDC number does not need to be on the content of labeling.

As discussed in greater detail in section IV.D.4 of this document, we are proposing that you need not submit the content of labeling for human prescription or OTC drugs approved under section 505 of the act or section 351 of the PHS Act if you provide the application number when listing the drug or requesting an NDC number for the drug. Incorporating the content of labeling by reference to the application number would eliminate unnecessary duplication of effort and cost to industry.

The submission of the content of labeling in an electronic format would assist us in several ways:

• The use of computer technology to identify changes in different versions of the labeling would greatly enhance our accuracy and efficiency in updating our listing database.

• Our ability to protect the public health would be enhanced because electronic review and comparison of labeling files would provide a higher degree of certainty that all portions of the labeling are consistent and up to date.

• Our ability to protect the public health would be enhanced because we could provide and make easily accessible up-to-date product labeling through the DailyMed initiative, as described in section IV.C.2 of this document.

• Our ability to protect the public health would be enhanced by supporting the implementation of the electronic prescribing provisions of the Medicare Modernization Act. The product labeling information we would make available through DailyMed would be associated with the unique NDC number for each drug, supporting electronic prescribing.

• In the future, the electronic submission of the content of labeling would enable us to receive much of the drug listing information through the labeling, thus improving efficiency in the drug registration and listing system. Industry would be able to satisfy many drug listing requirements through the submission of the content of labeling.

The proposed requirement to provide the content of labeling would not significantly burden industry because labeling is maintained in electronic format by most manufacturers. In addition, our proposal seeks to limit industry costs by avoiding unnecessary duplication of effort—for example, as mentioned previously, if the content of labeling has already been submitted in an approved application, supplement, or annual report, the manufacturer would only have to reference the application number to comply with this listing requirement. In addition, only the manufacturer would be required to submit the content of labeling.

We would require, under proposed 207.61(a)(4), that the information in electronic format be submitted in a form we can process, review, and archive. We are prepared at this time to receive the content of labeling as a portable document format (PDF) file that is searchable. Using commercially available software, an electronic source document created by any number of programs (for example, word processors and desktop publishing programs) can be converted to a PDF file, preserving the fonts, formatting, and graphics of the source document, regardless of the application and platform used to create it. The PDF file can be copied onto a disk or CD–ROM and shared with other users who can use PDF reading software to view, navigate through, and print the document, as well as view, search, and print the file, and copy text, tables, and figures from the file.

However, to be responsive to technological advances, we may recommend in the future that new file formats such as extensible markup language and software applications be used to submit labeling electronically. The language in proposed § 207.61(a)(4), that electronic format submissions must be in a form that we can process, review, and archive, will provide us with the flexibility to recommend file formats or software other than PDF, if appropriate, such as SPL (described earlier in sections III.B and IV.C.2 of this document). We will provide advance notice, in accordance with FDA's good guidance practice regulations under § 10.115 (21 CFR 10.115), so that affected parties will have adequate time to convert to any new format or software. In addition, we expect that such format or software will be widely available before we switch to a new technology. Changes in format and/or software will be identified in public docket number 92S–0251.[11] During any such transition, we will accept submissions using either file format or software.

5. Would the Proposal Require Electronic Submission of Advertisements and Other Labeling?

Under proposed § 207.61(a)(3), advertisements and labeling, other than the content of labeling, required under proposed §§ 207.49(g) and (h) and 207.53(d) and (e) would be provided to us in paper or electronic format. Information on how and where to send labeling and advertisements that are not provided electronically will be described in the guidance document we intend to develop, as discussed in section IV.E.6 of this document. Although we are proposing to require that only registration and listing information, information submitted to receive an NDC number, and the content of labeling need be submitted in electronic format, we expect to identify in public docket number 92S–0251 copies and samples of labeling and advertisements as types of documents we accept in electronic format. Under the proposal, you would have the option of submitting advertisements and labeling either electronically or in paper.

[11] This docket may be accessed on the Internet at *http://www.fda.gov/ohrms/dockets.*

The proposed requirement to submit advertisements is consistent with section 510(j)(1)(B)(i) of the act, which requires, among other things, the submission of a representative sampling of advertisements and, upon request, a copy of all advertisements for prescription drugs not subject to section 505 of the act. The proposed requirement to submit labeling is, as explained previously, consistent with the statutory requirements of section 510(j)(1)(A), (j)(1)(B)(i), and (j)(1)(B)(ii) of the act.

6. What Guidance Documents Do We Intend To Issue on Providing Registration and Listing Information Electronically?

We plan to publish draft guidance and technical specifications on the electronic submission of registration and listing information through our electronic drug registration and listing system (the draft guidance). The draft guidance and technical specifications will explain the electronic process for providing registration and listing information and for providing the information that would be required to obtain an NDC number, including step-by-step instructions on entering information required under proposed part 207. We are also planning to issue guidance on providing registration and listing information in electronic format (concerning the method of transmission, media, file formats, and preparation and organization of files), and this guidance will be updated regularly to reflect the evolving nature of the technology.

In addition to the draft guidance and the guidance on providing registration and listing information in electronic format under development, we have issued other guidances that explain the process for submitting information to us in electronic format. These guidance documents are available at FDA's Web site *http://www.fda.gov/cder/guidance/index.htm* under the heading ''Electronic Submissions.''

7. How Would Part 11 Apply to the Electronic Submission of Registration and Listing Information?

Under proposed § 207.61(a)(1), the submission of registration and listing information (except for the content of labeling and advertisements and labeling) and the information required to receive an NDC number would be made in accordance with part 11, except for the requirements under § 11.10(b), (c), and (e) and the corresponding requirements under § 11.30. Under proposed § 207.61(a)(2) and (a)(3), the submission of the content of labeling, and advertisements and other labeling in electronic format, would be made in accordance with part 11, except for the requirements under § 11.10(a), (c) through (h), and (k), and the corresponding requirements under § 11.30. In the **Federal Register** of March 20, 1997 (62 FR 13430), we published regulations on electronic records and electronic signatures (part 11). Part 11 regulations, among other things, set forth the criteria under which records submitted to us may be submitted in electronic format in lieu of paper records. Section 11.2(b) states that, for records submitted to us, persons may use electronic records in lieu of paper records, in whole or part, provided the requirements of part 11 are met and the documents or parts of documents to be submitted have been identified by us in public docket number 92S–0251 as being the type of submission we are prepared to accept in electronic format.

Part 11 permits the widest possible use of electronic technology, compatible with our responsibility to promote and protect the public health (62 FR 13430). Part 11 helps to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records. Part 11 also helps to safeguard against the possible repudiation of those records. The controls in subpart B of part 11 are intended to further this purpose.

We recently announced in the **Federal Register** our current thinking on part 11. In the **Federal Register** of September 5, 2003 (68 FR 52779), we announced the availability of a guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' (the part 11 guidance). The part 11 guidance explains our current thinking regarding the requirements and application of part 11 and states that we intend to exercise enforcement discretion in the manner specified in the guidance with respect to the validation (§ 11.10 (a)), audit trail (§§ 11.10(e) and (k)(2)), record retention (§ 11.10(c)), and copies of records (§ 11.10(b)) requirements of part 11, and any corresponding requirements in § 11.30. In addition, we announced that we intend to exercise enforcement discretion and do not intend to take (or recommend) action to enforce any part 11 requirements with regard to systems that were operational before August 20, 1997, the effective date of part 11 (commonly known as legacy systems) under the circumstances described in section III.C.3 of the part 11 guidance. Although we explain the relationship between the part 11 guidance and this proposal, as discussed below, you should refer to the guidance we intend to issue on electronic registration and listing for information on complying with part 11 when providing registration and listing information electronically. The part 11 requirements from which we propose exemptions in this proposal differ from the part 11 requirements for which we intend to exercise enforcement discretion, as described in the part 11 guidance. They differ because the proposed exemptions in this rule are specific to the electronic submission of registration and listing information, including information that must be submitted to receive an NDC number and the content of labeling, for drugs that would be covered under proposed part 207, whereas the part 11 draft guidance applies to the maintenance of all electronic records and to all electronic submissions subject to part 11.

With respect to the electronic submission of registration and listing information, including the information required to receive an NDC number but not including the content of labeling and advertisements and other labeling, as previously noted, we believe, as provided in proposed § 207.61(a)(1), that several of the requirements in subpart B of part 11 are not necessary to further the goals of part 11. Because we control the electronic drug registration and listing system, certain controls for systems would not apply to the submission of registration and listing information, such as:

- The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency (§ 11.10(b));
- The protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10(c));
- The use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records (§ 11.10(e)); and
- The corresponding controls of § 11.30.

You would be exempt from these subpart B controls because our registration and listing database is designed to ensure the authenticity, integrity, and confidentiality of this information in several ways. For example, we would control the database, and you would only be able to enter and/or revise information in your own account. In addition, the database would contain records of registration and listing information, and we could generate accurate and complete copies of records.

With respect to the electronic submission of the content of labeling and advertisements and other labeling, as previously noted, we believe, as provided in proposed § 207.61(a)(2) and (a)(3), that several of the requirements in subpart B of part 11 are not necessary to further the goals of part 11. For the reasons described below, certain controls for systems would not apply to the submission of the content of labeling and advertisements and other labeling, such as:

- The validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records (§ 11.10(a));
- The protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10(c));
- Limiting system access to authorized individuals(§ 11.10(d));
- The use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records (§ 11.10(e));
- The use of operational system checks to enforce permitted sequencing of steps and events, as appropriate (§ 11.10(f));
- The use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand (§ 11.10(g));
- The use of device checks to determine, as appropriate, the validity of the source of data input or operational instruction (§ 11.10(h));
- The use of appropriate controls over certain systems documentation (§ 11.10(k));and
- The corresponding controls of § 11.30.

We are proposing to exempt the submission of electronic content of labeling from certain part 11 requirements because we believe these part 11 requirements are not critical to ensure the quality of the content of labeling that would be submitted under this proposed rule and we do not think it is necessary for industry to expend resources on controls that are not necessary to further the goals of part 11. For example, validation for the system used to generate the labeling record is not necessary because the manufacturer's verification that the information in the labeling record is accurate serves the same objective. Our review of the content of labeling is based on the version of the labeling record submitted to us. Earlier versions of the record, as well as changes made to the earlier versions, are not relevant to our analysis. In addition, our registration and listing database is designed to ensure the authenticity, integrity, and confidentiality of this information. As mentioned, we would control the database, you would only be able to enter and/or revise information in your own account, and the database would contain records of the information from which we could generate accurate and complete copies. Thus, controls related to the creation, modification, and maintenance of the content of labeling are not needed.

For the content of labeling and advertisements and other labeling, we recognize that there are some differences with respect to the exemptions from part 11 requirements provided in this proposal (that is, § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30), and the part 11 requirements set forth in the part 11 guidance for which we intend to exercise enforcement discretion (that is, § 11.10(a) through (c), (e), and (k)(2), and any other corresponding requirements in § 11.30)). Although the proposal does not provide an exemption from § 11.10(b) for the content of labeling and advertisements and other labeling, the part 11 guidance announces that we intend to exercise enforcement discretion with respect to that section in the manner described in the guidance.

If this proposed rule is finalized, we intend to identify in docket number 92S–0251 the registration and listing information and the content of labeling specified previously as the types of records that we are prepared to accept in electronic format.

8. What Language Would Be Used to Provide Registration and Listing Information?

Under proposed § 207.61(b), we would require that all registration and listing information be submitted in the English language. We are also proposing that labeling be submitted in the English language except, as provided under current 21 CFR 201.15(c), when drugs are distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English. In those instances, the predominant language may be substituted for English. We are proposing § 207.61(b) because providing information in languages other than English would lead to problems using the registration and listing computerized database and problems with our review of registration and listing information and the content of labeling. Foreign establishments are currently required to submit all registration and listing information in the English language under current § 207.40(b). Because all domestic manufacturers, repackers, relabelers, and drug product salvagers currently submit this information in English, and because foreign establishments are already subject to this requirement, we do not believe the proposed requirement would increase the burden on industry.

9. Could the Electronic Format Requirements Be Waived?

Under proposed § 207.65, manufacturers, repackers, relabelers, and drug product salvagers may request a waiver from the proposed requirement in § 207.61(a) that information be provided to us in electronic format. This proposed waiver provision is consistent with the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) which amended section 510 of the act to add section 510(p) to explicitly give the Secretary discretion to require the electronic submission of registration information upon a finding that electronic receipt of such registration information is feasible, unless the Secretary grants a request for a waiver because the use of electronic means is not reasonable for the person requesting the waiver. Under proposed § 207.65, we may grant a waiver request if the manufacturer, repacker, relabeler, or drug product salvager does not have an e-mail address and access to a computer and an ISP that can access our Web-based registration and listing database and communicate with us. The request must include a telephone number and/or mailing address where we can contact the person making the request. We intend to provide the mailing address for submitting a waiver request in the draft guidance and technical specifications on the electronic submission of registration and listing information.

We do not anticipate many waiver requests because the expenses associated with owning a personal computer, obtaining an e-mail address, and subscribing to Internet access are low. If owning a computer is not possible, however, only access to a computer and an ISP as well as having an e-mail address would be needed to input information electronically in accordance with the registration and listing requirements under this part, including the requirements for obtaining an NDC number. There would be no need for you to maintain data files on disks or other formats; all data would be

maintained in our database and accessed electronically via the Internet. We would control the database and the information contained in it, and you would only enter new information and/or revise your own previously submitted information.

In those instances when we grant a request for a waiver, we would provide information on how to submit registration and/or listing information. One option may be to make available a paper form for submitting the required registration and listing information (including the information required to obtain an NDC number).

F. Miscellaneous

1. What Are the Proposed Requirements for an Official Contact and a United States agent?

Under proposed § 207.69(a), manufacturers, repackers, relabelers, and drug product salvagers that are subject to the registration requirements in proposed part 207 would designate an official contact for each establishment. The official contact would be responsible for:

- Ensuring the accuracy of registration and listing information; and
- Reviewing, disseminating, routing, and responding to communications from us.

We are proposing to require an official contact to facilitate communications between you and us and to help ensure compliance with the registration and listing requirements. On numerous occasions, we have found it difficult to contact certain manufacturers, repackers, relabelers, and drug product salvagers to discuss registration and listing issues.

In addition to the proposed requirement to designate an official contact, each foreign manufacturer, foreign repacker, foreign relabeler, and foreign drug product salvager would be required, under proposed § 207.69(b), to designate a single United States agent. The United States agent would be responsible for:

- Helping us communicate with the foreign manufacturer, foreign repacker, foreign relabeler, and foreign drug product salvager;
- Responding to questions concerning those drugs that are imported or offered for import to the United States; and
- Helping us schedule inspections.

We would not object if the same individual serves as both the United States agent and the official contact for a foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager, or if the same individual serves as the United States agent for more than one foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager.

We are proposing that each foreign manufacturer, foreign repacker, foreign relabeler, and foreign drug product salvager designate a single United States agent. (We note, however, the United States agent may be a company comprised of more than one person). As we explained in the final rule entitled ''Foreign Establishment Registration and Listing'' (66 FR 59138 at 59140), we interpret section 510(i) of the act as allowing only one United States agent for each foreign establishment because section 510(i) of the act refers to the United States agent in singular, rather than plural, terms. We also explained in that final rule (66 FR 59138 at 59141) that we interpret section 510(i) of the act as requiring that the United States agent must be in the United States. These proposed provisions are also consistent with the use of ''U.S. agent'' in the interim final rule entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002'' (68 FR 58894 at 58915, October 10, 2003).

Currently, the provisions concerning a United States agent, as well as other requirements for foreign manufacturers, foreign repackers, foreign relabelers, or foreign drug product salvagers, are set forth under § 207.40. In addition, current § 207.3(a)(11) defines United States agent as a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. The definition states that ''United States agent'' excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present. We are proposing to revoke current §§ 207.3(a)(11) and 207.40 and include these requirements (as revised), for example, under proposed §§ 207.1, 207.9, 207.13, 207.17, 207.33, 207.41, 207.61, and 207.69.

Under proposed § 207.69(b)(2) through (b)(4), the United States agent would be required to reside or maintain a place of business in the United States. A United States agent may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present. If we are unable to contact the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager directly or expeditiously, we may provide information or documents to the United States agent, which we would consider equivalent to providing the same information or documents to the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager.

We are proposing the requirements for a United States agent to facilitate communications between you and us and to help ensure compliance with the registration and listing requirements. On numerous occasions, we have found it difficult to contact certain foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers, resulting in their drugs being detained because certain registration and/or listing issues have not been resolved.

2. What Legal Status Is Conferred by Registration and Listing?

Under proposed § 207.77(a), registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing would be misleading and would constitute misbranding under section 502 of the act. To clarify and consolidate current regulations, we are proposing to revise and move a similar provision in current § 207.39 to proposed §§ 207.77(a) and 207.37. Current § 207.39 states that registration of a drug establishment or drug wholesaler, assignment of a registration number, or assignment of an NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number or NDC number is misleading and constitutes misbranding. The registration provisions in current § 207.39 would be included in proposed § 207.77(a), and the NDC number provisions in current § 207.39 would be included in proposed § 207.37. Proposed § 207.37(c) states that the NDC number must not be used to denote FDA approval of that drug. We are proposing to include in proposed § 207.77(a) that listing a drug would not denote approval of the drug and that any such representation would be misleading and constitute misbranding.

Under proposed § 207.77(b), assignment of an establishment registration number, inclusion of a drug in our database of drugs, or assignment of an NDC number does not denote approval of the establishment or the

drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed. Any representation that creates an impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned a NDC number, or the establishment has been assigned an establishment registration number, is misleading and constitutes misbranding. Failure to comply with proposed § 207.37 also constitutes misbranding. We are proposing to add this provision to clarify that a drug's marketing approval status is determined, for example, under section 505 or 512 of the act, section 351 of the PHS Act, and parts 314, 514 (21 CFR part 514), and 601 of the regulations, and not under section 510 of the act or part 207 of the regulations.

Under proposed § 207.77(c), neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the act. This provision reflects a revision and relocation of current § 207.20(e) to proposed § 207.77(c). Current § 207.20(e) states that registration and listing do not constitute an admission, agreement, or determination that a product is a drug as defined under section 201(g) of the act. Proposed § 207.77(c) also states that registration and listing may be evidence that a facility is manufacturing, repacking, relabeling, or salvaging drugs or that a product is a drug. Thus, the proposed rule revises current § 207.20(e) such that, while neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by the act, registration and listing may be evidence that a facility is manufacturing, repacking, relabeling, or salvaging drugs or that a product is a drug.

FDA is proposing to delete the statement in current § 207.35(c) that validation of registration and the assignment of a drug listing number do not, in themselves, establish that the holder of the registration is legally qualified to deal in such drugs. As explained in sections IV.B and IV.C of this document, FDA is proposing to discontinue the validation of registration. As explained previously in this document, the provision on the legal status of registration and listing is included in proposed § 207.77, and proposed § 207.37(c) sets forth restrictions pertaining to the use of the NDC number (e.g., the NDC number must not be used to denote FDA approval of the drug).

3. What Registration and Listing Information Would Be Made Available for Public Disclosure?

Current § 207.37 pertains to the public availability of registration and listing information. Proposed § 207.81 would revoke, in part, and revise current § 207.37. The heading ''Inspection of registrations and drug listings'' in current § 207.37 would be changed to ''What registration and listing information will we make available for public disclosure?'' This heading would more accurately describe the scope of the provision in that the provision relates to the type of registration and listing information that we intend to make available for public disclosure.

The proposal would revoke the introductory text of current § 207.37(a), which includes a description of the types of forms available for inspection, the addresses at which such forms can be inspected, and the addresses that requests for verification of registration numbers and requests for locations of registered establishments can be directed. We are proposing to revoke this introductory text because these forms would no longer be used under the proposed scheme. Instead, we intend to make most information that is available for public disclosure accessible via the Internet. This initiative would be consistent with the GPEA and would also help to reduce the number of Freedom of Information Act (5 U.S.C. 552) requests we receive for registration and listing information. Accordingly, we are also proposing to revoke current § 207.37(b), which sets forth the address to which requests for information about drug registration and listing can be directed. We note that persons may still submit Freedom of Information Act requests to the agency for drug registration and listing information that is not available on the Internet.

Current § 207.37(a)(1) sets forth 11 categories of information that, when compiled, will be available for public disclosure. Proposed § 207.81(a) would simplify this section to reference the following information as generally available for public disclosure: All registration information and, after a drug is listed, all information obtained for that drug under proposed §§ 207.33, 207.49, 207.53, and 207.54, except for that information obtained under proposed §§ 207.33(d)(1)(ii) and 207.54(b)(1) or the information that would otherwise be exempt from disclosure under proposed § 207.81(b) or (c).

Proposed § 207.81(a) would add registration information to the list of the types of information that would generally be considered to be publicly available. Registration information is currently available for public inspection as referenced in § 207.37(a).

For various reasons, proposed § 207.81(a) would not include certain specific categories of information that are listed in current § 207.37. The provision relating to a list of all drug products arranged by labeled indications or pharmacological category would not be included in the proposal because we currently do not compile or index drug registration and listing information by labeled indication. The provisions related to a list of drug products newly marketed or for which marketing is resumed, a list of drug products discontinued, and information that has become a matter of public knowledge would be deleted because these categories of information would also be disclosable under the general provision of proposed § 207.81(a).

We are proposing to exempt proposed §§ 207.33(d)(1)(ii) and 207.54(b)(1) from proposed § 207.81(a) because this information may disclose a business relationship between the manufacturer, repacker, relabeler, or drug product salvager and the business from which they obtained the drug, and may constitute commercial or financial information that is exempt from public disclosure under § 20.61(c). We are proposing to exempt from public disclosure the information collected under proposed § 207.33(d)(1)(ii), which would require that repackers or relabelers, to obtain an NDC number, must provide, among other things, the NDC number assigned to the drug immediately before the drug is received by the repacker or relabeler. We also are proposing to exempt from public disclosure the information collected under proposed § 207.54(b)(1), which would require that drug product salvagers, to list a drug, must provide, among other things, the NDC number assigned to the drug immediately before the drug is received by the drug product salvager.

In addition to these changes, the proposal would make some fundamental changes to the disclosure provision in current § 207.37. We are proposing to add one category of listing information to the list of information that would generally be regarded as publicly available information. Specifically, proposed § 207.81 generally would make available for public disclosure a drug product's inactive ingredients when provided under § 207.33(c)(2)(ii) and (c)(3). When the firm provides the approved application number, we can link to the

application and retrieve the names of the inactive ingredients included in the approved application. We will then make the names of the inactive ingredients available to consumers unless they are subject to trade secret protection, as discussed below. Proposed § 207.81 would change the current provision in § 207.37(a)(2). Current § 207.37(a)(2)(ii) and (a)(2)(iii) provide that information on inactive ingredients will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if we find that it would be inconsistent with the protection of the public health).

We are proposing, under § 207.33(c)(2)(ii), to give manufacturers the opportunity at the time of listing to identify inactive ingredients that they consider trade secret. Information identified by the applicant as trade secret would not be routinely posted on the Internet. Public disclosure of inactive ingredients not designated as trade secret at the time of listing would be authorized by the proposed regulations. We would evaluate claims of trade secret protection based on the definition of a trade secret in § 20.61(a) when making disclosure decisions in response to requests made under the Freedom of Information Act for this information and would withhold the information from public disclosure, when appropriate, under § 207.81(c). This evaluation is consistent with how FDA evaluates requests asking for inactive ingredient information that is included in approved U.S. applications. When manufacturers submit the approved application number instead of listing inactive ingredients under proposed § 207.33(c)(2)(ii), they similarly would need to identify any inactive ingredients they considered to be trade secret. Proposed §§ 207.33(c)(2)(ii), 207.81(a), and 207.81(c) would strike a balance between manufacturers' commercial interests and the fact that it would generally be inconsistent with protection of the public health to withhold inactive ingredient information. We expect that manufacturers would only avail themselves of the opportunity to claim trade secret protection in extremely limited circumstances. We note that information in a drug's labeling, including the names of inactive ingredients, is not trade secret information.

The proposal to add information about inactive ingredients to the list of categories considered to be public information is also consistent with section 510(f) of the act. Section 510(f) of the act generally provides that listing information shall be exempt from inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health. We find that exempting, among other things, a list of inactive ingredients from public disclosure would be inconsistent with the protection of the public health. It is important for consumers to know the inactive ingredients of the drugs they might be taking because such information can be important in certain situations. For example, some inactive ingredients can trigger allergic reactions in patients. If a particular inactive ingredient appeared to trigger such reactions in an individual, and the name of the inactive ingredient was available to the public, individuals and their caregivers would be able to access such information to prevent potentially serious reactions. Additionally, some inactive ingredients may be particularly toxic to individuals with certain medical conditions and some may exacerbate a person's medical condition. If inactive ingredient information is available for drugs, individuals and their caregivers could get this information and avoid adverse reactions. We could also use inactive ingredients information to help us investigate possible drug contamination, counterfeiting, or adulteration. For example, if a drug appeared to be linked to an unexpected number of adverse drug events or seemed less effective than expected, an analysis of the drug showing the presence of unidentified (i.e., not previously listed) inactive ingredients in that drug could suggest that the drug was adulterated or counterfeit, or that the unidentified inactive ingredient may interfere with the drug's mode of action. Additionally, the presence of an unidentified inactive ingredient in a drug product may suggest contamination or that the drug was not manufactured by the legitimate manufacturer. Generally, we believe that knowing about a drug's inactive ingredients and having such information readily available in an electronic database is consistent with protection of the public health.

We recognize that because we may make a large amount of registration and listing information publicly available under proposed § 207.81, there may be instances where some of the information authorized by this proposed rule for public disclosure could identify business relationships. We believe that many of these business relationships could be identified currently, but that the electronic registration and listing system may make it somewhat easier to do so. For example, a contractual relationship that might not otherwise be publicly disclosed may be revealed when a manufacturer of a sole source material provides the drug's established name under proposed § 207.33(c)(1)(ii) or when a manufacturer provides registration numbers of each establishment where manufacturing is performed under proposed § 207.49(d). Also, for example, business relationships between private label distributors and manufacturers, repackers, relabelers may be revealed when providing information under § 207.33(c) or (d)(2). However, we believe this would be a rare event and that exemption of the information required by these regulatory provisions from public disclosure would be inconsistent with protection of the public health. For example, we believe that we should not exempt from public disclosure the names of inactive ingredients that would be submitted under proposed § 207.33(c)(2)(ii) because of the remote possibility that the names, along with other information that may be disclosed under this proposal, could reveal a business relationship. We believe that the potential public health benefits of releasing the names of the inactive ingredients justify our decision not to exempt them from public disclosure because they outweigh the remote possibility that a business relationship could be revealed. Therefore we have concluded that the public interest in disclosure of most registration and listing information supports the proposals in the rulemaking.

We also note that, for foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers, the name of each importer and the names of persons who import a drug or offer a drug for import would be required for registration and we are proposing that this information would be available for public disclosure. Disclosure of this information would be consistent with section 510(f) of the act, which requires that any registration filed be made available for inspection.

We invite comments on which specific registration and listing information should be available for public disclosure. We request that you identify the specific registration and listing information on which you are commenting and explain why you believe the information should or should not be publicly disclosed.

Proposed § 207.81(b) would make one other conforming change to the current

disclosure provision. Current § 207.37(a)(2) sets forth three categories of information that will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if we find that confidentiality would be inconsistent with protection of the public health). Proposed § 207.81(b) would retain the category treating as nondisclosable any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the act. As explained previously in this document, we are moving two previously nondisclosable categories (now disclosable) regarding information on inactive ingredients to proposed § 207.81(a) that relate to information generally regarded as publicly available. Those categories, in current § 207.37(a)(2)(ii) and (a)(2)(iii), would be disclosable under proposed § 207.81(a). Proposed § 207.81(c) would allow FDA to determine, in limited circumstances and on a case-by-case basis, that it would be consistent with protection of the public health and the Freedom of Information Act to exempt from public disclosure specific information in paragraph (a) of this section. As explained previously in this document, we are proposing, under § 207.33(c)(2)(ii), to give manufacturers the opportunity at the time of listing to identify inactive ingredients that they consider trade secret and therefore, prohibited from disclosure under § 20.61. There may be other appropriate reasons for exempting certain drug listing and registration information from public disclosure. For example, FDA may decide for security reasons, and consistent with the Freedom of Information Act, not to publicly disclose the manufacturing site location for certain drugs.

G. Conforming Actions

1. Withdrawal from Sale of Drugs with Approved Marketing Applications

We are proposing to revise our human drug regulations on applications for approval to market a new drug to make them consistent with proposed part 207. Under current § 314.81(b)(3)(iii)(*a*), holders of new drug applications must report to us the withdrawal from sale of a drug product. Under this provision, the information must be submitted on Form FDA 2657 within 15 working days of the drug product's withdrawal from sale. The following information must be submitted: The NDC number; the identity of the drug by established name and by proprietary name; the new drug application number or abbreviated application number; and the date of withdrawal from sale. The reason for withdrawal of the drug from sale is requested but not required to be submitted. Section 314.81(b)(3)(iii)(*b*) provides the address for submitting the completed form, and § 314.81(b)(3)(iii)(*c*) states that reporting under § 314.81(b)(3)(iii) constitutes compliance with the requirements under current § 207.30(a) to report ''at the discretion of the registrant when the change occurs.''

We are proposing to revise this requirement to be consistent with the requirements in proposed §§ 207.57 and 207.61. Proposed § 314.81(b)(3)(iii)(*a*) would provide that within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are manufacturers, repackers, or relabelers subject to proposed part 207 would be required to submit certain information about the withdrawn drug in electronic format, in accordance with the applicable requirements described in § 207.61(a).

Under proposed § 314.81(b)(3)(iii)(*b*), applicants who are not subject to proposed part 207 would submit the information specified under proposed § 314.81(b)(3)(iii)(*a*) on the appropriate form, which would be submitted to the Drug Listing Branch, Food and Drug Administration, CDER Central Document Room, 5901B Ammendale Rd., Beltsville, MD 20705–1266. We are proposing to require applicants who are subject to proposed part 207 to submit the information specified under proposed § 314.81(b)(3)(iii)(*a*) in electronic format, in accordance with the applicable requirements described in proposed § 207.61(a). Consistent with the proposed requirements in § 207.61, and discussed in section IV.E.3 of this document, these applicants would be required to obtain an account number, user name, and password to sign onto the electronic drug registration and listing system. We are considering this requirement because we believe the electronic submission of this information would be more efficient for applicants than the preparation and mailing of paper forms. Electronic submission would also make our review and processing of this information more efficient. We request comments on requiring applicants who are not subject to proposed part 207 to submit electronically the information specified in proposed § 314.81(b)(3)(iii)(*a*).

Currently, we do not have a provision in our regulations for reporting withdrawals from sale of biological products. We are proposing to revise our regulations to include such a provision. Under proposed § 601.2(f), holders of BLAs must report to us, electronically in accordance with part 207, the withdrawal from sale of licensed biological products. The information must be submitted to us within 30 working days of the biological product's withdrawal from sale. The following information would be submitted: The holder's name; product name; BLA number; the NDC number, if applicable; and the date of withdrawal from sale. The reason for the withdrawal of the biological product would be requested but not required.

2. Proposed Revisions to Other Regulations

In addition to the revisions of regulations discussed previously in this document, we are also proposing revisions to other FDA regulations as a result of this proposed rule. The proposed revisions are as follows:

- Section 20.100(c)(9): The reference to § 207.37 would be changed to § 207.81 to correspond to the proposed provision on disclosure of registration and listing information.
- Section 20.116: The reference to § 207.37 would be changed to § 207.81 to correspond to the proposed provision on disclosure of registration and listing information.
- Section 201.1(f): The reference to § 207.3(b) would be changed to § 207.1 to correspond to the proposed definitions section.
- Section 330.1(b): As explained in section IV.C.5 of this document, the NDC number would be required to appear on OTC drug labels.
- Section 514.111(a)(12): As explained in section IV.B.2 of this document, we would refuse to approve an NADA if the drug is manufactured in an establishment that is not registered.
- Section 515.10(b)(8): The reference to ''§§ 207.20 and 207.21'' would be changed to ''part 207'' as a result of the proposed reorganization and revision of part 207.
- Section 607.3(b): Current § 607.3(b) defines ''blood and blood product'' to mean a drug which consists of human whole blood, plasma, or serum or any product derived from human whole blood, plasma, or serum, hereinafter referred to as ''blood product.'' The current definition also states that ''blood and blood product'' also means those products that meet the definition of a device under the act and that are licensed under section 351 of the PHS Act. We are proposing to amend this definition to add the phrase ''as well as licensed biologic components used in the manufacture of a licensed device.'' This proposed revision is intended to

clarify that licensed biologic components used in the manufacture of a licensed device are covered under the definition of ''blood and blood product'' and that manufacturers of licensed biologic components used in the manufacture of a licensed device are required to register and list under part 607. It is important that manufacturers of licensed biologic components used in the manufacture of a licensed device register and list because licensed devices are used to ensure the safety of blood and blood products.

- Section 607.3(k): We are proposing to define ''importer'' as a company or individual in the United States that is the owner, consignee, or recipient of the foreign establishment's blood product that is imported into the United States.
- Section 607.7: Current § 607.7(a) states that all owners or operators of establishments that engage in the manufacturing of blood and blood products are required to register, and that registration and listing of blood and blood products must comply with part 607. Current § 607.7(a) also states that registration does not permit blood banks or similar establishments to ship blood products in interstate commerce. Current § 607.7(b) and (c) explain how the registration form for these establishments may be obtained from CBER and where the completed form should be mailed to.

We are proposing to delete current § 607.7(b) and (c) and explain where to obtain establishment registration forms and where to send completed forms in proposed § 607.22(b) (discussed below in this document). We are deleting these provisions from current § 607.7 to eliminate redundancy in part 607. We are proposing to redesignate paragraph (a) in § 607.7 as the introductory paragraph.

- Section 607.22: For clarity, we are proposing to revise the title of current § 607.22—''How and where to register establishments and list blood products''—to read ''How to register blood product establishments and list blood products.''

Current § 607.22(a) requires the first registration of an establishment to be on Form FDA 2830 (Blood Establishment Registration and Product Listing), provides the mailing address where the Form FDA 2830 may be obtained and submitted, states that FDA will furnish a Form FDA 2830 before November 15 of each year to establishments whose registration for that year was validated under § 607.35, and states that the completed form must be mailed to us before December 31 of that year. Current § 607.22(b) states that the first and subsequent blood product listing updates shall be on Form FDA 2830.

We are proposing to reorganize and update current § 607.22 as follows: Initial and subsequent registrations and product listings by a blood product establishment for blood products would be on Form FDA 2830 (Blood Establishment Registration and Product Listing). Manufacturers may obtain, complete, and submit the form in the following ways:

- Complete the form online and submit electronically at *http://www.fda.gov/cber/blood/bldreg.htm*; this information must be submitted in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30 (as discussed in section IV.E.7 of this document); or
- Download the form from the Internet at *http://www.fda.gov/cber/blood/bldreg.htm*, and mail the completed form to the address in § 607.22(e); or
- Request the form by mail using the address in § 607.22(e), or by e-mail at *bloodregis@cber.fda.gov*, and mail the completed form to the address in § 607.22(e).
- For subsequent annual registration renewals, we will furnish the establishment's most recent Form FDA 2830 before November 15 of each year. The updated Form FDA 2830 would be submitted to us before December 31 of that year.
- Forms may be requested from and mailed to: Center for Biologics Evaluation and Research (HFM–370), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

We are proposing these revisions to current § 607.22 to make the registration and blood product listing process for blood product establishments more efficient by utilizing the latest technology for completing and submitting registration and listing forms.

- Section 607.25(b)(1): Current § 607.25(b) lists the information required for blood product listing. Currently, blood establishments that manufacture bulk product substances and finished dosage forms must list their products under part 607 and also under part 207 to receive a NDC number. We are proposing to revise current § 607.25(b)(1) to delete the phrase ''including bulk product substances as well as finished dosage forms'' because we are proposing to require these manufacturers to list only under part 207 to reduce their reporting burden. In addition, we are proposing to add the phrase ''if any'' after ''by proprietary name'' because not all of these products have a proprietary name. We are also proposing to delete the reference to Form FDA 2250 (National Drug Code Directory Input) because this form is no longer being used by CDER or CBER.
- Section 607.35: For clarity, we are proposing to revise the title of current § 607.35—''Notification of registrant; blood product establishment registration number and NDC Labeler Code''—to read ''Blood product establishment registration number.''

Current § 607.35(a) states that FDA will send a validated copy of Form FDA 2830 as evidence of registration to the registering establishment, and that FDA will assign a permanent registration number to each establishment. We are proposing to revoke the provision that we will send a validated copy of Form FDA 2830 to blood establishments. All registration information will be available to registered blood establishments on the Internet; therefore, to increase efficiency we will discontinue sending the validated copy of Form FDA 2830. Proposed § 607.35 would state only that we will assign a permanent registration number to each blood product establishment registered in accordance with part 607.

Current § 607.35(b) states that if a registered blood product establishment has not previously participated in the NDC system or in the National Health Related Items Code system, the NDC numbering system must be used. We are proposing to revoke this section because blood product manufacturers that obtain a NDC number for their products will register under proposed part 207 and not under part 607. We are also proposing to delete reference to the National Health Related Items Code system because it is a voluntary system for medical device manufacturers that is managed by CDRH.

Current § 607.35(c) states that although establishment registration and blood product listing are required, validation of registration and the assignment of a NDC Labeler Code do not, in themselves, establish that the holder of the registration is legally qualified to deal in such products. We are proposing to incorporate into proposed § 607.39 the provision that validation of registration does not establish that the holder of the registration is legally qualified to deal in such products. We are proposing to revoke the provision concerning the assignment of a Labeler Code because the NDC number requirements would be covered under proposed part 207 and not proposed part 607.

• Section 607.37(a): Current § 607.37(a) states that a copy of Form FDA 2830 will be available for inspection under section 510(f) of the act at FDA headquarters and at each of the FDA district offices. In addition, current § 607.37(a) states that FDA will provide by mail verification of registration number and location of a registered establishment. Current § 607.37(a) also gives examples of the blood product listing information that will be available for public disclosure.

Under proposed § 607.37(a), information submitted on Form FDA 2830 would be available for inspection at *http://www.fda.gov/cber/blood/bldregdata.htm* and at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

• Section 607.39: Current § 607.39 states that registration of an establishment or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products, and that any representation that creates an impression of official approval because of registration is misleading and constitutes misbranding.

We are proposing to revise current § 607.39 to delete the reference to the NDC number, to incorporate the provision from current § 607.35(c) that validation of registration does not establish that the holder of registration is legally qualified to deal in blood products, and to revise the title accordingly. Manufacturers of blood products that obtain a NDC number would not register under proposed part 607; therefore, it is not necessary to reference NDC numbers under this part. Proposed § 607.39 would state that registration of an establishment, validating registration, or obtaining a registration number does not in any way denote approval of the firm or its products nor does it establish legal authority for the holder of the registration number to market such products.

• Section 607.40: As discussed in section IV.A.2 of this document, we are proposing to revoke current § 207.40, establishment registration and drug listing requirements for foreign establishments, and revise and move the requirements elsewhere in proposed part 207. Consistent with the revisions to proposed part 207, we are proposing to revoke certain provisions of current § 607.40(a) and (b). We are proposing to revoke the exemption in current § 607.40(a) relating to foreign establishments whose blood products enter a foreign trade zone and are reexported from that foreign trade zone without having entered United States commerce. We are also proposing to revoke, in part, current § 607.40(b), which allows for blood, blood components, Source Plasma, or Source Leukocytes, or a component or part, under section 801(d)(4) of the act, to be imported or offered for import into the United States even if the product is not listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. We are proposing to eliminate these two exemptions because of certain statutory changes that have occurred since the publication of the final rule on foreign establishment registration and listing. Those changes include, as discussed in section IV.A.2 of this document, enactment of the Bioterrorism Act, which reflects Congress' desire to increase the Nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies. Consistent with the provisions of the Bioterrorism Act, we are proposing to amend § 607.40(c) to require each foreign establishment to submit the name of each importer of the foreign establishment's blood products that is known to the establishment, and the name of each person who imports or offers for import such blood products to the United States.

We are also proposing to amend §§ 607.40(d) and (d)(3) to require each foreign establishment to submit the telephone and fax numbers and e-mail address of its United States agent. The name, address, and phone number of the United States agent is required under current § 607.40(d). We are proposing to require the submission of the information on importers and persons who import because the Bioterrorism Act requires foreign establishments to submit, among other things, the name of each importer of such blood product that is known to the establishment, and the name of each person who imports or offers for import such blood product to the United States for purposes of importation. In addition to the name, the proposal would require that the address, telephone and fax numbers, and e-mail address of each importer and of each person who imports or offers for import be provided to enable us to contact these persons. Proposed § 607.40(d)(3) would also require the foreign establishment to report changes in the United States agent's name, address, telephone and fax numbers, and e-mail address to FDA within 30 calendar days of the change. Currently, § 607.40(d)(3) requires notification to FDA within 10-business days.

Proposed § 607.40(e) would make electronic registration and listing mandatory for foreign establishments, consistent with proposed § 607.22(a). For those foreign establishments that are unable to register and list blood products using the electronic registration and listing system, we are proposing waiver provisions in § 607.40(f)(1). We may grant a request for a waiver from a foreign establishment if the foreign establishment does not have an e-mail address and access to a computer and an Internet service provider that can access the electronic registration and listing system. We are also proposing in § 607.40(f)(2) to require that waiver requests include a telephone number and/or mailing address where the agency can contact the foreign establishment. In addition, we are proposing to add § 607.40(f)(3) which states that if the agency grants the waiver request, the foreign establishment must register and list blood products in accordance with § 607.22(b) or (c).

• Section 607.65: Proposed § 607.65 would be amended by redesignating paragraph (f) as paragraph (g) and by adding new paragraph (f). Proposed § 607.65(f) would exempt certain blood product manufacturers from registration and product listing under part 607 because FDA is proposing that manufacturers of these products register and list only under part 207. Because these products routinely bear NDC numbers, FDA believes it is more efficient to have manufacturers of these products register and list under part 207. The products that would be included under proposed § 607.65(f) are all plasma derivatives such as albumin, Immune Globulin, Factor VIII, and Factor IX, bulk product substances such as fractionation intermediates or pastes, recombinant versions of plasma derivatives or animal derived plasma derivatives. Under current § 607.20, manufacturers of plasma derivatives such as albumin, Immune Globulin, Factor VIII, and Factor IX are required to register and list under part 607 and under part 207 to obtain an NDC number.

• Sections 1271.1(a), 1271.1(b)(2), and 1271.20: We are proposing to amend §§ 1271.1(a), 1271.1(b)(2), and 1271.20 by removing ''207.20(f)'' and by adding in its place ''207.9(c)(2)''.

• Section 1271.3: For consistency with parts 207 and 607, we are proposing to define ''importer'' at

proposed § 1271.3(mm) to mean a company or individual in the United States that is the owner or consignee or recipient of the foreign establishment's HCT/P that is imported into the United States. For consistency with part 607, we are proposing to define ''United States agent'' at proposed § 1271.3(nn) to mean a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. The definition of ''United States agent'' would exclude mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present. The United States agent would be responsible for helping FDA communicate with you, responding to questions concerning your HCT/Ps that are imported or offered for import to the United States, and helping FDA schedule inspections.

- Section 1271.22: We are proposing to make electronic registration and listing mandatory for HCT/P establishments. As a result, we are proposing to revise current § 1271.22 as follows:

Replace ''Form FDA 3356'' in current § 1271.22(a) with ''the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm*'';

Revise current § 1271.22(b) and (c) to implement the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm* and remove references such as ''Form FDA 3356,'' mailing addresses, and telephone numbers.

In the **Federal Register** of January 19, 2001 (''Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing,'' (66 FR 5447)), FDA announced its intention to develop an electronic submission process for HCT/P registration and listing. The agency has developed such a system and it is currently in use on a voluntary basis.

Consistent with proposed § 207.61(a)(4), proposed § 1271.22(b) states that FDA will periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation, and organization of files) for HCT/Ps.

Consistent with proposed § 207.61(a)(1), proposed § 1271.22(c) states that HCT/P manufacturers must provide the information under § 1271.22(a) in accordance with part 11, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30.

- Section 1271.23: Proposed § 1271.23 would permit HCT/P establishments that do not have an e-mail address and access to a computer and an Internet service provider that can access the Web-based FDA registration and listing database to request a waiver from electronic registration and listing. This is consistent with proposed § 207.65 and the Bioterrorism Act.
- Section 1271.25: We are proposing to amend § 1271.25, ''What information is required for establishment registration and HCT/P listing,'' as follows:

Delete the reference to ''Form FDA 3356'' in current § 1271.25;

Amend current § 1271.25(a)(2) and (a)(3) to require the submission of the telephone and fax numbers and an e-mail address;

Add § 1271.25(a)(5) to require each foreign establishment to also submit the name, the address, telephone and fax numbers, and e-mail address of each importer that is known to the establishment and the name of each person who imports or offers for import such HCT/P to the United States for purposes of importation;

Add proposed § 1271.25(a)(6) to require each foreign establishment to also submit, the name, address, telephone and fax numbers, and e-mail address of its United States agent. Under proposed § 1271.25(a)(6), each foreign establishment would have only one United States agent, and that United States agent must reside or maintain a place of business in the United States. Upon request from FDA, the United States agent must assist us in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist us in scheduling inspections of the foreign establishment. If we are unable to contact the foreign establishment directly or expeditiously, we may provide information or documents to the United States agent. The foreign establishment would report to FDA changes in the United States agent's name, address, telephone and fax numbers, and e-mail address within 30 calendar days of the change.

Add proposed § 1271.25(d) to clarify that if your HCT/P is regulated as a drug, device, and/or biological product under current § 1271.20, you must submit the information required under part 207 using the procedures under part 1271.

- Section 1271.26: For consistency with proposed § 207.29(a), we are proposing to amend current § 1271.26 to include a change in the United States agent's name, address, telephone and fax numbers, and e-mail address. All changes in proposed § 1271.26 would be reported within 30 calendar days instead of the current requirement to report the change within 5 days.
- Section 1271.37 would be revised to delete the reference to ''Form FDA 3356''.

3. Compliance Verification Reports

On November 26, 2004 (69 FR 68831), FDA withdrew its September 2, 1993, proposal (58 FR 46587; Docket Number 92N–0291) to amend part 207 to require the completion of ''compliance verification reports.'' These reports are printouts of information as reported to FDA on Form FDA 2657 or Form FDA 2658. FDA had periodically mailed to domestic establishments the compliance verification report for listed prescription drugs and requested that the establishments verify or correct the information and return it to the agency within 30 calendar days. The completion of the report served to satisfy, in most cases, the drug listing updates required under current § 207.30(a). FDA provided this service to increase the accuracy of its computerized drug listing files. Because FDA is now proposing to require the electronic submission of all registration and most listing information, FDA in anticipation of this proposal has already withdrawn the September 2, 1993, proposal and has discontinued the use of the compliance verification reports. Electronic submission of registration and most listing information would make it easier for establishments to register and list. In addition, FDA's electronic registration and listing database would save registration and listing information that was submitted, thereby making it easier for establishments to access, review, and update information.

V. Legal Authority

We have the legal authority to amend our regulations on foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a BLA, and animal drugs. The statutory basis for our authority includes sections 201, 301, 501, 502, 503, 505, 506, 506A, 506B, 506C, 510, 512, 513–516, 518–520, 701, 704, 721, 801, and 903 of the act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 360, 360b, 360c–360f, 360h–360j, 371, 374, 379e, 381, and 393); 15 U.S.C. 1451–1561; the PHS Act; and section 122, Public Law 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

Section 510(c) of the act requires every person upon first engaging in the manufacture, preparation, propagation,

compounding, or processing of a drug to immediately register with the Secretary his name, place of business, and the establishment. The provisions in section 510(b) and (d) of the act require annual registration and registration of additional establishments, respectively. Section 510(i) of the act requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the Secretary by providing certain information. These provisions, together with section 701(a) of the act (among others), authorize us to require the submission of the registration information specified in the proposal. The information specified in this proposal would help us identify who is manufacturing, repacking, relabeling, or salvaging drugs and where those operations are being performed. In addition, some information (e.g., official contact information) would help us communicate with establishments more effectively and schedule inspections more efficiently.

Section 510(j)(1) of the act requires every person who registers to file with the Secretary, at the time of registration, a list of all drugs that are being manufactured, prepared, propagated, compounded, or processed by the registrant for commercial distribution. That list must be prepared in the form and manner prescribed by the Secretary and must be accompanied by a copy of labeling (or the label and package insert) and, in some cases, advertising. Section 510(j)(2) of the act requires listing information updates every June and December. This listing information gives us a current inventory of marketed drugs. These provisions of the act and others, together with section 701(a) of the act, provide authority for requiring the submission of listing information set forth in this proposal. The drug listing information specified in this proposal would help us: (1) Develop a more current, robust inventory of drugs as a counter-terrorism measure; (2) more effectively administer our postmarketing surveillance programs; (3) facilitate recalls of products; (4) identify drugs or ingredients in short supply in the event of a national emergency; and (5) identify drugs marketed in violation of the law.

Sections 510(j)(1), (i), and (p), and 701(a) of the act also give us the discretion to require that registration and listing information be submitted in electronic format. Electronic receipt of registration and listing information would enable us to shift resources from more ministerial tasks, such as data entry, to the important public health objectives described previously in this document. Additional authority for requiring that content of labeling be submitted in electronic form stems from, among others, sections 201(n) and (p), 501, 502, 503, 505, 510(j)(1)(A) and (j)(1)(B), and 512 of the act. The certification requirement would help us with the efficient enforcement of the act because we would be able to distinguish between situations where there has been noncompliance with registration and listing requirements from situations where there have been no changes in information. The failure to register or list is a prohibited act under section 301(p) of the act and the failure to do either renders a drug misbranded under section 502(o) of the act.

We also have the authority to require the appropriate NDC number (in human-readable form) on certain drug labels for the efficient enforcement of various sections of the act. The appropriate NDC number in human readable form would, among other things, serve as a backup for the appropriate NDC number encoded in the bar code. That is, the human readable form of the NDC number could be manually keyed into a computer system by a health care provider if the bar code is damaged, cannot be read, or is otherwise illegible. Our legal authority to impose the human readable NDC number requirement, at least in part, is similar to that for requiring bar codes on labels (69 FR 9120, 9147–9149). These sections include sections 201(n) and (p), 501, 502, 503, 505, and 701(a) of the act, and sections 351 and 361 of the PHS Act.

Other sections of the act also provide authority for the human-readable NDC number requirement. The failure to register and list are prohibited acts and render drugs misbranded under sections 301(p) and 502(o) of the act. It would be possible for FDA investigators to read the NDC number on the drug's label and review information in our database to ascertain compliance with registration and listing requirements. Where a drug does not bear the appropriate NDC number, investigators can conduct further followup to discern, for example, whether there has been a failure to comply with registration and listing requirements (including those for NDC numbers). Accordingly, sections 201, 301(p), 502(o), 510, and 701(a) of the act provide additional authority for requiring the appropriate NDC number in human readable form on certain drug labels.

There is also additional legal authority for the rule's requirements as to biological products regulated under the PHS Act. Section 351(a) of the PHS Act provides for the approval, as well as the suspension and revocation, of biologics license applications. The human-readable NDC requirement for biological drugs and blood and blood components is designed to ensure the continued safe and effective use of licensed biological products. Additionally, section 361 of the PHS Act authorizes regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. With specific regard to blood and blood components, the human- readable NDC number requirement will aid in the control of units that are at risk of spreading communicable diseases.

VI. Analysis of Economic Impacts

A. Introduction

We have examined the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and the Congressional Review Act.

Executive Order 12866 directs regulatory agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is not considered economically significant under Executive Order 12866.

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act), if a regulation has a significant economic impact on a substantial number of small entities, we must analyze regulatory options that would minimize the impact on small entities. We have conducted a preliminary regulatory flexibility analysis for the proposed rule, and we believe it will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation) in any one year. Currently, such a statement is required if costs exceed about $115 million for any one year. UMRA does not require us to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result

in any 1-year expenditure that would exceed $115 million.

The Congressional Review Act requires that regulations determined to be major must be submitted to Congress before taking effect.

We contracted with the Eastern Research Group, Inc. (ERG), to collect data, interview industry experts, and estimate the costs and benefits of the proposed rule. The analysis and references in support of the effects of the proposed rule are summarized in table 2 and are included in the docket as Reference 3. Although we were unable to quantify specific benefits attributable to the proposed rule, we believe the ultimate use of electronic registration and listing data justify taking this action.

TABLE 2.—SUMMARY OF ANNUAL COSTS AND BENEFITS OF THE PROPOSED RULE[1]

Annual Discount Rate	Average Annual Costs (in Millions)	Average Annual Benefits	Average Annual Net Benefits
3%	$5.6	Unquantified. Benefits accrue by having accurate and unique identification of drugs that would allow greater use of technology.	N/A
7%	$5.8	Unquantified. Benefits accrue by having accurate and unique identification of drugs that would allow greater use of technology.	N/A

[1]Based on 10-year evaluation period.

B. Objective

The objective of the proposed regulation is to update our process for registering drug establishments and listing drugs. The current system does not allow for timely updates of important information and the current system for NDC numbers has introduced the potential for the misidentification and mistaken administration of drugs. We believe that electronic submission of registration and listing information, as well as our assignment of specific identifiers (i.e., the NDC number), would improve the quality and timeliness of information available to health care professionals and consumers. We further believe that these quality improvements would result in safer and more effective use of drugs by providing up-to-date and easily accessible relevant information. We also believe that we should develop and maintain a high quality database of drugs available on the market to enhance future uses of technology in the delivery of health care.

C. Baseline Conditions and Scope

As discussed elsewhere in this preamble, we currently maintain databases that contain establishment registration and drug listing information. However, these databases rely on paper forms that manufacturers, repackers, relabelers, drug product salvagers, and private label distributors of drugs (both human and animal) must submit to us. The completed forms are then entered into our databases. These databases are intended to include identification of establishments involved in the manufacturing, preparation, propagation, compounding or processing of drugs, including the repacking, relabeling, and salvaging of drugs (human and animal prescription and OTC drugs, as well as active pharmaceutical ingredients), the procedures that take place at each establishment (e.g., repacking, or relabeling), and a list of each drug being manufactured, prepared, propagated, compounded, or processed for commercial distribution at each site. We rely on these databases to identify manufacturers, repackers, relabelers, drug product salvagers, and private label distributors, of human and animal drugs, specific drugs or ingredients, to facilitate recalls or information alerts in the case of potential safety concerns, and to otherwise exercise competent oversight of this important industry.

The quality and completeness of these databases depends on prompt submission of updated information from manufacturers, repackers, relabelers, drug product salvagers, and (currently) private label distributors, as well as our immediate inclusion of the data into our system. We are currently unable to verify the accuracy of the information submitted, and some manufacturers, repackers, relabelers, drug product salvagers, and private label distributors are not prompt in informing us of changes. For example, some changes in processing or packaging might be submitted periodically rather than when such changes actually occur. In addition, forms may be mishandled, or even lost, which further reduces confidence in the databases.

Using a 5-digit labeler code, we estimate that we have the capacity for NDC numbers for up to 100,000 registered establishments, each having a capacity for up to 100,000 product/package size combinations (using the 5 remaining digits). If a registered establishment requires more than 100,000 product/package size codes, we could issue that establishment an additional labeler code. We currently have about 25,000 active establishments in our registration database, utilizing less than half of the 5-digit labeler code capacity. We currently issue about 1,000 new labeler codes annually. If we reach NDC number capacity (possibly in 30 to 50 years), we could propose to either add alphanumeric capability or expand the number of numeric digits to 11 or 12 (current § 207.35(b)(2)(i) states that FDA will go from a 5- to 6-digit labeler code if needed). This change in NDC numbers will necessitate advances in current UPC technology (due to the need for bar code reading), which we anticipate will likely occur prior to our reaching the 10-digit NDC numeric capacity.

TABLE 2A.—COUNT OF POTENTIALLY AFFECTED HEALTHCARE ENTITIES

Type of Entity	Establishments	Source	Additional Comment
Pharmaceutical manufacturers (human)	666	Orange Book, 2003	Includes only those pharmaceutical firms that have at least one currently marketed product in the United States. Might be an overestimate due to the possibility of applicant name duplication in the database. Does not include firms that only manufacture unapproved drug products.

TABLE 2A.—COUNT OF POTENTIALLY AFFECTED HEALTHCARE ENTITIES—Continued

Type of Entity	Establishments	Source	Additional Comment
Pharmaceutical manufacturers (animal)	80	Census, 2004	Includes firms that own establishments that manufacture animal drugs. Includes some firms that manufacture both human and animal drugs, so overstates the number that manufacture animal drugs exclusively. Does not include firms that only manufacture unapproved drug products.
Pharmacies	67,434	Listed below	Sum of pharmacy categories (chain store headquarters offices are not counted in this total)
Chain store (headquarters office)	25	NWDA, 2000	Covers headquarters for firms ranging from CVS (4,100 stores) to companies operating over approximately 35 stores.
Chain	20,493	NACDS, 2001	National Association of Chain Drug Stores Web site (*http://www.nacds.org*)
Independent	24,500	NCPA, 2002	National Community Pharmacists Association Web site (*http://www.ncpanet.org*)
Mass merchant	5,910	NACDS, 2001	National Association of Chain Drug Stores Web site (*http://www.nacds.org*)
Supermarket	8,531	NACDS, 2001	National Association of Chain Drug Stores Web site (*http://www.nacds.org*)
Institutional	7,950	ERG, 2001	Profile of the Pharmaceutical Compounding Industry: Draft Final Report. Submitted to FDA, Office of Policy, Planning, and Legislation, Office of the Commissioner, August 27, 2001.
Mail order	50	ERG, 2001	Based on discussions with Winkelman (2004)
Pharmacy benefit management companies (PBMs)	76	ERG, 2001	Profile of the Prescription Drug Wholesaling Industry: Final Report, February 12, 2001. Submitted to Office of Policy, Planning, and Legislation, Office of the Commissioner, FDA. The figure is reported by SMG Marketing Group, Inc.
Hospitals	6,116	AHA, 2002	American Hospital Association Web site (*http://www.ahadata.org*)
Compendium companies	5	ERG, 2004	Estimate based on discussions with Winkelman (2004)
Wholesalers/distributors	6,500	ERG, 2001	Profile of the Prescription Drug Wholesaling Industry: Final Report, February 12, 2001. Submitted to Office of Policy, Planning, and Legislation, Office of the Commissioner, FDA. The report notes that this is probably an underestimate.
Group purchasing organizations	701	ERG, 2001	See note in previous row.
State Medicare agencies	50	ERG, 2003	Allocated one per State.
Physician offices	195,655	Census, 2000	NAICS 62111 from County Business Patterns 2000, U.S. Census Bureau.
Dentist offices	116,494	Census, 2000	NAICS 62121 from County Business Patterns 2000, U.S. Census Bureau.

Note: ERG did not include various health care facilities, such as nursing homes and rehabilitative care facilities, that generally do not have on-site pharmacies.

The pharmaceutical and biological products industries (as defined by the North American Industrial Classification System (NAICS)) consist of 1,218 establishments (NAICS 325412 and NAICS 325414). ERG examined the 2003 ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the ''Orange Book'') to estimate the number of companies currently operating establishments that are marketing drugs. While the Orange Book covers only products approved under section 505 of the act, there is sufficient overlap between manufacturers of products listed in the Orange Book and manufacturers of other types of products (e.g., manufacturers of OTC monograph products and animal drugs) to provide a basis for estimating the industry sector affected by the proposed rule. ERG estimates that a total of 666 companies own and operate manufacturing establishments. In addition, according to U.S. Census data, there are an estimated 80 companies that manufacture animal drugs in the United States. (There is likely overlap between human and animal drug companies.) Finally, the packaging and labeling services industry (NAICS 561910) consists of 229 companies. Each of these establishments would be affected by the proposed rule.

Several provisions of the proposed rule affect establishments rather than companies. We used FDA's drug registration system to estimate that there are approximately 9,700 domestic sites.

There are approximately 200,000 distinct packaged products of human and animal (both prescription and OTC) drugs. The information generated by the drug listing process is used by many organizations for many purposes. Each specific drug is entered into our listing database. If the drug is later withdrawn from the market, for example, this is also noted. The pharmaceutical industry is undergoing corporate changes through mergers, acquisitions, and closings. These activities result in additional reporting requirements (via the current paper system) to keep our databases up-to-date. However, the magnitude of information required to

keep the system current and the number of activities that would generate changes in the data have weakened our ability to rely on the current database.

In addition, the current drug listing system includes the use of the NDC system. Using this system, manufacturers, repackers, and relabelers of drugs (including human prescription, human OTC, certain biologics, and animal drugs) assign unique NDC numbers to each drug. An NDC number consists of 10 characters, including a 4- or 5- character labeler code, a 4- or 3-character product code, and a 1- or 2-character package code, and is presented in one of three formats (4–4–2, 5–3–2, or 5–4–1). Manufacturers, repackers, and relabelers notify us of the assigned NDC number at the time of drug listing, and the numbers may be printed on the label and labeling of each drug.

As discussed earlier in this document, we currently assign the labeler code to registered manufacturers, repackers, and relabelers of drugs. The manufacturer, repacker, or relabeler assigns the product code and package code to its drugs and must report the NDC number to us. Currently, when a manufacturer, repacker, or relabeler withdraws a drug from the distribution chain, NDC numbers for the discontinued drugs may be reused after 5 years.

This process and format for NDC numbers was introduced over 20 years ago as a means of identifying individual drugs by distinguishing, among other things, between specific strengths and package sizes for reimbursement purposes. Since the NDC system was created in 1969, a variety of uses for the NDC number have developed within the healthcare industry.

We have used the NDC number to facilitate recalls of drugs for a number of years. The identification system allows for notification throughout the distribution chain in the event of a recall or other warning about specific drugs.

The development of computerized systems and the ability to electronically transmit information have had a major effect on the ways NDC numbers are used. Because the NDC numbers are designed to be unique identifiers, many sectors of the industry have built systems to maximize the usefulness of this information. Compendium service companies assemble and distribute information to retail stores, hospitals, prescription benefit managers (PBMs), insurance companies, and electronic medical record companies among other users. These users rely on NDC numbers to identify drugs within their tracking or processing systems. The NDC numbers are incorporated into their internal software to facilitate scanning (such as by cashiers or hospital personnel) or for the operation of data processing systems for reimbursement (both private and public) or inventory management. In addition, these compendium databases often include drug price information directly associated with the NDC numbers.

In some cases, the designers of the information systems that use NDC numbers convert the NDC number for use in industry databases. They add a zero to result in a consistent 11-digit format (5–4–2). Also, while visual use of NDC numbers uses hyphens to differentiate between the labeler-product-package codes, these hyphens are not read when scanned (as a bar code, for example). Because three formats are used within the current NDC system, removing hyphens introduces potential duplicates.

Other government entities, such as the Center for Medicare and Medicaid Services (CMS) and the Drug Enforcement Administration (DEA) use the NDC numbers to meet their mission requirements. The numbers are used to provide data for negotiated rebates or notification of distribution of controlled substances.

Companies are continually updating their drug information and price data. Generic relabeling companies and OTC manufacturers often repackage or remarket their products. These fairly constant revisions present a challenge to both compendium companies and us because maintaining the accuracy of the NDC database relies on prompt notification of any changes, but notification is not always prompt or consistent.

The NDC components (labeler, product, and package codes) have presented issues that may compromise the current database. For example, we assign only one labeler code to each manufacturer, repacker, or relabeler, but many companies have multiple labeler codes due to mergers and acquisitions and may use them to distinguish between different divisions within the new company. Pharmaceutical companies have taken different approaches to handling product codes. For example, some firms assign product codes sequentially while others use predefined blocks of numbers for each operating division. Similarly, the methods used to assign package codes are not uniform.

Many repackers currently use the manufacturer's NDC number instead of their own when repacking drugs into smaller packages for pharmacies. Among the reasons such repackers do this is because Medicaid and other third-party payers use the NDC number presented on the drug to file rebate claims with the manufacturers. Such repackers sometimes present the manufacturer's NDC number in an effort to fall under the manufacturer's agreement with payers.

D. The Proposed Regulation

This proposed regulation would require the electronic submission of registration and listing information. The proposed rule would require, for example, drug product salvagers to list drugs and would not permit private label distributors to register establishments or list drugs, and would specifically define the responsibilities associated with each type of establishment covered by the proposal. The proposed rule would not permit manufacturers, repackers, and relabelers to assign the product code and package code for newly listed drugs. We would assign the entire NDC number for drugs.

Under the proposed rule, the electronic establishment registration and drug listing system must be used to enter and update all registration, listing, and NDC number information no later than 9 months after the effective date of a final rule. (We are proposing that any final rule based on the proposal become effective 90 days after publication in the **Federal Register**.) Manufacturers, repackers, and relabelers would have until 9 months after the effective date of a final rule to review and update the NDC number information in our databases for each of their drugs to ensure that it complies with the proposal. In addition, manufacturers, repackers, and relabelers would have, for prescription drugs, 3 years after the effective date of a final rule and, for OTC drugs, 7 years after the effective date of a final rule, to ensure that the appropriate NDC number correctly appears on the label of each of their listed drugs, in accordance with the proposal. These costs have been accounted elsewhere in this analysis.

By requiring electronic drug registration and listing, this proposed rule would enhance the use of technology and provide the basis for efficiencies in the proper use of drugs. For example, the use of bar coded information to avoid adverse events associated with medication errors requires consistent information on the drug label. Other initiatives, such as electronic prescribing, may require the electronic accessibility of this information. This proposed rule would be an important step for the timely and useful availability of information that would benefit patients.

E. Costs

The major potential cost of the proposed rule is the assignment of NDC numbers by FDA. Although the proposed rule includes a selected alternative to minimize this cost, the potential impact could be very large, and is discussed in the Alternatives section of this document. Other costs associated with electronically submitting registration and listing information are discussed later. Costs have been analyzed and discounted using the methodology suggested by OMB's Circular A–4 (September 2003).

1. Costs of a Single Method of Assigning NDC Numbers

Currently, each manufacturer, repacker, and relabeler has its own method for assigning the product code and package code to its drugs. Under the proposed rule, we would assign the product code and package code. Existing NDC numbers would not be affected, as long as they meet the proposed requirement for NDC numbers.

Because, the proposed changes to the NDC numbering system would affect product codes and package codes, and because NDC numbers are used by some sectors of the health care industry for reimbursement or inventory purposes, we expect that the proposed changes would have some effect on the data processing infrastructure. The primary area of impact would be in PBM tasks such as generation and maintenance of drug formularies for insurance coverage purposes. Other areas that would be affected include data analyses conducted by manufacturers, repackers, and relabelers, especially with respect to rebate predictions and market forecasts.

a. *Pharmaceutical manufacturers.* Changes to the NDC number would likely affect rebate processing by manufacturers as well as the ability of pharmaceutical firms to conduct market research analyses.

Common practice in the prescription pharmaceutical industry includes agreements that provide rebates from manufacturers to large insurance payers for use of a manufacturer's drugs by the insurer's enrollees. Medicaid and other large programs have negotiated these rebates with individual manufacturers. Each firm's staff reviews invoices, makes corrections, resolves disputes, and remits rebate payments to insurers based on reported volumes of sales to patients enrolled in the insurance plans. Most manufacturers use the current NDC numbers to identify the dispensed products during this process. A common practice among manufacturers is to group reimbursement data by product code in order to analyze payment history and resolve disputes with insurance carriers.

Because new product codes may be assigned without sequencing under the proposed rule, this may require manufacturers to devote more staff-time to manually group products for rebate processing. Additional data entry work would be required if, for example, an additional data field were added to reports in order to retain the ability to sort products on the basis of product codes.

Market research departments within the pharmaceutical industry also use the current configuration of NDC numbers when conducting analyses that affect product pricing and packaging. The ability to sort by product code allows for efficient use of data records, and randomization of product codes would result in additional staff-time to conduct rebate processing.

Initially, the loss of the ability to group products based on sequential product codes could require staff to either manually sort products or map the new randomized NDC number into another, internal sorting system. Over time, as new NDC numbers are assigned with new product codes and package codes, we expect that all manufacturers, repackers, and relabelers would eventually use automated mapping systems to track product codes. ERG has determined through interviews with industry information technology staff that it would take approximately 80 hours of programming to devise, validate, and introduce an automated mapping system for each affected company. In addition, ERG interviews determined that approximately 100 new packaged products are marketed per year for each manufacturer, and it would take approximately 0.083 hours (5 minutes) per product to map and validate the assigned NDC number to a new internal number for each internal database. ERG further determined that an average manufacturer is likely to have three internal databases that would utilize the new NDC numbers. Each manufacturer would require about 25 hours of programmer time per year in maintenance of these systems. The 2003 Bureau of Labor Statistics (BLS) has published hourly pay and benefit rates of $64 for senior computer programmers. Thus, each manufacturer would incur first-year costs of about $5,100 (80 hours x $64 per hour) and annual costs of about $1,600 (100 product packages x 0.083 hours x 3 databases x $64 per hour). During 2003, according to estimates based on FDA's Orange Book and the Census of Manufacturers, 746 manufacturing companies marketed at least one prescription, OTC, or animal drug product in the United States (666 domestic human drug manufacturers and 80 domestic animal drug manufacturers). These manufacturers would incur first-year costs of $3.8 million ($5,100 x 746 companies) and annual costs of $1.2 million ($1,600 x 746 companies) because of newly assigned product codes and package codes.

Although not included as a cost of the proposed regulation, we estimate that foreign manufacturers of drug and biological products would incur first-year and annual costs due to the proposed rule. The magnitude of any costs would depend on the specific prevailing wage rate for computer programmers in the respective countries. We note that foreign establishments would also experience some increase in costs because of the proposed rule. OMB Circular A–4 allows for the consideration of regulatory costs to foreign establishments, and requires such an analysis if the costs are significant. However, the relatively small marginal costs of the proposed rule and the undertainty of the effect, if any, on consumer prices convinced us to limit the analysis on the costs to domestic establishments and companies.

b. *Pharmacies.* We believe that retail pharmacies (that would not be required to register or list) would generally be unaffected by the proposed rule because most pharmacy processing systems do not use the internal component of NDC codes. In those cases where pharmacies use the components, we believe software vendors will make any appropriate revisions.

However, ERG found that large pharmacy chains were concerned about possible changes in NDC numbers. Some large chains use the current NDC numbers for the adjudication of claims. (''Adjudication'' refers to the process by which pharmacists submit reimbursement claims to customer health plans.) Most formularies are built and maintained by PBMs or individual State Medicaid plans, but the chains have noted an increase in smaller plans that are maintained by individual retail stores. In order to serve these small, local insurance plans, data entry staff at the participating stores enter NDC numbers of the requested drugs using ''wild card'' symbols (such as asterisks) to indicate that any number in the wild card position is acceptable. For example, the package code of an NDC number may be entered as a wild card

symbol to indicate that any package or strength of the indicated product is acceptable for reimbursement under that specific insurance plan. This ability allows data entry clerks to add groups of products quickly.

The proposed assignment by us of product codes and package codes could affect this practice. Several executives in the chain drug industry asserted to ERG that this change would result in possibly hiring as many as four additional data entry clerks. Although other respondents felt that this claim overstated the expected increased effort, they could not provide alternative estimates. According to the BLS, the annual salary for a data entry operator in 2003 was $33,240 plus about 38 percent in benefits. We have used approximately $50,000 per year as typical annual compensation for this industry. Therefore, using this estimate of additional staff, each affected chain would experience an increased annual cost of $200,000 (4 additional clerks x $50,000).

According to the National Wholesale Drug Association, there are 25 large chain headquarters offices of corporations that operate at least 35 separate retail drug store outlets. ERG expects that only 10 percent of these corporations would potentially be affected by the proposed rule because relatively few chain stores use software that enables the use of ''wild card'' data entry for portions of the NDC numbers. This results in total industry annual operating costs of $500,000 (25 large chain operations x 0.10 x $200,000).

c. *Pharmaceutical benefit managers*. PBMs are the entities that build formularies and adjudication services for insurance plans. The software used for these services usually makes use of the NDC number. For example, when a PBM builds a formulary for an insurance plan, the data entry staff may enter the NDC numbers of the selected drugs into processing software. As discussed previously in the section on the expected effect on retail pharmacy chains, wild card symbols may be used to indicate that any number in the position of the wild card symbol is acceptable to the formulary and, thus, reimbursable. This practice works in cases where the product code of the NDC number is in sequence. In some cases, only the labeler code may be entered and wild card symbols are used for the rest of the NDC number to signify that any product from that company (i.e., manufacturer, repacker, relabeler, or private label distributor) is acceptable. This use of wild card symbols allows data entry clerks to quickly add groups of products, and according to respondents of ERG interviews, saves substantial time. Several managers of PBMs suggested that manual entry of all NDC numbers would be similar to those of pharmacy chain operators and could result in hiring as many as four additional employees (FTEs) per year. Using the BLS data, the annual salary of $33,240 and industry benefits of approximately 38 percent of salary results in typical compensation of around $50,000 per FTE. If so, then increased costs to PBMs would be approximately $200,000 per year per affected PBM (4 additional clerks x $50,000).

However, not all PBMs would be affected by this change in NDC numbers. In discussions with ERG, only one supplier of adjudication software was identified as providing the ''wild card'' feature. This provider estimated that his clients constituted about 10 percent of the industry, so we have assumed that about 10 percent of the PBMs use this feature. Therefore, ERG has estimated that only 10 percent of PBMs would likely experience increased costs because of the proposed rule. ERG identified 76 PBMs for a 2001 profile of the prescription drug wholesaling industry (Ref. 4). Using this estimate, annual costs of the proposed rule for this industry segment are estimated to be $1.5 million (76 PBMs x 0.10 affected by the proposed rule x $200,000).

d. *Other entities*. ERG examined the potential effect of the proposed revisions to the NDC number on hospitals, compendium companies, wholesalers/distributors, group purchasers, State Medicaid agencies, physician offices, and dental offices. None of these sectors were identified as being significantly affected by the proposed rule. These sectors maintained that as long as the NDC number maintained its format, any adjustments would be minimal. In particular, respondents asserted that preservation of the labeler code in the NDC number would be sufficient for many of these users of NDC numbers. Other users of the NDC numbers (such as hospitals) are expected to be able to accommodate any changes without major modifications to their data systems.

e. *Total costs of NDC number revision*. Overall, we expect that revising the process by which NDC numbers are assigned will have a one-time cost during the first year of $3.8 million and annual, recurring costs of $3.2 million.

2. Other Costs of the Proposed Rule

Potential costs of the proposed rule also include: (1) The costs and cost savings for obtaining NDC numbers and recurring electronic registration and listing submissions; (2) the costs of label revisions for some drugs to include NDC numbers; (3) the costs of setting up electronic submissions of registration information, listing information, and content of labeling; and (4) the costs of continuing the submission of content of labeling. In addition, discussions with industry revealed two areas of potential concern that are not specific costs of the proposed rule. The first area of concern is potential delay in the assignment of NDC numbers, and the second area of concern is the use of repacker or relabeler NDC numbers on drug labels (rather than the manufacturer's NDC number) and the effect on negotiated reimbursements with third-party payers, including CMS.

a. *Costs and cost savings for obtaining NDC numbers and recurring electronic registration and listing submissions*. This category consists of eight types of identified costs or cost savings:

- Costs for prospectively obtaining NDC numbers for human prescription drug products, human OTC drug products, animal prescription drug products, animal OTC drug products, and active pharmaceutical ingredients.
- Costs for electronic submission of new drug listings.
- Costs for electronic submission of changes to drug listings.
- Costs to certify no drug listing changes.
- Costs for drug product salvagers to list.
- Costs to register new establishments electronically.
- Costs to review and update establishment registration electronically, including certifying no changes.
- Costs to obtain user accounts from FDA.

Currently, manufacturers, repackers, relabelers, and drug product salvagers register establishments and (except for salvagers) list their drugs. This can be a time-consuming procedure involving different forms that collect data for later computer entry. Forms must be completed by hand and changes to information to be submitted to us require that the entire form be redone.

With electronic submission of this information under the proposed rule, information may be keyed in and any changes may be made to the information submitted. Information would not have to be resubmitted each time. We expect the proposed rule will result in substantial time and cost savings in the use of electronic submissions.

New NDC numbers for drugs: ERG used FDA drug listing data to determine that over 11,000 new domestic drug

listings occur each year (foreign drug listings are not counted in this analysis). The time required to submit information and coordinate with FDA for an NDC number is estimated to be 0.5 hours per drug (incremental to the time required for a firm to assign NDC numbers to themselves.) The BLS reports that the compensation (including benefits) for a mid-level manager within this industry is $51.73. We expect the annual cost to obtain NDC numbers for new drugs to equal about $0.3 million (11,000 new drug listings x 0.5 hours x $51.73 per hour.)

Electronic submission of new drug listings: Currently, it takes approximately 2.5 hours to compile, copy, and mail drug listings to FDA. The annual cost for this activity is currently $1.4 million (11,000 drug listings x 2.5 hours x $51.73 per hour.) We expect that this activity will only require approximately 1 hour per drug listing if submitted electronically under the proposed rule. The annual cost would then be $0.6 million (11,000 new drug listings x 1 hour x $51.73 per hour.) Electronic submission of drug listings would result in annual cost savings of $0.8 million.

Electronic submission of changes to drug listings: Currently, any changes to drug listings entail that the entire form be redone by hand. Therefore, approximately 2.5 hours is currently required to compile, copy, and mail any change to FDA. FDA's drug listing data estimate that there are approximately 36,000 changes to domestic drug listings each year. The current cost of this activity is $4.7 million (36,000 annual changes x 2.5 hours x $51.73 per hour.) Electronic submission of changes is expected to require only 0.5 hours per submission. The expected annual cost of using electronic submissions would be $0.9 million (36,000 annual changes x 0.5 hours x $51.73 per hour). Electronic submission of changes to drug listings would result in annual cost savings of $3.8 million.

Electronic certification of no drug listing changes: As discussed earlier in this document, there are 83,600 domestic drug listings that must be reviewed twice a year to certify that there are no changes to the listing. There are approximately 36,000 annual changes to domestic drug listings, so we expect 131,200 annual certifications ((83,600 drug listings x 2 annual reviews)—36,000 changes). The time required to electronically certify that there have been no changes is not expected to be more than 0.25 hours (15 minutes.) The total cost of certification of no drug listing changes is $1.7 million (131,200 annual certifications x 0.25 hours x $51.73.)

Drug product salvagers: According to industry experts, only about 5 percent of all listed drugs may be salvaged during any year. According to our listing data, there are approximately 83,600 domestic drug listings (foreign listings are not counted here), so approximately 4,200 domestic drugs are estimated to be salvaged each year (83,600 x 0.05.) Since the original manufacturer usually acts as the salvager, under the proposed rule, the original drug listing would be available electronically and could be easily copied to produce the drug listing for the salvaged drug. We expect that copying and submitting that drug listing (or withdrawal) would take 0.167 hours (10 minutes) and result in total annual costs of only $36,000 (4,200 salvaged drugs x 0.167 hours x $51.73 per hour.)

Electronic submission of new establishment registrations: According to our registration database, there are an average of approximately 1,100 new sites registered each year, of which about 900 are domestic. The current registration process for new establishments takes 2.5 hours. The annual cost to register new establishments is about $0.1 million (900 new domestic registrations x 2.5 hours x $51.73 per hour). The proposed rule will require new registrations to be done electronically and we expect this will take approximately 1 hour per registration. The cost of registering new establishments with the proposed rule would equal about $47,000 (900 new domestic registrations x 1 hour x $51.73 per hour.) The use of electronic submissions for new establishments would result in cost savings of about $0.1 million.

Electronic review and update of establishment registration: There are currently 9,700 domestic registered sites that must reregister each year, including certification of no changes to their registration information, and there are about 1,500 annual updates to domestic registration forms. The current estimate for this activity is 2.5 hours per submission for a current cost of about $1.4 million ((9,700 registered sites + 1,500 annual updates) x 2.5 hours x $51.73 per hour). We expect each annual registration will take 0.5 hours and each amendment will be expedited and take only 0.25 hours under the proposed rule. Annual registration would have a cost of about $0.3 million (9,700 registered sites x 0.5 hours x $51.73 per hour). FDA has estimated that expedited updates of changes to registration under the proposed rule would require only 0.25 hours (15 minutes) per update. The cost of this activity under the proposed rule would be only $20,000 (1,500 annual updates x 0.25 hours x $51.73 per hour.) This includes the costs to review and certify that there are no changes to registration information. The proposed rule is expected to result in annual cost savings of $1.1 million from electronic review and update of establishment registration.

FDA user accounts: Prior to submitting electronic registration and listing information, the proposed rule requires manufacturers, repackers, relabelers, and drug product salvagers to obtain a user account from FDA. The proposed rule has us contacting each manufacturer, repacker, relabeler, and drug product salvager to request information to establish an account. FDA data suggest that 8,300 such requests would be made, based on primary registrants, of which 6,700 would be domestic firms. We expect each request to take about 0.25 hours (15 minutes.) The total one-time cost of this requirement is about $0.1 million (6,700 companies x 0.25 hours x $51.73 per hour.)

Total cost savings of electronic registration and listing: Overall, the proposed rule is expected to result in annual cost savings of approximately $3.8 million due to electronic submission of registration and listing information. There is a one-time cost of $0.1 million for obtaining FDA user accounts.

Some manufacturers expressed concerns about potential time lags due to our assignment of product codes and package codes, but the electronic process should provide for prompt responses to requests for NDC numbers from FDA. Also, manufacturers commented that if labeler codes must be consolidated across subsidiaries or divisions, additional costs would occur.

We do not anticipate that we will receive requests for waiver of the requirement to submit registration and listing information electronically. However, if we receive waiver requests, we do not expect the costs to exceed those that would be incurred by paper submission of the information.

b. *Costs of label revisions to include NDC numbers.* The proposed rule would require that appropriate human-readable NDC numbers appear on the labels of all drugs that are required to be listed, including biological products and active pharmaceutical ingredients.

Prescription human drugs: Many manufacturers, repackers, relabelers and private label distributors, particularly those subject to the regulation addressing bar code label requirements (''Bar Code Label Requirements for

Human Drug Products and Human Biological Products''; 69 FR 9120, February 26, 2004), already voluntarily include the NDC number in human-readable form under the barcode representation, as space permits. This proposed rule would require the appropriate human-readable NDC number to appear on drug labels for drugs subject to the listing requirements. Some packaging lines for prescription drugs have already been retooled to accommodate the unit-of-use requirement as set forth in the bar code rule. The costs of retooling these package lines have been analyzed in the bar code rule. However, we still expect as many as 60 percent of all prescription separately packaged drug products[12] to be revised because of the proposed rule.

Currently, human-readable NDC numbers appear with an ''N'' or ''NDC'' prefix. The proposed rule would require use of only the ''NDC'' prefix. In addition, there are classes of prescription drugs that are exempt from the bar code rule that would be subject to the requirement in this proposed rule (i.e., that the drug labels for drugs subject to listing requirements bear the appropriate NDC number in human-readable form). There are some products (e.g. allergenic extracts) that do not currently print NDC numbers on labels that would be obligated to do so under the proposed rule.

We lack specific data on the proportion of affected labels, but believe that 50 percent would be revised to include the ''NDC'' prefix and an additional 10 percent may be accounted in one of the other categories. (Although the exact proportion of labels affected by this provision is unknown, we expect between 25 and 75 percent of all drug labels to require revisions. We have assumed that 50 percent of all labels will be affected for analytic purposes.) Therefore, ERG estimated that 46,800 separately packaged drug products would need revised relabels under the proposed rule.

Prescription drugs would be required to have revised labels that include appropriate human-readable NDC numbers within 3 years of the effective date of the final rule. Therefore, incremental regulatory costs would occur for any product label not revised during routine label changes that may occur during the 3-year period. (ERG has assumed that no incremental cost occurs if required label changes occur during other label revisions.) FDA has examined a number of prescription drug files and found that prescription products are sometimes revised as frequently as once a year. However, some prescription products rarely have label revisions in response to market conditions. We have assumed that 25 percent of prescription drug labels would not be revised during the 3-year implementation period in the absence of the proposed rule, or 11,700 separately packaged drug products.

ERG has estimated weighted label revisions as costing an average of about $1,600 per separately packaged product (Ref. 5.) The cost of revising prescription human drug labels to include NDC numbers is estimated to total $18.7 million (11,700 separately packaged drug products x $1,600 per label revision.) However, these costs are not expected until 3 years after the implementation of the final rule because companies would not know if there would be market driven label changes and therefore wait until the end of the implementation period. The present values of the cost of these label revisions are $17.1 million (using a 3-percent annual discount rate) and $15.3 million (using a 7-percent annual discount rate.)

OTC human drugs: FDA has estimated that only 30 percent of all human OTC separately packaged products currently have human-readable NDC numbers printed on labels. However, the proposed rule allows for a 7-year implementation period for OTC drugs to include NDC numbers on labels. Based on previous studies of the OTC drug industry (Ref. 5), ERG has estimated that virtually all OTC drugs have label revisions within 6-year periods. Label changes over this period are mostly motivated by marketing trends and because ample space is usually available on most OTC labels, the inclusion of NDC numbers could be accommodated during these revisions at minimal additional cost.

However, ERG discussions with industry contacts raised concerns about the new label requirements as they apply at the OTC unit-of-use level (e.g., blister packs). Most drugs marketed as units-of-use, including those subject to the bar code rule, would require label changes, but not changes to packaging or printing equipment, and are of sufficient size to accommodate human-readable NDC numbers. However, some packaging lines for unit-of-use OTC products not subject to the bar code rule might need to be retooled to accommodate human-readable NDC numbers. These modifications are expected to be fairly challenging and the costs of applying NDC numbers to blister packs would be in addition to normal label revisions. ERG discussed the costs of these changes and found that line retooling costs to be approximately 150 percent of a normal label revision, or $2,400 for each affected drug. Industry consultants estimated that as many as 5,000 units-of-use packaged OTC human drugs could be affected. The cost to label units-of-use drugs is $12.0 million (5,000 drugs x $2,400 per drug). Unlike voluntary label revisions, manufacturers are not expected to routinely retool production lines during the implementation period. Therefore, affected companies are expected to upgrade lines during the 7-year implementation period with an industry cost of $1.7 million each year. The present values of this cost are equal to $10.6 million (using a 3-percent annual discount rate) and $9.2 million (using a 7-percent discount rate).

Prescription and OTC animal drugs: ERG estimated that each of the 2,100 registered domestic animal drug sites produce 4 separately packaged drug products and that normal label revisions occur at the same rate as for human drugs. In addition, industry consultants have estimated that approximately 40 percent of animal drugs currently have readable NDC numbers on labels and would not be affected by the proposed rule. Thus, ERG expects that of the 60 percent of labels that would need revisions, 75 percent would be revised in the normal course of business during the 3 years after implementation of the final rule. Therefore, a total of approximately 1,300 animal drugs would require revised labels to include human readable NDC numbers (both prescription and OTC) (2,100 sites x 4 separately packaged products x 0.6 needing label revisions x 0.25). Using a weighted cost per labeling revision of $1,600, the cost during the third year to the industry of applying NDC numbers to labels due to the proposed rule would be $ 2.1 million (2,100 separately packaged products x $1,600 per label change). The present value of this cost is $1.9 million (using a 3-percent annual discount rate) and $1.7 million (using a 7-percent discount rate). We do not believe there will be costs associated with retooling package lines for animal drugs.

Active pharmaceutical ingredients. Active pharmaceutical ingredients would be required to bear appropriate human-readable NDC numbers on drug labels under the proposed rule. Currently, many active pharmaceutical ingredients are shipped with bills of

[12] The number of separately packaged drug products is the number of drugs times the number of dosage forms times the number of concentrations times the number of package sizes. There are currently about 78,000 separate domestic prescription separately packaged drug products based on NDC number listings.

lading that are prepared for each shipment and an NDC number could be easily added for a negligible incremental cost. For the purposes of this analysis, we have assumed that 50 percent of all active pharmaceutical ingredients will be required to add human-readable NDC numbers as a result of this proposed rule. According to FDA's current registration and listing data, there are about 4,300 domestic bulk drug substances so about 2,150 are expected to require label changes because of the proposed rule. The costs of providing label changes for active pharmaceutical ingredients are assumed to be equal to the cost of label revisions for prescription drug products, or $1,600 per revised label. The total cost of revising active pharmaceutical ingredient labels is $3.4 million (2,150 labels x $1,600 per label). We have no data on voluntary label revisions for active pharmaceutical ingredients and have assumed that the revisions will occur throughout the implementation period (approximately $1.1 million per year). The present values for this cost are $3.2 million (using a 3-percent annual discount rate) and $3.0 million (using a 7-percent annual discount rate).

Total costs of label revisions. The overall incremental costs of label revisions under the proposed rule have present values of $34.0 million (using a 3-percent annual discount rate) and $30.3 million (using a 7-percent discount rate).

c. *Costs of setting up electronic submission of registration, listing, and content of labels.* The proposed rule would require manufacturers, repackers, relabelers, and drug product salvagers of drugs, including human and animal drug products, active pharmaceutical ingredients, and biological products to register establishments, list drugs, and, for manufacturers, to provide the content of labeling electronically using specific software. Most, but not all, manufacturers of human prescription drug and biological drug products are already subject to requirements to submit content of labeling in electronic format, but manufacturers of OTC monograph and animal drug products not currently subject to these labeling requirements would not necessarily have this software. The current requirement to submit content of labeling in electronic form does not extend to repackers and relabelers. In addition, active pharmaceutical manufacturers producing ingredients for OTC drug products may not have the correct software to submit registration and listing information electronically.

According to discussions with industry consultants, approximately 75 percent of drug product manufacturers market only OTC monograph products. Using U.S. Census estimates of the industry, we believe about 550 firms would need to purchase needed software for electronic submissions for content of labeling. We note that this estimate is based on the first level of ownership and does not account for multiple layers of corporate hierarchy. We surveyed a range of prices for software (such as Adobe Acrobat Standard, for example) that would be expected to be used in a professional environment. The estimated price of this software is approximately $250, with some variance for the specific desired features and sophistication. We note that this cost represents the marginal difference between any current software and new software with the capability to work with assigned NDC numbers, and is an incremental cost of the proposed rule. After discussing this estimate with industry IT personnel, we expect $250 to represent a reasonable cost of software acquisition. In addition, training for 2 employees is expected to cost $150 per employee. Training is expected to require 6 hours for each employee at a cost of $51.73 per hour (based on fully loaded BLS wage rates for mid-level management within this industry). The total cost per firm is about $1,000 ($250 + (2 employees x $150) + (2 employees x 6 hours x $51.73) for a total cost to the OTC monograph industry for software acquisition and training to be $0.6 million to submit content of labeling electronically.

We expect similar costs of $1,000 would accrue for all 350 companies that are predominantly involved in medicinal and botanical manufacturing (Census, 2004), which includes active pharmaceutical ingredient manufacturers, in order for these companies to electronically submit registration and listing information. According to Small Business Administration data, as well as industry consultants, there are approximately 250 repackers and relabelers that serve the pharmaceutical industry. Each of these entities would require software and training in order to register and list. Finally, there are 80 firms that, according to U.S. Census data, predominantly or secondarily manufacture animal drugs that would require software and training to electronically submit content of labeling. The total costs of software acquisition and training for these segments is an additional $0.7 million ((350 active pharmaceutical ingredient manufacturers + 250 repackers and relabelers + 80 animal drug manufacturers) x $1,000).

The overall cost of software acquisition and training under the proposed rule is $1.4 million.

d. *Costs of continuing submissions of content of labeling.* Additional costs might be incurred to submit the incremental content of labeling for a small proportion of drugs for which there have been labeling changes. The content of labeling, as described elsewhere in this proposal, must be submitted electronically. Makers of active pharmaceutical ingredients are not affected by this provision because they would not be expected to submit content of labeling electronically.

For affected OTC drugs, we have assumed that two content of labeling submissions per listed drug will occur twice a year to account for the possibility of multiple dosage forms and concentrations in a product line. Animal products are expected to have an average of 1.5 content of labeling submissions per product twice a year. According to our drug listing system, there are about 30,400 domestic OTC drugs and about 4,200 domestic animal drugs. Using the assumption that each submission would entail 0.25 hours (15 minutes), and using the industry wage rate of $51.73 per hour, the annual cost of this provision is $1.7 million ((((30,400 domestic OTC drugs x 2 content of labeling submittals) + (4,200 domestic animal drugs x 1.5 content of labeling submittals)) x 2 times per year) x 0.25 hours per submission x $51.73 per hour).

e. *Delays in NDC Assignment.* We understand from discussions with manufacturers that many manufacturing processes are dependent on timely assignment of NDC numbers. According to industry consultants, before drugs can be mass-produced, manufacturers of both prescription and OTC drug products need to know the NDC number for the production run. Currently, manufacturers control the assignment of NDC numbers once they have a labeler code, so this is not a problem that could affect the production process. There is concern about delays in production because new NDC numbers assigned by us might not be timely from a manufacturer's viewpoint and could result in major costs.

However, in discussions with several manufacturers, comments to ERG reflected that if the assignment of NDC numbers by FDA was done electronically and transmitted to the companies electronically, there would likely be a negligible impact on operations. Since FDA intends to assign and transmit NDC numbers

electronically, we do not believe this provision would result in additional costs to industry.

f. *Effect of the proposed rule on third-party reimbursement.* Under the proposal, repackers and relabelers would not be allowed to use the manufacturer's human-readable NDC numbers on their drug labels. Many companies noted that reimbursement arrangements are contracted between drug manufacturers and third-party payers (including Medicaid programs) that provide for rebates for sales of a manufacturer's drug. Most reimbursement plans use NDC numbers as the appropriate billing code, and repackers and relabelers note that they are not part of the negotiated rebate plans between manufacturers and third-party payers. Repackers and relabelers further claim that profit margins for their firms will not allow for such reimbursements. Thus, the process of negotiating these payments would be affected by the proposed rule, but we did not estimate the outcome of future negotiations.

g. *Other potential costs.* The proposed rule might have other impacts on various industry sectors. For example, the relationships between drug manufacturers and private label distributors may be altered because of the proposed registration, listing, and NDC requirements. Some industry sources have asserted that the proposed rule may make private label distributors unprofitable and that manufacturers would directly supply drugs to retailers. We are unable to assess this impact, and are unsure whether it would, in fact, result in market inefficiencies, but note that there would likely be changes in the current relationships between these sectors. We specifically request comment on any economic impact the proposal would have on this relationship between drug manufacturers and private label distributors.

3. Costs to FDA for Implementing the Proposed Rule

We do not expect a major increase in the need for internal resources associated with the proposed rule. Activities related to the assignment of NDC numbers are expected to be equivalent to our current activity of receiving notifications from industry and manually inputting the information into our databases. Similarly, we expect any increased workloads caused by increased submissions of registration or listing information or content of labeling to be approximately equivalent to the internal reduction in workload from electronically updating our databases. The database of NDC numbers for marketed drugs would require maintenance and updating to ensure the quality of the data, and we would make this database available for other users, but the costs associated with activity have been accounted for in previous rule-making (see Bar Code Label Requirements for Human Drug Products and Human Biological Products, 69 FR 9120 at 9156). The registration and listing information will also be included in the database and we do not expect any additional costs to be associated with maintenance of this information.

However, the requirement that manufacturers, repackers, relabelers, and drug product salvagers obtain a user account from us would require increased use of our resources. We have estimated that 6,700 entities would be contacted in order to provide them with their user accounts, and that each contact would require 0.25 hours (15 minutes). This would require about 1,600 hours of FDA resources, or about 0.8 FTEs. The current weighted cost per FTE is approximately $120,000, so the one-time cost to FDA for providing access codes for the proposed rule would be approximately $0.1 million.

4. Total Costs of the Proposed Rule

Table 3 shows the initial investment costs and annual costs of the proposed rule over a 10-year period by cost category.

TABLE 3.—UNDISCOUNTED COSTS OF PROPOSED RULE BY CATEGORY (IN MILLIONS OF DOLLARS)

Cost Category	Initial Investment/One Time	Annual Costs/Recurring
Single Method of Assigning NDC Numbers	$3.8	$3.2
Electronic Drug Registration and Listing	$0.2	(-$3.8)
Label Revisions	$36.2	———
Software Acquisition and Training	$1.3	———
Continued COL Submissions	———-	$1.7

Table 4 shows the expected expenditures per year for the evaluation period and includes total present values based on 7 percent and 3 percent discount rates. Recurring costs include the retooling of OTC packaging systems to provide NDC numbers for units-of-use during the first 7 years of the proposed regulation.

TABLE 4.—COSTS PER YEAR FOR THE PROPOSED RULE (IN MILLIONS OF DOLLARS)

Year	One-Time Costs	Recurring Costs
1	$8.1	$1.1
2	$2.8	$1.1
3	$23.7	$1.1
4	$1.7	$1.1
5	$1.7	$1.1
6	$1.7	$1.1

TABLE 4.—COSTS PER YEAR FOR THE PROPOSED RULE (IN MILLIONS OF DOLLARS)—Continued

Year	One-Time Costs	Recurring Costs
7	$1.8	$1.1
8	-	$1.1
9	-	$1.1
10	-	$1.1
Present Value	3% - $38.1	3% - $9.4
	7% - $33.0	7% - $7.7

Average annualized costs of the proposed rule are estimated to be $5.6 million using a 3 percent annual discount rate or $5.8 million using a 7 percent annual discount rate.

F. Benefits

Benefits of the proposed rule will result because the improved processes in the proposed regulation would generate up-to-date, complete medication information, including NDC numbers, to support a growing number of medical and health information technology initiatives. The potential benefits of these initiatives are significant. For example, the final regulation that required bar coded NDC numbers on some human drugs and biological products (69 FR 9120) estimated benefits of approximately $5 billion per year for the avoidance of over 500,000 adverse drug events associated with medication errors. These benefits are dependent on correct and unique NDC numbers being read by scanners at patient bedsides. The lack of accurate NDC numbers may delay the acceptance of this technology and decrease the potential patient benefits. We have estimated that if the lack of reliable NDC numbers would delay the rate of technological acceptance by 1 year, the potential benefits of the bar code regulation would be reduced by about $600 million per year and an average of 25,000 additional adverse drug events would occur.

We believe it is critical to other patient safety initiatives, such as DailyMed or electronic prescribing, that a reliable and consistent NDC numbering system be in place. The potential benefits of these initiatives could be similar to the benefits of the bar code rule, and any delay in implementing these programs because of the lack of electronic access to reliable identifying information could seriously limit their impacts.

The proposed rule would allow increased access to information in our databases. Increased use of these databases to efficiently treat patients would rely on the availability of information electronically. A key element for encouraging the use of technology to ensure public health will be the assurance that NDC numbers are unique and accurately identify drugs. The proposed rule would accomplish this by making assignment of NDC numbers our responsibility, rather than a responsibility diffused throughout the industry. In addition, by ensuring that these NDC numbers are available in human-readable format, patients and others would be able to access important patient safety information from the DailyMed system, the NDC Directory, or other drug information electronic systems without the use of bar code scanners. Human-readable NDC numbers would allow patients to report any adverse events easily and ensure that our adverse event reporting system is as accessible as possible. Also, the human-readable NDC number would enable us to trace the origin of each product (a particularly important issue when dealing with recalls or drug quality issues) and more easily identify drug products and their sources (this is particularly important when dealing with import and counterfeiting issues). We specifically request comments on quantitative benefits resulting from the requirement that the NDC number be included on the drug label.

The proposed rule would increase the efficiency of the registration and listing process by eliminating most paper submissions. We would be able to review the submitted information more quickly and contact submitting firms immediately if any additional information were needed. The resulting database of registered establishments and listed drugs would provide the basis for increased patient safety by being complete and up-to-date. For example, an electronic database of drugs would allow for timely notification of any recalls of unsafe drugs and identification of affected manufacturers, repackers, relabelers, or drug product salvagers.

By changing the way that NDC numbers are assigned, we would increase the confidence that each drug being manufactured, repacked, or relabeled for commercial distribution has a unique identifier that we have assigned. After we have introduced increased oversight for new product codes and package codes, the likelihood of unsafe counterfeit drug products entering the supply chain would decline because would-be counterfeiters would be unsure of numerical sequences used for NDC numbers. Our assignment of NDC numbers would reduce the possibility of duplicate numbers appearing in various medical and reimbursement databases. Currently, firms have been reusing NDC numbers at times without informing us, and this practice has added uncertainty into these systems. There has been reported confusion about coverage of drugs for reimbursement and our control of the NDC system would ensure that only qualified drugs are subject to reimbursement.

In addition, the current NDC number makeup (using dashes to distinguish between the components) allows for potential duplicate numbers when the dashes are not read by scanners reading NDC numbers encoded in bar codes. This happens because the components used to indicate labeler codes, product codes, and package codes are of differing lengths, and are currently separated by hyphens. If those NDC numbers are barcoded, the differing components may lead to duplicate numbers since bar code scanners don't read hyphens. This would not happen under the proposed rule.

Although we know that the proposed rule will result in significant benefits, we are not able to quantify these benefits. We are confident that moving to electronic registration and listing processes, as well as assignment of NDC numbers, would encourage development of technology in the delivery of health care. We know that the successful development of medical and health information technology initiatives (such as the DailyMed, bar code label, and the electronic prescription drug program described below) will depend in large part on an accurate, reliable NDC number and that this proposed rule would further that development. Therefore, there are real benefits associated with the proposed changes to the NDC number and the NDC number assignment process. However, we are not able to quantify those benefits because they rely in part on further development of technology initiatives. Similarly, there are significant benefits associated with the proposed changes to the collection of registration and listing information. For example, ready access to complete and accurate registration and listing information helps to ensure the success of many of our programs, such as postmarketing surveillance (including FDA inspections), bioterrorism initiatives, responses to drug shortages, and user fee assessments. We know there are benefits associated with the efficiencies achieved by improved access to more complete information, but we are not able to quantify those benefits.

We also note that continuation of a paper registration and listing system is likely to act as a deterrent to investment in new initiatives. As discussed earlier in this document, the recently issued final regulation that requires NDC numbers to be encoded in bar codes on certain prescription drugs, certain OTC products, and human blood products helps to avoid adverse drug events due to medication errors. The benefits for that rule would be reduced by as much as $600 million per year if unique NDC numbers are not universally available and this results in delays in the use of this technology. Lack of universal

identifiers would likely discourage investment in machine-readable technology and make access to electronic information difficult.

The proposed rule would provide necessary assurances to health professionals and patients that they have access to up-to-date labeling information and that the safety of the drug supply is assured. It would also encourage investment in installed scanners and readers at points of administration such as hospitals or physician clinics that rely on this information. The existence of this system may support the development of electronic prescribing or other efficiencies in health care that may save money and reduce medication errors that may cause adverse reactions in patients. The electronic prescription drug program (electronic prescribing) established by the Medicare Modernization Act promotes uniform standards that permit (among other things) electronic exchange of drug labeling and drug listing information maintained by us and by the National Library of Medicine. The goal behind the program is to reduce transcription and dispensing errors (which, in turn, lead to medication errors) and to prevent adverse drug interactions. The proposal to assign the NDC number, resulting in an accurate and reliable NDC number, would also facilitate development of the DailyMed). The DailyMed is an up-to-date, computerized repository of medication information, including drug product labeling. The DailyMed, maintained by the National Library of Medicine in cooperation with FDA, is a new way to distribute current and comprehensive medication information in a computerized format for use in health care information systems. Health care information suppliers will be able to use the information from the DailyMed in their computer systems, allowing providers, patients, and the public access to reliable, up-to-date information on the medications they use. The DailyMed would enable drug product users and health care providers to have electronic access to up-to-date information about a drug.

Although the scope of the proposed rule does not extend beyond registration and listing, the high-quality, electronic database that would result from the proposed rule would enable future uses of technology for the public benefit.

G. Small Business Analysis and Discussion of Alternatives

We believe the proposed rule is unlikely to have a significant impact on a substantial number of small entities. Despite this, we have prepared an initial regulatory flexibility analysis and invite comment from affected entities.

1. Affected Sectors and Nature of Impacts

The proposed rule would directly affect manufacturers of pharmaceutical and biological products (NAICS 325412 and NAICS 325414), packaging services (NAICS 561910), retail pharmacy chains (NAICS 446110; Pharmacies), and prescription benefit managers (NAICS 524292; Insurance Plan Administrative Services, Third Party). We assessed data on these industries from the 2002 Economic Censuses and estimated revenues per establishment. The affected establishments are shown in table 2a of this document. Although other economic measures, such as profitability, may provide preferable alternatives to revenues as a basis for estimating the significance of regulatory impacts in some cases, use of any reasonable estimate of profits would not change the results of this analysis. As discussed earlier in the Analysis of Economic Impacts (see section VI.B of this document), we are proposing this rule in order to improve the quality and timeliness of information available to patients and health care professionals. We believe this improvement would result in improved outcomes by providing better uses of medicines by patients.

a. *Pharmaceutical manufacturers (NAICS 325412).* The Small Business Administration (SBA) has defined as small any entity in this industry with fewer than 750 employees. According to census data, 94 percent of the industry is considered small. The average annual revenue for these small entities is $54.7 million per entity. Small entities would be affected by the proposed rule. We estimate the annualized compliance cost for small entities in this industry to average $30,200. This is about 0.1 percent of their annual revenue. We believe this cost does not constitute a significant impact on a substantial number of small entities in this industry.

b. *Biological product manufacturers (NAICS 325414).* The SBA has defined as small any entity in this industry with fewer than 750 employees. According to census data, 97 percent of the industry is considered small. The average annual revenue for these small entities is $15.5 million per entity. Small manufacturers of biological products would be affected by the proposed rule. We estimate the annualized compliance cost for a small entity in this industry to be $30,200. This is about 0.2 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

c. *Packaging services (NAICS 561910).* The SBA has defined as small any entity in this industry that has less than $6.5 million in annual revenue. On this basis, almost 94 percent of the industry is considered small. The average annual revenue for small entities is $1.4 million per entity. We have not identified specific regulatory costs of compliance to this industry. We have no confident data that the extent of electronic registration and listing would increase or decrease costs to these entities. At this point, we tentatively believe the proposed rule would not constitute a significant impact on a substantial number of small entities in this industry and solicit comment in this area.

d. *Retail pharmacy chains (NAICS 446110).* The SBA has defined as small any entity in this industry that has less than $6.5 million in revenue. On this basis, almost 100 percent of the industry is considered small. The average annual revenue for small entities is $3.8 million per entity. We expect that some large pharmacy chains with 35 or more operations would experience increased operating cost of $200,000 due to the proposed rule. However, these large chains do not meet the criteria for small entities because their annual revenues are at least $133 million ($3.8 million times 35 outlets). We do not believe this impact constitutes a significant impact on a substantial number of small entities in this industry.

We do not believe that independent retail pharmacies will be adversely affected by the proposed rule because most pharmacy systems do not use the internal component of NDC numbers. We found no evidence of any impacts, but specifically request comment on this issue.

e. *Prescription benefit managers (NAICS 524292).* The SBA has defined as small any entity in this industry that has less than $6.5 million in annual revenues. On this basis, over 92 percent of the industry is considered small. The average annual revenue for small entities is $1.6 million per entity. We are unable to distinguish PBMs from other insurance administrative services, but have used aggregate industry data. Some PBMs would be expected to experience annual cost increases of $200,000 due to the proposed rule. This constitutes 12.5 percent of annual revenues for the affected entities. However, of the 11,584 small entities in this industry (there are only 76 PBMs of any size) we expect that between 7 and 8 entities would be affected. We do not believe this constitutes a significant

impact on a substantial number of small entities in this industry.

2. Alternatives

We considered several alternatives to the proposed rule. Each is discussed below.

a. *Completely reassign NDC numbers, including existing numbers.* We considered removing the existing format of the NDC number and reassigning randomized numbers for all products. We believe this would improve the robustness of the NDC and allow more numbers to be available for future drugs as well as improve our industry oversight responsibilities. However, discussions with industry representatives suggested that the first-year cost of such an approach could reach more than $900 million. Pharmaceutical manufacturers would be required to completely remap the newly assigned NDC numbers so that existing data processing, rebate, and market analyses tasks could continue. While individual retail pharmacies would not likely be affected, chain stores and PBMs would require large internal reprogramming in order to manage repayment options. Additional quality control procedures would be required to ensure proper reimbursement. Wholesalers and distributors would also require major internal reprogramming to account for the loss of sequential NDC numbers. For this alternative, each State Medicaid program would require an estimated $3 million to reprogram reimbursement software so that each prescription could be tracked. This alternative is described in more detail in Reference 3.

b. *Implementation period.* We considered (and are still considering) different implementation periods. Under the proposal, manufacturers, repackers, and relabelers of prescription drugs would have 3 years to provide NDC numbers on their labels, while manufacturers, repackers, and relabelers of OTC drugs would have 7 years. We examined a total of 25 different implementation plans. These plans include prescription products having between 1 year and 5 years to comply and OTC products having between 5 years and 9 years to comply with the proposed rule. Table 5 shows the difference in average annualized costs between the current implementation plan and the other 24 combinations.

TABLE 5.—DIFFERENCES IN ANNUALIZED COSTS OF DIFFERING IMPLEMENTATION PERIODS (IN MILLIONS OF DOLLARS; 7 PERCENT DISCOUNT RATE)

	5 Year OTC	6 Year OTC	7 Year OTC	8 Year OTC	9 Year OTC
1 Year Prescription	+$2.1	+$2.0	+$1.9	+$1.9	+$1.9
2 Year Prescription	+$1.4	+$1.2	+$1.2	+$1.2	+$1.1
3 Year Prescription	+$0.2	0	——	-$0.1	-$0.1
4 Year Prescription	-$0.9	-$1.0	-$1.0	-$1.0	-$1.1
5 Year Prescription	-$1.4	-$1.5	-$1.5	-$1.6	-$1.6

There was relatively little difference in changes to the OTC drug implementation period because of the ongoing normal revisions to labeling. Only if a 5-year implementation period is selected are there noticeable cost increases. However, shorter implementation periods for prescription products increase costs by about 20 percent for a 2-year implementation period and about 33 percent for a 1-year period. Conversely, while longer implementation periods would reduce annualized costs by similar amounts, the delay in ensuring that medical information technologies would be able to use efficiencies expected from the proposed rule seemed high. Therefore, we selected the proposed implementation periods as a reasonable balance. We solicit public comment on the proposed implementation period and the effect on expected costs and benefits.

c. *Exemption for small entities.* We considered exempting small entities, but rejected the alternative due to the relatively modest impact of this initiative on small businesses and the lack of label standardization that would result. Any potential exemptions to this proposed rule would be on a product basis, not an entity basis. In addition, benefits of having a standardized identification system would be reduced by such blanket exemptions.

Outreach: We will specifically solicit comment from affected small entities on the proposed rule.

d. *Conclusion.* We have analyzed the expected impacts of the proposed rule. This proposal is expected to have average annualized costs of $5.6 million (using a 3 percent annual discount rate) or $5.8 million (using a 7 percent annual discount rate). The benefits include assurance of correct NDC numbers, which would also mean correct bar-coded information, and electronic access to important product information for patients that will improve public health. Despite the fact that we are unable to specifically quantify patient benefits directly attributable to the proposed rule, we believe the benefits would be greater than the expected costs and the proposed rule should be implemented.

VII. Paperwork Reduction Act of 1995

This proposed rule contains collections of information 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). ''Collection of information'' includes any request or requirement that persons obtain, maintain, retain, or report information to the agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). The title, description, and respondent description of the information collection are shown under this section with an estimate of the annual reporting 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 the collection of information.

We invite comments on these topics: (1) Whether the collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be

collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: *Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs*

Description: The proposed rule would reorganize, consolidate, clarify, and modify current regulations on registering establishments and listing human and animal drugs under part 207, blood and blood products under part 607, and HCT/Ps under part 1271. The proposal describes when and how to register and list and what information must be submitted for registration and listing. The proposal makes certain changes to the NDC system for drugs and would require the appropriate NDC number to appear on drug labels (for drugs subject to the drug listing requirements). The proposed regulations would require the electronic submission of all registration and most listing information instead of the current use of paper forms.[13]

FDA currently reviews completed registration and listing forms and other submissions required under current parts 207, 607, and 1271. The information collection for current part 207 is approved by OMB until December 31, 2007, under OMB Control Number 0910–0045. The information collection for current part 607 and Form FDA 2830 is approved by OMB until March 31, 2009, under OMB Control Number 0910–0052. The information collection for current part 1271 and Form FDA 3356 is approved by OMB until July 31, 2007, under OMB Control Number 0910–0469.

FDA has estimated, in Tables 6, 7, and 8 of this document, the burden to comply with all of the information collection requirements for proposed parts 207, 607, and 1271. These estimates are based on FDA's experience in reviewing registration and listing submissions and on the number of submissions currently received, the number of respondents submitting this information, and the number of registered establishments and listed drugs, blood products, and HCT/Ps currently in FDA's database. The estimates discussed below are for each section of proposed parts 207, 607, and 1271 that contain a reporting burden under the PRA.

A. Registration Information Under Part 207

1. Proposed Requirements

Under proposed § 207.17, manufacturers, repackers, relabelers, and drug product salvagers must register establishments. This is consistent with current registration requirements, except that currently private label distributors may submit information (similar to registration information) to obtain a labeler code from FDA. In addition, the estimates include PET drug producers who would not be exempt from registration under the proposal.

Under proposed § 207.21, domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers must complete initial registration of each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. In addition, foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers must register each establishment before the drug is imported or offered for import into the United States. This is consistent with current registration requirements, except that the proposal would include additional foreign establishments as a result of the revocation of the exemption for drugs that enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U.S. commerce, and for drugs imported under section 801(d)(3) of the act.

The information that must be provided to FDA for registration is described under proposed § 207.25. The information that would be required under proposed § 207.25 differs from the information currently required for registration. The following currently required information would not be required under the proposal: The kind of ownership or operation and the title of each corporate officer and director. New information required under the proposal would be the type of operations performed at each establishment and contact information about the official contact and the United States agent, each importer of the drug that is known to the establishment, and each person who imports or offers for import the drug to the United States.

Under proposed § 207.29, manufacturers, repackers, relabelers, and drug product salvagers must review annually their registration information. During the review, manufacturers, repackers, relabelers, and drug product salvagers must report all changes to their registration information or certify that no changes have occurred. In addition to the annual review and update, manufacturers, repackers, relabelers, and drug product salvagers must submit expedited reports of certain changes within 30 calendar days of the change. Currently, manufacturers, repackers, relabelers, and drug product salvagers must renew their registration information annually and submit certain amendments to registration within 5 days of a change. Proposed § 207.29 differs from the current requirement to submit amendments to registration in the following ways: The proposal would lengthen the current time period for reporting changes to registration information from 5 days (10 business days for a change in United States agent information) to 30 calendar days. The proposal would revoke the current requirement to report a change in individual ownership and corporate or partnership structure, and the current requirement to submit a signed statement for a change in a registered establishment's firm name. New requirements under the proposal would be to certify that no changes have occurred and to report as expedited updates certain changes within 30 calendar days, such as the close or sale of an establishment. Modified requirements would be to submit within 30 calendar days a change in the name or address of an establishment and a change in contact information for the official contact and United States agent.

2. Burden Estimates

Based on the number of new establishments that currently register each year by submitting Form FDA 2656, we estimate that approximately 987 manufacturers, repackers, relabelers, and drug product salvagers will provide electronically approximately 1,128 new establishment registrations annually. Based on the number of registered establishments in our database, we estimate that approximately 8,343 manufacturers, repackers, relabelers, and drug product salvagers will provide approximately 12,137 annual reviews and updates of registration information or reviews and certifications that no changes have occurred. Based on the number of changes to registration information that have been submitted annually on Form FDA 2656e, we estimate that approximately 775 manufacturers, repackers, relabelers, and drug product salvagers will provide approximately 1,921 expedited updates.

The estimates include the registration of establishments for both domestic and

[13] The electronic submission of registration and listing information would remain voluntary for blood products.

foreign manufacturers, repackers, relabelers, and drug product salvagers. The estimates for the number of manufacturers, repackers, relabelers, and drug product salvagers excludes the number of private label distributors currently in the database that submit information to receive a labeler code. The estimates include an additional 80 PET drug producers who would not be exempt from registration under the proposal, and approximately 30 manufacturers of plasma derivatives. In addition, the estimates include five additional foreign establishments that would be required to register as a result of the revocation of the exemption for drugs that enter a foreign trade zone and are reexported from that foreign trade zone without having entered U.S. commerce, and for drugs imported under section 801(d)(3) of the act.

We estimate that it will take approximately 60 minutes to provide electronically the initial registration information for each new establishment. This estimate is only until manufacturers, repackers, relabelers, and drug product salvagers become familiar with using the electronic drug registration and listing system. We intend to lower this burden estimate to approximately 30 minutes when we submit to OMB the request to renew approval of this information collection.

We also estimate that it will take approximately 30 minutes for each annual review and update of registration information or each review and certification that no changes have occurred. This estimate is only until manufacturers, repackers, relabelers, and drug product salvagers become familiar with using the electronic drug registration and listing system. We intend to lower this burden estimate to approximately 15 minutes when we submit to OMB the request to renew approval of this information collection.

We also estimate that it will take approximately 15 minutes to provide each expedited update. This estimate is only until manufacturers, repackers, relabelers, and drug product salvagers become familiar with using the electronic drug registration and listing system. We intend to lower this burden estimate to approximately 5 minutes when we submit to OMB the request to renew approval of this information collection.

The burden hour estimates above are based on our familiarity with the content of current registration forms and submissions and the times required by industry volunteers to input registration information during our electronic drug registration and listing system pilot project (discussed in section IV.E.3 of this document). The estimates are an average of the time it would take to register a domestic or foreign establishment and an average of the time it would take to review registration information and update several registration items in the database or review registration information and only certify that no changes have occurred. We note that these estimates for the electronic submission of this information would be a reduction in the currently approved estimate of 2.50 hours (OMB Control Number 0910–0045) for preparing and mailing to FDA Form FDA 2656.

We intend to migrate into our new database current registration information that had been submitted using paper forms. As a result, current manufacturers, repackers, relabelers, and drug product salvagers would require additional time to review in the new database all current registration information and make any necessary revisions. We assume that this one-time initial review will be the first annual review and update using the electronic system, and we estimate it will take an average of 30 minutes for each review and update.

B. Listing Information Under Part 207

1. Proposed Requirements

Under proposed § 207.41, manufacturers, repackers, relabelers, and drug product salvagers must list drugs they manufacture, repack, relabel, or salvage for commercial distribution (this includes drugs they manufacture, repack, relabel, or salvage for a private label distributor). This proposed requirement is consistent with the current listing requirements, except that drug product salvagers are not currently required to list under part 207 and private label distributors may submit listing information directly to FDA.

Under proposed § 207.45, manufacturers, repackers, relabelers, and drug product salvagers must list, at the time of initial registration of an establishment, any drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at that establishment. This is consistent with the current listing requirements, except that drug product salvagers are not currently required to list under part 207.

Under the proposal, the human-readable NDC number must appear on the drug's label (for drugs subject to the listing requirements). The information that must be provided electronically to us by manufacturers, repackers, and relabelers (including drug product salvagers who repack and relabel) to receive an NDC number is described under proposed § 207.33. Currently, the human-readable NDC number is not required to appear on the drug's label, but most prescription drugs and about one-third of the OTC drug products have the NDC number on the label. We currently assign a labeler code to each manufacturer, repacker, relabeler, and private label distributor to be part of the NDC number, and the manufacturer, repacker, relabeler, and private label distributor assigns the remainder of the NDC number to each drug product. Under the proposal, for drugs listed after the effective date of the proposal, the NDC number for a drug must be obtained from us before (or at the time) that drug is listed. Some of the information currently required to list the drug would be submitted under the proposal to receive the NDC number. The assigned NDC number would be submitted as part of the listing information and would serve as a link to the information already submitted for the drug to obtain the NDC number.

The information that must be provided electronically to us by manufacturers, repackers, and relabelers to list a drug is described under proposed §§ 207.49, 207.53, 207.54, 207.55, and 207.61. As mentioned previously in this document, drug product salvagers are not currently required to list the drugs they salvage. The listing information and the NDC number information required under the proposal is consistent with the information currently submitted to FDA on Forms FDA 2657 or 2658, except for the following: (1) The proposal would require identification information about the name of each importer of the drug that is known to the establishment and each person who imports or offers for import a drug to the United States (importer information is currently required under the Bioterrorism Act); (2) the content of labeling would be submitted electronically (for approved human drugs, the information collection burden for this requirement is accounted for under current § 314.50(l)(1)(i), approved under OMB Control Number 0910–0001); (3) the quantity of the active pharmaceutical ingredient would be required for all drugs subject to the listing requirements (unless the approved application number is provided) (this requirement is substantially the same as the current requirement); (4) the name of the inactive ingredients for certain drugs would be required under the proposal (unless the approved application number is provided); (5) repackers and relabelers would be required to submit

the NDC number assigned to the drug immediately before they received the drug; (6) additional information to identify the manufacturer, repacker, relabeler, and drug product salvager would be required (such as e-mail address, fax number, and labeler code); (7) the submission of a representative sampling of labeling would include advertisements under § 202.1(l)(1); (8) certain listing information would not have to be submitted if the approved U.S. application number for the drug is provided; (9) the DMF number would be submitted by the manufacturer to obtain an NDC number for an active pharmaceutical ingredient; and (10) drug product salvagers (who do not repack or relabel) would submit the lot number and expiration date and NDC number assigned to the drug immediately before the drug is received by the drug product salvager.

Under proposed § 207.57, manufacturers, repackers, relabelers, and drug product salvagers must review each June and December all drug listing information that has been provided to us and must report all material changes or certify that no changes have occurred. Manufacturers, repackers, and relabelers must also notify us at this time if any listed drug has been discontinued from marketing or if any discontinued drug has resumed marketing and provide listing information for any drug not yet listed. Under the proposal, all manufacturers, repackers, relabelers, and drug product salvagers must review the listing information for each drug listed and report any material changes. Current regulations do not specify that the information for each listed drug needs to be reviewed, nor is a certification required if there are no changes. Only material changes to listing information must be reported. Under the proposal and consistent with section 510 of the act, manufacturers, repackers, relabelers, and drug product salvagers must also update their listing information for drug products that have not been previously listed at the time registration information for each establishment is updated.

Under proposed § 207.33(f), manufacturers, repackers, and relabelers must notify us of a change in any of the drug characteristics (except certain identifying information) for an NDC number in § 207.33, and we would assign a new NDC number for that drug.

Under proposed § 314.81(b)(3)(iii), applicants under part 314 must report electronically within 30 calendar days the withdrawal of an approved drug product from sale (the current requirement is to report within 15 days).

2. Burden Estimates

Based on the current receipts of Forms FDA 2657 and 2658 for new listings, we estimate that approximately 1,812 manufacturers, repackers, relabelers, and drug product salvagers will provide electronically approximately 13,821 new listings annually.

Based on the number of drugs in our listing database and the current receipts of Forms FDA 2657 and 2658 for changes to listing information (and, until recently, the number of receipts of compliance verification reports), we estimate that approximately 2,278 manufacturers, repackers, relabelers, and drug product salvagers will provide approximately 22,568 June and 22,568 December reviews and updates of listing information (a total of 45,136 submissions annually), and that approximately 5,594 manufacturers, repackers, relabelers, and drug product salvagers will provide approximately 81,980 June and 81,980 December reviews and certifications that no changes have occurred (a total of 163,960 submissions annually).

The estimates for the number of drug listings submitted by manufacturers, repackers, relabelers, and drug product salvagers include both domestic and foreign listings and the listings that would be submitted by manufacturers, repackers, relabelers, and drug product salvagers for private label distributors. The estimates also include the time for submitting information for an NDC number under proposed § 207.33. The drugs that would be listed include PET drugs, an additional 57 drugs listed by approximately 5 foreign establishments as a result of the revocation of the exemptions for foreign establishments, and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information or reviews and certifications that no changes have occurred would include the number of changes to drug characteristics submitted to obtain a new NDC number under proposed § 207.33(f) and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii) and, for biological products, under § 601.2(f).

Based on our familiarity with the content of current listing forms and submissions and the time required to input listing information during our electronic drug registration and listing system pilot project, we estimate that it will take manufacturers, repackers, relabelers, and drug product salvagers approximately 1 hour and 30 minutes to provide electronically information for each drug they list for the first time (for both foreign and domestic listings). This estimate is an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers, with drug product salvagers taking considerably less time than manufacturers. This estimate includes the time for submitting the content of labeling in electronic format under proposed § 207.61(a)(2) and for submitting other labeling and advertisements in paper or electronic format under proposed §§ 207.49(g) and (h) and 207.53(d) and (e). This estimate is only until manufacturers, repackers, relabelers, and drug product salvagers become familiar with using the electronic drug registration and listing system. We intend to lower this burden estimate to approximately 45 minutes when we submit to OMB the request to renew approval of this information collection.

We also estimate that it will take approximately 30 minutes for each June and December review and update of listing information, and approximately 15 minutes for each review and certification that no changes have occurred. These estimates include the time for submitting any labeling and advertisements for each drug, changes to the drug's characteristics submitted for a new NDC number under proposed § 207.33(f), and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii). This estimate is only until manufacturers, repackers, relabelers, and drug product salvagers become familiar with using the electronic drug registration and listing system. We intend to lower this burden estimate to approximately 15 minutes for each review and update and approximately 5 minutes for each review and certification when we submit to OMB the request to renew approval of this information collection. We note that these estimates for the electronic submission of this information would be a reduction in the currently approved estimate of 2.50 hours (OMB Control Number 0910–0045) for preparing and mailing to FDA Form FDA 2657 and FDA Form FDA 2658.

We intend to migrate into our new electronic drug registration and listing system current listing information that had been submitted using paper forms. As a result, current manufacturers, repackers, relabelers, and drug product salvagers will need additional time to review all current listing information in the new database and make any necessary revisions. We estimate that it will take on average 45 minutes to review and update each drug's listing

information (the listing information includes information submitted for an NDC number).

C. Registration and Listing Information Under Part 607

1. Proposed Requirements

Under proposed § 607.22, manufacturers may electronically obtain, complete, and submit to FDA Form FDA 2830 (Blood Establishment Registration and Product Listing) or may request a copy of the form by e-mail. Currently, under § 607.22, manufacturers must register establishments and list blood products on Form FDA 2830. The proposal is consistent with the current requirement to register establishments and list products approved under OMB Control Number 0910–0052.

Under proposed § 607.25(b)(1), blood establishments are required to list blood products by the established and proprietary name. This proposal is consistent with the current listing requirement approved under OMB Control Number 0910–0052. Currently, blood establishments list bulk product substances as well as finished dosage forms under both parts 607 and 207 to obtain an NDC number. The proposal would reduce reporting burden by requiring blood establishments to list only under part 607. To be consistent with part 207, we are also proposing to delete the reference in part 607 to Form FDA 2250 (National Drug Code Directory Input) because this form is no longer being used by CDER or CBER.

Under proposed § 607.40, foreign establishments must register each establishment before their blood product enters a foreign trade zone and are reexported from that foreign trade zone without having entered U.S. commerce. This proposal is consistent with the current registration requirement in that establishments must register before their blood products are imported or offered for import into the United States. The proposal would also include additional foreign establishments as a result of the revocation of the exemption under section 801(d)(4) of the act for blood products that enter a foreign trade zone and are reexported from that foreign trade zone without having entered U.S. commerce. Under the proposal, we are requiring additional information for each foreign establishment. The proposal would also require the foreign establishment to report to FDA changes in the United States agent's name, address, telephone and fax numbers, and e-mail address within 30 calendar days of the change. The proposal would lengthen the time period from 10 business days to 30 calendar days for reporting changes in the United States agent to FDA.

2. Burden Estimates

Based on the number of new establishments that currently register with FDA each year, we estimate that approximately 15 foreign establishments would provide new establishment registrations annually. Based on the number of registered establishments in our database, we estimate that approximately 21 foreign establishments would provide approximately 105 annual reviews and updates of registration information or reviews and certifications that no changes have occurred. Based on the number of changes to registration information that have been submitted annually on Form FDA 2830, we estimate that approximately 21 foreign establishments would provide approximately 80 product listing updates.

The estimates above include 10 foreign establishments with blood products that enter a foreign trade zone and are reexported from that foreign trade zone without having entered U.S. commerce under section 801(d)(4) of the act. We estimate that it would take approximately 60 minutes to provide the initial registration and listing information for each new establishment.

We estimate that it would take approximately 30 minutes for each annual review and update of registration and listing information, including each review and certification that no changes have occurred.

We estimate that it would take approximately 15 minutes to provide the product listing update for each establishment.

The burden hour estimates above are based on institutional experience with the current registration and listing requirements. The estimates are an average of the time it would take to register a foreign establishment and an average of the time it would take to review registration and listing information and update several registration and listing items in the database or review information and only certify that no changes have occurred.

D. Registration and Listing Information Under Part 1271

1. Proposed Requirements

Under proposed § 1271.22, establishments must register, list products, and provide updates electronically. The current regulation requires registration, listing, and updates either electronically or in paper form using Form FDA 3356 and is approved under OMB Control Number 0910–0469.

Under proposed § 1271.25, establishments would submit the telephone and fax numbers, and e-mail address of the reporting official. Each foreign establishment would submit the name, the address, telephone and fax numbers, and e-mail address of each importer that is known to the establishment and the name of each person who imports or offers for import such HCT/P to the United States. Foreign establishments would also submit the name, the address, telephone and fax numbers, and e-mail address of their United States agent.

Under proposed § 1271.26, establishments must report a change to the United States agent's name, address, telephone and fax number, and e-mail address. The proposal would also lengthen to 30 calendar days the current requirement of reporting the changes within 5 days.

2. Burden Estimates

Based on the number of new establishments that currently register with FDA each year, we estimate that approximately 300 establishments would provide new establishment registration annually. Based on information from FDA's database, we estimate that approximately 2,000 establishments are registered and listed with FDA. The number of establishments that currently register and list with FDA include both foreign and domestic establishments. Based on information from FDA's database, we estimate that approximately 1,400 establishments would provide establishment and listing updates. If no change has occurred, an update is not required. Based on the number of establishments from FDA's database, we estimate that approximately 1,800 establishments would provide approximately 2,100 changes to establishment ownership or location, or changes to the United States agent's information.

We estimate that it would take approximately 45 minutes to provide the initial registration and listing information for each new establishment.

We estimate that it would take approximately 30 minutes for each annual review and update of registration and listing information for each establishment.

We estimate that it would take approximately 15 minutes for each establishment to provide a change in ownership and location, or a change to the United States agent's information.

The burden hour estimates above are based on institutional experience with the current registration and listing requirements. The estimates are an average of the time it would take to register an establishment, and an average of the time it would take to review registration and listing information, and update several registration and listing items in the database.

E. User Account Information for Electronic System

Under proposed § 207.61, establishment registration and drug listing information must be submitted to us in electronic format. In addition, the content of labeling must be submitted in electronic format. Other labeling and advertisements may be provided in paper or electronic format. Electronic format submissions must be in a form that we can process, review, and archive. Prior to accepting registration and listing information from the online system, we may need to authenticate the source (that is, manufacturer, repacker, relabeler, or drug product salvager) providing the data. We are proposing to authenticate entry into the electronic drug registration and listing system by establishing user accounts based on the current registration information. We would contact currently registered manufacturers, repackers, relabelers, or drug product salvagers and request that they provide electronic contact information to establish an administration account.

We estimate that approximately 8,343 manufacturers, repackers, relabelers, and drug product salvagers will provide this information (approximately 8,343 submissions) and that it will take approximately 15 minutes to provide the requested information.

F. Waiver Request Information

1. Part 207

Under proposed § 207.65, manufacturers, repackers, relabelers, and drug product salvagers may request a waiver from the requirement in § 207.61 that information must be provided to us in electronic format. We expect very few waiver requests because only a computer, Internet access, and an email address are needed to register and list.

We estimate that approximately two manufacturers, repackers, relabelers, or drug product salvagers would request a waiver annually, and that each request would take approximately 1 hour to prepare and submit to us.

In those instances when we grant a request for a waiver, we intend to make available to the manufacturer, repacker, relabeler, or drug product salvager paper forms—revised Form FDA 2656 for registration and revised Form FDA 2657 for listing (the listing form would include a section for submitting the information required to obtain an NDC number). We intend to request public comment and OMB approval for the revised forms before the effective date of any final rule. The proposed form will be available from the Division of Compliance Risk Management and Surveillance, Office of Compliance, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8920, *herbert.gerstenzang@fda.hhs.gov* or *john.gardner@fda.hhs.gov*.

2. Part 607

Under proposed § 607.40(f)(1), foreign establishments may request a waiver from the requirement in § 607.40(e) that information must be provided to FDA in electronic format. We expect very few waiver requests because only a computer, Internet access, and an e-mail address are needed to register and list.

We estimate that approximately two manufacturers would request a waiver annually, and that each request would take approximately 1 hour to prepare and submit to us.

In those instances when we grant a request for a waiver, we intend to make available to the manufacturer the paper form—Form FDA 2830 for registration and listing.

3. Part 1271

Under proposed § 1271.23, manufacturers may request a waiver from the requirement in § 1271.22 that information must be provided to FDA in electronic format. We expect few waiver requests because only a computer, Internet access, and an e-mail address are needed to register and list.

We estimate that approximately 100 manufacturers would request a waiver annually, and that each request would take approximately 1 hour to prepare and submit to FDA.

In those instances when we grant a request for a waiver, we intend to make available to the manufacturer the paper form—revised Form FDA 3356 for registration and listing. We intend to request public comment and OMB approval for the revised form before the effective date of any final rule.

G. Public Disclosure Exemption Requests

Under proposed § 207.81(c), manufacturers, repackers, relabelers, and drug product salvagers may request that certain information in proposed § 207.81(a) not be made available from their registration and listing information. Based on our experience with registration and listing information inspection requests under current § 207.37, we estimate that approximately 100 manufacturers, repackers, relabelers, or drug product salvagers would submit this request annually, and that each request would take approximately 1 hour to prepare and submit to us.

H. Revised Labeling Submitted With Annual Report

Under the proposal, the NDC number must appear on all drug labels for drugs subject to the listing requirements. Manufacturers, repackers, and relabelers for drug products that do not already have an NDC number on the label would be required to include the NDC number assigned by us. Manufacturers, repackers, and relabelers for drug products that have an NDC number on the label as it is currently required would be required to examine their current NDC number to ensure that it complies with the NDC number requirements in proposed §§ 201.2, 207.33, and 207.37, and would have to obtain a new NDC number from us if necessary.

When there is a change in the NDC number on a drug label, or when an NDC number is added to a label, application holders must submit revised labeling to us with their annual reports under § 314.81(b)(2) for human drugs, § 514.80(b)(4) for animal drugs (''periodic reports'' are required instead of ''annual reports''), and § 601.12(f)(3) for biological drugs. The submission of annual reports (or periodic reports for animal drugs) under these regulations is already approved by OMB under Control Number 0910–0001 for human drugs (approval expires 5/31/08), Control Number 0910–0284 for animal drugs (approval expires 9/30/06), and Control Number 0910–0338 for biological products (approval expires 9/30/08). There would be no additional information collection burden associated with any labeling revision because of a new NDC number assigned by us because it would be ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' and exempt under the PRA (5 CFR 1320.3(c)(2)). However, we have estimated a burden of approximately 5 minutes per annual report as the time required to state in the annual report that the labeling has been revised to include a new NDC number and the additional time

required to submit to us the revised labeling with the annual report. For the number of submissions, we estimate that no more than approximately one-half of all annual reports submitted for products already listed with FDA on the effective date of the final rule would include this information.

I. Capital Costs

There are one-time capital costs associated with this proposed rulemaking. These costs are discussed in section VI of this document, ''Analysis of Economic Impacts.''

We specifically request comments on the burden hour estimates described previously in this document and in tables 6, 7, and 8 of this document.

Description of Respondents: Manufacturers, repackers, relabelers, and drug product salvagers.

Burden Estimate: Tables 6, 7, and 8 of this document provide an estimate of the annual reporting burden for the proposed registration and listing requirements.

TABLE 6.—ESTIMATED ANNUAL REPORTING BURDEN UNDER PROPOSED PART 207

21 CFR Sections and Reporting Requirements	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Registration and Listing	Total Hours
Initial Establishment Registration (207.25)	987	1.14	1,128	1 hour	1,128
Annual Review and Update of Registration Information (207.29)	8,343	1.45	12,137	.50 hours	6,068.5
Expedited Updates (207.29)	775	2.46	1,921	.25 hours	480.25
Initial Listing and NDC Number Information (207.33, 207.49, 207.53, 207.54, 207.55)	1,812	7.63	13,821	1.50 hrs.	20,731.50
Review and Update of Listing Information (June and December) (207.33, 207.37, 207.57, 314.81(b)(3)(iii), 601.2(f))	2,278	19.81	45,136	.50 hours	22,568
Review and Certification of Listing Information (June and December) (207.57, 601.2(f))	5,594	29.29	163,960	.25 hours	40,990
Review of registration information already in FDA database on effective date of final rule	8,343	1.45	12,137	.50 hours	6,068.5
Review of listing information already in FDA database on effective date of final rule	7,962	13.13	104,548	.75 hours	78,411
User accounts for electronic system	8,343	1	8,343	.25 hours	2,085.75
Waiver requests (207.65) Revised Forms FDA 2656 and 2657	2	1	2	1 hour	2
Public disclosure exemption requests (207.81(c))	100	1	100	1 hour	100
Annual report revision for new NDC number (314.81(b)(2), 514.80(b)(4), 601.12(f)(3))	3,981	13.13	52,289	5 minutes	871.5
Total Reporting Burden					179,505

TABLE 7.—ESTIMATED ANNUAL REPORTING BURDEN UNDER PROPOSED PART 607

21 CFR Sections	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Registration and Listing	Total Hours
Initial Establishment Registration and Blood Product Listing (607.40)	15	1	15	1	15
Annual Review and Update of Establishment Registration and Blood Product Listing (607.40)	21	5	105	0.5	52.5
Product Listing Update (607.40)	21	3.8	80	0.25	20
Waiver requests (607.40(f)(1)) Revised Form FDA 2830	2	1	2	1	2
Total Reporting Burden					89.5

TABLE 8.—ESTIMATED ANNUAL REPORTING BURDEN UNDER PROPOSED PART 1271

21 CFR Sections	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Registration and Listing	Total Hours
Initial Establishment Registration and Listing (1271.25)	300	1	300	0.75	225
Annual Review and Update of Establishment Registration and Listing (1271.25)	2,000	1.4	1,400	0.5	501.5
Waiver requests (1271.23) Revised Form FDA 3356	100	1	100	1	100
Amend Establishment Registration (1271.26)	1800	1.16	2100	0.25	525
Total Reporting Burden					1550.5

In compliance with section 3507(d) of the PRA, we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to fax comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington DC 20503, Attn: Desk Officer for FDA, FAX: (202) 395–6974.

VIII. Environmental Impact

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

IX. Proposed Effective Date

We propose that any final rule based on this proposal become effective 90 days after publication in the **Federal Register**.

X. Proposed Compliance Dates

We are proposing that our electronic drug registration and listing system be used to enter and update all registration, listing, and NDC number information no later than 9 months after the effective date of a final rule. As discussed in section IV.C.4.a of this document, manufacturers, repackers, and relabelers would have until 9 months after the effective date of a final rule to review and update the NDC number information in our database for each of their drugs to ensure that it complies with proposed §§ 201.2, 207.33, 207.37, 610.60, and 610.61. In addition, as discussed in section IV.C.4.b of this document, manufacturers, repackers, and relabelers would have, for prescription drugs, 3 years after the effective date of a final rule and, for OTC drugs, 7 years after the effective date of a final rule, to ensure that the appropriate NDC number correctly appears on the label of each of their listed drugs, in accordance with the requirements in proposed §§ 201.2, 207.33, 207.37, 610.60, and 610.61. We are considering shortening the compliance dates by which the appropriate NDC number must appear on drug labels to 2 years after the effective date of a final rule for prescription drugs and 5 years after the effective date of a final rule for OTC drugs. We discuss this issue further in section VI of this document, ''Analysis of Economic Impacts.''

We specifically request comments on these proposed compliance dates.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XII. Request for 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.

XIII. References

The following references have been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from John M. Coster, Vice President, Policy and Programs, NACDS, and Lisa Clowers, Senior Vice President, Industry Relations, HDMA, to Michael D. Jones, FDA, dated September 27, 2004.

2. Letter from the Deputy Director, Division of Prescription Drug Compliance and Surveillance, CDER, FDA to John M. Coster, National Association of Chain Drug Stores, August 24, 1997.

3. Eastern Research Group, Inc., Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Certain Biological Drugs, and Animal Drugs, August 2005.

4. Eastern Research Group, Inc., Profile of the Prescription Drug Wholesale Industry, February 2001.

5. Eastern Research Group, Inc., Cost Impacts of the Over-the-Counter Pharmaceutical Labeling Regulation, March 1999.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 330

Over-the-counter drugs.

21 CFR Parts 514 and 515

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 607

Blood.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 20, 201, 207, 314, 330, 514, 515, 601, 607, 610, and 1271 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa-l.

§ 20.100 [Amended]

2. Section 20.100 is amended in paragraph (c)(9) by removing ''§ 207.37'' and by adding in its place ''§ 207.81''.

3. Section 20.116 is revised to read as follows:

§ 20.116 Drug and device registration and listing information.

Information submitted to the Food and Drug Administration pursuant to section 510(a) through (j) of the act shall be subject only to the special disclosure provisions established in §§ 207.81 and 807.37 of this chapter.

PART 201—LABELING

4. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.1 [Amended]

5. Section 201.1 is amended in paragraph (f) by removing ''§ 207.3(b)'' and by adding in its place ''§ 207.1''.

6. Section 201.2 is revised to read as follows:

§ 201.2 Drugs; National Drug Code (NDC) number.

(a) What drugs must have an NDC number in human-readable form on the label? Drugs subject to the drug listing requirements of part 207 of this chapter must have labels that bear the appropriate NDC number in human-readable form, in accordance with the provisions of this section.

(b) What is the appropriate NDC number? The appropriate NDC number is the NDC number of the manufacturer, repacker or relabeler (including a drug product salvager who repacks or relabels the drug), or private label distributor, as defined in § 207.1 of this chapter, that is the last manufacturer, repacker, relabeler, or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer. The appropriate NDC number is assigned to the drug as described in §§ 207.33 and 207.37 of this chapter. The unique NDC number assigned to each package size and type of a drug must appear on the corresponding label for the particular package size and type of the drug.

(c) May any other NDC number appear on the label? No. Only the appropriate NDC number required by paragraph (b) of this section to appear on the label may appear on the label.

(d) What prefix must be used to identify the NDC number on the label? The NDC number in human-readable form must be immediately preceded by the letters NDC.

(e) Must the NDC number appear at a specific location on the label? No. However, the appropriate NDC number must appear clearly on the drug's label as defined by section 201(k) of the Federal Food, Drug, and Cosmetic Act.

7. Section 201.25 is amended in paragraph (c)(1) introductory text by adding a sentence after the first sentence and by adding paragraph (e) to read as follows:

§ 201.25 Bar code label requirements.

* * * * *

(c) * * *

(1) * * * For purposes of this section ''appropriate NDC number'' is described in § 201.2(b). * * *

* * * * *

(e) Can a drug that is not subject to the bar code requirement display a bar code? A drug product that is subject to the drug listing requirements of part 207 of this chapter but is not subject to this section may display a bar code on the label only if the bar code meets the requirements of paragraph (c) of this section.

8. Part 207 is revised to read as follows:

PART 207—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Subpart A—General

Sec.

207.1 What definitions and interpretations of terms apply to this part?
207.5 What is the purpose of this part?
207.9 Who does this part cover?
207.13 Who is exempt from the registration and listing requirements?

Subpart B—Registration

207.17 Who must register?
207.21 When must initial registration information be provided?
207.25 What information is required for registration?
207.29 What are the requirements for reviewing and updating registration information?

Subpart C—National Drug Code Number

207.33 What is the National Drug Code (NDC) number, who must obtain it, and what information must be submitted?
207.37 What restrictions pertain to the use of NDC numbers?

Subpart D—Listing

207.41 Who must list drugs?
207.45 When must initial listing information be provided?
207.49 What listing information is required for manufacturers?
207.53 What listing information is required for repackers and relabelers?
207.54 What listing information is required for drug product salvagers who are not repackers or relabelers?
207.55 What additional drug listing information may be required?
207.57 What are the requirements for reviewing and updating listing information?

Subpart E—Electronic Format for Registration and Listing

207.61 How is registration and listing information provided to FDA?
207.65 How is a waiver from the electronic format requirement requested?

Subpart F—Miscellaneous

207.69 What are the requirements for an official contact and a United States agent?
207.77 What legal status is conferred by registration and listing?
207.81 What registration and listing information will we make available for public disclosure?

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

Subpart A—General

§ 207.1 What definitions and interpretations of terms apply to this part?

The definitions and interpretations of terms in section 510 of the act apply to the terms used in this part. The following definitions also apply to this part:

Act means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, *et seq.*, as amended (21 U.S.C. 301, *et seq.*)), except as otherwise provided.

Active pharmaceutical ingredient means any substance that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.

Commercial distribution means any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or an animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of an active pharmaceutical ingredient between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign manufacturers, foreign repackers, foreign relabelers, foreign drug product salvagers, foreign private label distributors, and foreign establishments, the term ''commercial distribution'' has the same meaning except the term does not include distribution of any drug that is neither imported nor offered for import into the United States.

Content of labeling means: (1) For human prescription drugs that the manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act: The content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(2) For human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act: The labeling equivalent to the content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(3) For human over-the-counter (OTC) drugs: The content of the drug facts labeling required by § 201.66 of this chapter, including all text, tables, and figures.

(4) For animal drugs (including, but not limited to, drugs that the manufacturer regards as subject to section 512 of the act): The content of the labeling that accompanies the drug that is necessary to enable safe and proper administration of the drug (e.g., the labeling specified in §§ 201.1 and 201.5 of this chapter), including all text, tables, and figures.

Domestic for the purposes of registration and listing under this part, when used to modify the term ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' ''private label distributor,'' or ''establishment,'' refers to a manufacturer, repacker, relabeler, drug product salvager, private label distributor, or establishment within any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Drug(s) for the purposes of registration and listing under this part, has the meaning given in section 201(g)(1) of the act.

Drug product salvager means a person who owns or operates an establishment that engages in drug product salvaging. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic drug product salvagers and foreign drug product salvagers.

Drug product salvaging means applying manufacturing controls such as those required by current good manufacturing practice in parts 210 and 211 of this chapter to drug products and segregating out those drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products to the marketplace.

Establishment for purposes of registration and drug listing means a place of business under one management at one geographic location. One geographic location may include separate buildings within the same city if their activities are closely related to the same business enterprise and are under the supervision of the same local management. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic and foreign establishments.

Establishment registration number means the number assigned by FDA to the establishment during the establishment registration process required in this part.

Foreign for the purposes of registration and listing under this part:

(1) When used to modify the term ''manufacturer,'' ''repacker,'' ''relabeler,'' ''drug product salvager,'' or ''private label distributor'' refers to a manufacturer, repacker, relabeler, drug product salvager, or private label distributor who is located in a foreign country and who manufactures, repacks, relabels, salvages, or distributes a drug that is imported or offered for import into the United States.

(2) When used to modify the term ''establishment'' refers to an establishment that is located in a foreign country and is the site where a drug that is imported or offered for import into the United States was manufactured, repacked, relabeled, salvaged, or distributed.

Importer means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's drug that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or is administered the drug, unless the foreign establishment ships the drug directly to the consumer or patient.

Manufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug. Manufacture includes the making by chemical, physical, biological, or other procedures or manipulations of a drug, including control procedures applied to the final product or to any part of the process. Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs, for another registered establishment's drug. For purposes of this part, and in order to clarify the responsibilities of the different parties, the term manufacture is defined and used separately from the terms relabel, repackage, and salvage, although the term ''manufacture, preparation, propagation, compounding, or processing,'' as used in section 510 of the act, includes relabeling, repackaging, and drug product salvaging activities.

Manufacturer means a person who owns or operates an establishment that manufactures a drug. This term includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug as defined in this paragraph. For purposes of this part, and in order to clarify the responsibilities of the different parties,

the term manufacturer is defined and used separately from the terms relabeler, repacker, and drug product salvager, although the term ''manufacture, preparation, propagation, compounding, or processing,'' as used in section 510 of the act, includes the activities of relabelers, repackers, and drug product salvagers. Repackers, relabelers, and drug product salvagers are subject to the provisions of this part that are applicable to repackers, relabelers, and drug product salvagers, but are not subject to the provisions of this part that are applicable to manufacturers. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic manufacturers and foreign manufacturers.

Material change means any change in any drug listing information, as required under §§ 207.49, 207.53, 207.54, 207.55, or 207.57 except changes in arrangement or printing of labeling, labeling changes of an editorial nature, or inclusion of a bar code or NDC number on the label.

Person who imports or offers for import means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its drug into the United States.

Private label distributor means a person who owns or operates an establishment that commercially distributes, under its own label or trade name, any drug manufactured, repacked, relabeled, or salvaged by a registered establishment. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic private label distributors and foreign private label distributors.

Relabel means to change the label or labels on a drug or drug package, or add to the labeling for a drug or drug package, without repacking the drug or drug package.

Relabeler means a person who owns or operates an establishment that relabels a drug. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic relabelers and foreign relabelers.

Repack means to repack or repackage or otherwise change the container or wrapper of a drug or drug package.

Repacker means a person who owns or operates an establishment that repacks a drug or drug package. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic repackers and foreign repackers.

Representative sampling of advertisements means typical advertising material (including the promotional material described in § 202.1(l)(1) of this chapter, but excluding labeling as determined in § 202.1(l)(2) of this chapter), that gives a balanced picture of the promotional claims used for the drug.

Representative sampling of any other labeling means typical labeling material (including the promotional material described in § 202.1(l)(2) of this chapter, but excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug.

§ 207.5 What is the purpose of this part?

Establishment registration information helps us to identify who is manufacturing, repacking, relabeling, or salvaging drugs and where those operations are being performed. Drug listing information gives us a current inventory of marketed drugs. Both types of information facilitate our implementation and enforcement of the act and are used for many important public health purposes.

§ 207.9 Who does this part cover?

(a) This part applies to domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers, not exempt under section 510(g) of the act or § 207.13, regardless of whether their drugs enter interstate commerce.

(b) This part applies to foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers, not exempt under §§ 207.13(c) through (h).

(c) This part applies to certain manufacturers of drugs regulated under a biologics license application (BLA):

(1) Except as provided in paragraphs (c)(2) and (c)(3) of this section, this part applies to manufacturers of drugs regulated under a BLA, including but not limited to the following:

(i) Plasma derivatives such as albumin, Immune Globulin, Factor VIII and Factor IX, and recombinant versions of plasma derivatives or animal derived plasma derivatives;

(ii) Vaccines;

(iii) Allergenic products;

(iv) Bulk product substances such as fractionation intermediates or pastes; and

(v) Therapeutic biological products.

(2) This part, as well as part 1271 of this chapter, applies to establishments solely engaged in the manufacture (as defined in § 1271.3(e) of this chapter) of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (as defined in § 1271.3(d) of this chapter) that, under § 1271.20 of this chapter, are also drugs regulated under section 351 of the Public Health Service Act or section 505 of the act. These establishments must:

(i) Register and list those HCT/Ps with the Center for Biologics Evaluation and Research by following the procedures described in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing described in this part, and

(ii) Submit to the Center for Biologics Evaluation and Research the information specified in §§ 207.33(c)(2)(i) and (c)(2)(ii), 207.49(a), (b), (g), and (h)(2), 207.53(a), (c), (d), and (e)(2), 207.54(b)(1), and 207.55.

(3) This part does not apply to owners and operators of human blood and blood product establishments, except as provided in paragraphs (c)(1)(i) and (c)(1)(iv) of this section. Establishments that collect or process whole blood and blood products as well as establishments involved in testing of whole blood and blood products must register and list under part 607 of this chapter. Manufacturers of licensed devices and manufacturers of licensed biologic components used in a licensed device must register and list under part 607 of this chapter.

(d) This part does not apply to establishments that solely manufacture, prepare, propagate, compound, assemble, or process medical devices. Registration and listing regulations for such establishments are codified in part 807 of this chapter.

§ 207.13 Who is exempt from the registration and listing requirements?

Except as provided in § 207.13(i), the following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g) of the act or because we have found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. This exemption is limited to establishment registration and drug listing requirements and does not relieve a person from other statutory or regulatory obligations.

(a) *Pharmacies.* (1) Pharmacies that:

(i) Operate in conformance with all applicable local laws regulating the practice of pharmacy, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture (as defined in § 207.1), repack, or relabel drugs for sale other than in the regular course of the

practice of pharmacy, including dispensing and selling drugs at retail.

(2) The exemption in paragraph (a) of this section is limited to pharmacies located in any State as defined in section 201(a)(1) of the act.

(b) *Hospitals, clinics, other health care entities, and public health agencies.* (1) Hospitals, clinics, other health care entities, and public health agencies that:

(i) Operate establishments in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs, other than human blood or blood products, upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture (as defined in § 207.1), repack, or relabel drugs other than in the regular course of the practice of pharmacy, including dispensing.

(2) The exemption in paragraph (b) of this section is limited to hospitals, clinics, other health care entities, and public health agencies located in any State as defined in section 201(a)(1) of the act.

(c) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture, repack, or relabel drugs solely for use in their professional practice.

(d) Manufacturers, repackers, relabelers, or drug product salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale.

(e) Manufacturers, repackers, relabelers, and drug product salvagers of harmless inactive ingredients that are excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs.

(f) Manufacturers, repackers, relabelers, or drug product salvagers of Type B or Type C medicated feeds, except for manufacturers, repackers, relabelers, or drug product salvagers of Type B or Type C medicated feeds made from Category II, Type A medicated articles. This exemption does not apply to persons that would otherwise be required to register (such as manufacturers, repackers, relabelers, or drug product salvagers of certain free-choice feeds, as defined in § 510.455 of this chapter, or certain liquid feeds, as defined in § 558.5 of this chapter, where the specifications and/or formulas are not published and a feed mill license is required). All manufacturers, repackers, relabelers, or drug product salvagers of Type B or Type C medicated feeds are exempt from listing.

(g) Any manufacturer, repacker, relabeler, or drug product salvager of a virus, serum, toxin, or analogous product intended for the treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)), provided that this exemption from registration applies only to the manufacturer, repacker, relabeler, or drug product salvager of that animal virus, serum, toxin, or analogous product.

(h) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

(i) The exemptions provided in paragraphs (a) through (h) of this section do not apply to such persons if they:

(1) Manufacture (as defined in § 207.1), repack, relabel, or salvage compounded positron emission tomography drugs as defined in section 201(ii) of the act.

(2) Manufacture (as defined in § 600.3(u) of this chapter) a biological product subject to licensing under section 351 of the Public Health Service Act;

(3) Manufacture (as defined in § 1271.3(e) of this chapter) an HCT/P that, under § 1271.20 of this chapter, are also drugs regulated under section 351 of the Public Health Service Act or section 505 of the act; or

(4) Engage in activities that would otherwise require them to register under this part.

Subpart B—Registration

§ 207.17 Who must register?

(a) All manufacturers, repackers, relabelers, and drug product salvagers must register establishments in accordance with this part. When operations are conducted at more than one establishment and joint ownership and control among all the establishments exists, the parent, subsidiary, and/or affiliate company may submit registration information for all establishments.

(b) Private label distributors must not register with us unless they also manufacture, repack, relabel, or salvage drugs and are required to register under paragraph (a) of this section.

§ 207.21 When must initial registration information be provided?

Domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers must register each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. Foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers must register each establishment before a drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.

§ 207.25 What information is required for registration?

Manufacturers, repackers, relabelers, and drug product salvagers must provide the following information to us:

(a) Name of the owner or operator of each establishment; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(b) Name of each establishment;

(c) Any trade name(s) of the establishment, names under which the establishment conducts business, and additional names by which the establishment is known;

(d) Address of each establishment;

(e) Registration number of each establishment, if previously assigned by us; if not previously assigned by us, we will assign a registration number after we receive the registration information;

(f) Type of operations performed at each establishment (for example, manufacturing, repacking, relabeling, or salvaging);

(g) Name, address, telephone and fax numbers, and e-mail address of the official contact, as provided in § 207.69(a), for each establishment; and

(h) With respect to foreign establishments only, for drugs manufactured, repacked, relabeled, or salvaged at the establishment, the name, address, telephone and fax numbers, and e-mail address must also be provided for:

(1) The United States agent, as provided in § 207.69(b);

(2) Each importer of such drug in the United States that is known to the establishment; and

(3) Each person who imports or offers for import such drug to the United States.

§ 207.29 What are the requirements for reviewing and updating registration information?

(a) *Expedited updates.* Manufacturers, repackers, relabelers, and drug product salvagers must update their registration information no later than 30 calendar days after:

(1) Closing or selling an establishment;

(2) Changing an establishment's name or address; or

(3) Changing the name, address, telephone and fax numbers, or e-mail address of the official contact or the United States agent. A manufacturer, repacker, relabeler, and drug product salvager, official contact, or United States agent may notify us about a change of information for the designated official contact or United States agent, but only a manufacturer, repacker, relabeler, or drug product salvager may designate a new official contact or United States agent.

(b) *Annual review and update of registration information.* Manufacturers, repackers, relabelers, and drug product salvagers must review and update all registration information required under § 207.25 for each establishment.

(1) The first review and update must occur no later than 1 year after the date of initial registration, and subsequent reviews and updates must occur no later than annually thereafter from the date of initial registration.

(2) The updates must reflect all changes that have occurred since the last annual review and update.

(3) If no changes have occurred since the last annual registration (accomplished through the review and update of registration information), manufacturers, repackers, relabelers, and drug product salvagers must certify that no changes have occurred.

Subpart C—National Drug Code Number

§ 207.33 What is the National Drug Code (NDC) number, who must obtain it, and what information must be submitted?

(a) *What is the NDC number?* The NDC number is a unique 10 digit number with 3 segments. The three segments are the labeler code, the product code, and the package code. We will assign the complete NDC number (that will include the existing labeler code, if any) to each drug that is subject to the listing requirements in this part.

(b) *Who must obtain an NDC number?*

(1) Manufacturers, repackers, or relabelers, must obtain an NDC number from us for each drug that is subject to the drug listing requirements in this part.

(2) Drug product salvagers must obtain an NDC number from us for each drug that is subject to the drug listing requirements in this part only if they repack or relabel the salvaged drug. Drug product salvagers must follow the requirements for repackers and relabelers in paragraphs (d), (e), (f), and (g) of this section.

(3) If you are a private label distributor, the manufacturer, repacker, relabeler or drug product salvager (described in paragraph (b)(2) of this section) who manufactures, repacks, or relabels a drug for you is responsible for obtaining an NDC number from us for each drug that is subject to the drug listing requirements in this part.

(c) *What information must a manufacturer submit before we will assign an NDC number to a drug?* Before we assign an NDC number to a drug, the manufacturer must submit the information required under paragraphs (c)(1), (c)(2), or (c)(3) of this section. If that information changes (or as otherwise specified in paragraph (f) of this section), we will assign a new NDC number as described in paragraph (f) of this section.

(1) *Assigning an NDC number to an active pharmaceutical ingredient.* We will assign a unique NDC number to a drug that is an active pharmaceutical ingredient when the manufacturer provides the following information for the drug:

(i) The manufacturer's name, address, telephone and fax numbers, e-mail address, and labeler code;

(ii) The drug's established name and proprietary name, if any;

(iii) The package size and type; and

(iv) The Drug Master File number or Veterinary Master File number, if any, assigned to the active pharmaceutical ingredient.

(2) *Assigning an NDC number to a manufacturer's drug other than an active pharmaceutical ingredient.* We will assign a unique NDC number to a drug when the manufacturer provides, in addition to the information described in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, the following information for the drug:

(i) The name and quantity of each active pharmaceutical ingredient unless the approved U.S. application number is provided;

(ii) Unless the approved U.S. application number is provided, the name of each inactive ingredient for each human and animal drug that the manufacturer regards as subject to section 505 or section 512 of the act or section 351 of the Public Health Service Act, and for each human over-the-counter drug that the manufacturer regards as not subject to section 505 of the act, and whether the name of the inactive ingredient falls under § 20.61 of this chapter or is otherwise prohibited from disclosure and, if so, why;

(iii) The dosage form;

(iv) The package size and type, including immediate unit-of-use container;

(v) The drug's marketing status (e.g., prescription or OTC);

(vi) The drug or drug product type (e.g., human drug or animal drug); and

(vii) For each drug product subject to the listing requirements and covered under § 206.1, including products that are exempted under § 206.7(b), manufacturers must provide the size, shape, color, and code imprint (if any).

(3) *Assigning an NDC number to a drug manufactured for a private label distributor.* We will assign a unique NDC number to a drug manufactured for a private label distributor when the manufacturer provides, in addition to the information described in paragraph (c)(1) of this section (for active pharmaceutical ingredients manufactured for a private label distributor) or paragraph (c)(2) of this section (for all other drugs manufactured for a private label distributor), the following information for the drug:

(i) The private label distributor's name, address, telephone and fax numbers, e-mail address, and labeler code; and

(ii) The drug's proprietary name, if any, assigned by the private label distributor.

(d) *What information must the repacker or relabeler submit before we will assign an NDC number to a drug*? Before we assign an NDC number to a drug, the repacker or relabeler must submit the information required under paragraphs (d)(1) or (d)(2) of this section. If that information changes, we will assign a new NDC number as described in paragraph (f) of this section.

(1) *Assigning an NDC number to a repacker's or relabeler's drug.* We will assign a unique NDC number to a drug, including an active pharmaceutical ingredient, when the repacker or relabeler of the drug provides the following information for the drug:

(i) The repacker or relabeler's name, address, telephone and fax numbers, e-mail address, and labeler code;

(ii) The NDC number assigned to the drug immediately before the drug is received by the repacker or relabeler;

(iii) The type of operation performed for the drug (that is, whether repacking or relabeling);

(iv) The drug's established name and proprietary name, if any; and

(v) For the repacker only, the package size and type, including immediate unit-of-use container, if any.

(2) *Assigning an NDC number to the drug repacked or relabeled for a private label distributor.* We will assign a unique NDC number to a drug repacked or relabeled for a private label distributor when the repacker or relabeler provides, in addition to the

information described in paragraph (d)(1) of this section, the following information for the drug:

(i) The private label distributor's name, address, telephone and fax numbers, e-mail address, and labeler code; and

(ii) The drug's proprietary name, if any, assigned by the private label distributor.

(e) *How must the information be submitted to us*? The information required in paragraphs (c), (d), and (f) of this section must be provided to us in accordance with § 207.61(a)(1)(ii) and (b), unless we grant a waiver under § 207.65.

(f) *What changes in the information will require a new NDC number*? (1) Manufacturers, repackers, and relabelers must obtain a new NDC number for a drug when there is a change in any of the information for the drug required under paragraphs (c) and (d) of this section. Changes must be submitted to us in accordance with paragraphs (e) and (g) of this section. However, we will not assign a new NDC number when the change involves only the following contact information for the manufacturer, repacker, relabeler, or private label distributor: Name, address, telephone and fax numbers, and e-mail address.

(2) In addition to the requirements in paragraph (f)(1) of this section, manufacturers must obtain a new NDC number when there is a change in an inactive ingredient for each human prescription drug that the manufacturer regards as not subject to section 505 of the act and for each animal drug that the manufacturer regards as not subject to section 512 of the act.

(g) *When must a manufacturer, repacker, or relabeler provide the information for an NDC number*? A manufacturer, repacker, or relabeler must provide the information in paragraphs (c), (d), and (f) of this section to us either before or at the time drug listing information is required under § 207.45 or § 207.57.

§ 207.37 What restrictions pertain to the use of NDC numbers?

Manufacturers, repackers, and relabelers must not:

(a) Use an NDC number to represent a different drug than the drug to which the NDC number has been assigned under § 207.33.

(b) Use a different NDC number if marketing is resumed for a drug that was discontinued earlier. If marketing is resumed for a drug, and no changes have been made to the drug that would require a new NDC number under § 207.33(f), the drug must have the same NDC number that was assigned to it under § 207.33 before marketing was discontinued.

(c) Use the NDC number to denote FDA approval of that drug.

(d) Use the NDC number on products that are not subject to this part, such as dietary supplements and medical devices.

Subpart D—Listing

§ 207.41 Who must list drugs?

(a) Manufacturers, repackers, relabelers, and drug product salvagers who are subject to the registration requirements under § 207.17 must list their drugs being manufactured, repacked, relabeled, or salvaged for commercial distribution. Domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers who are subject to the registration requirements under § 207.17 must list such drugs regardless of whether the drugs enter interstate commerce. When operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments, listing information may be submitted by the parent, subsidiary, and/or affiliate company for drugs at all establishments.

(b) Manufacturers, repackers, relabelers, and drug product salvagers who engage in more than one activity for drugs must list each drug in accordance with the requirements for the activity engaged in for that drug. For example, a company may manufacture Drug X and relabel Drug Y. The company must provide the information described in § 207.49 for Drug X and the information described in § 207.53 for Drug Y.

(c) Manufacturers, repackers, relabelers, and drug product salvagers must provide all listing information to us for drugs that they manufacture, repack, relabel, or salvage for private label distributors. Private label distributors must not list drugs that they do not manufacture, repack, relabel, or salvage for commercial distribution.

§ 207.45 When must initial listing information be provided?

At the time of initial registration of an establishment, manufacturers, repackers, relabelers, and drug product salvagers must list any drug being manufactured, repacked, relabeled, and salvaged for commercial distribution at that establishment.

§ 207.49 What listing information is required for manufacturers?

Manufacturers must provide all of the following listing information to us for each drug they list, including a drug manufactured for a private label distributor:

(a) The NDC number, assigned by us under § 207.33, for each drug; the NDC number must be provided for the drug to be considered listed;

(b) The route of administration of the drug;

(c) The approved U.S. application number or approved U.S. BLA number, if any;

(d) The registration number of each establishment where the manufacturing is performed for the drug;

(e) The schedule of the drug under section 202 of the Controlled Substances Act, if applicable;

(f) With respect to foreign establishments only, unless previously provided under § 207.25(h), the name, address, telephone and fax numbers, and e-mail address of each importer of such drug in the United States that is known to the establishment, and of each person who imports or offers for import such drug to the United States;

(g) *Labeling*—(1) *Human prescription drugs.* Unless the approved U.S. application number is provided under paragraph (c) of this section, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), including the content of labeling for each human prescription drug;

(2) *Human OTC drugs*—(i) *Manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act.* A copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), including the content of labeling for each human OTC drug that the manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act, unless the approved U.S. application number is provided under paragraph (c) of this section;

(ii) *Manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act.* A copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), the content of labeling, the package insert (if any), and a representative sampling of any other labeling for each human OTC drug that the manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act;

(3) *Animal drugs*—(i) *Manufacturer regards as subject to section 512 of the act.* A copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), including the content of labeling, for each animal drug that the manufacturer regards as subject to section 512 of the act;

(ii) *Manufacturer regards as not subject to section 512 of the act.* For all other animal drugs, a copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, the content of labeling, and a representative sampling of any other labeling, for each drug that the manufacturer regards as not subject to section 512 of the act;

(h) *Advertisements.* (1) A representative sampling of advertisements for human prescription drugs that the manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act;

(2) If we request it, for good cause, a copy of all advertisements for a particular drug described in paragraph (h)(1) of this section, including those described in § 202.1(l)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after our request; and

(i) If the drug is manufactured for a private label distributor, the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor.

§ 207.53 What listing information is required for repackers and relabelers?

Repackers and relabelers must provide all of the following listing information to us for each drug they list, including a drug repacked or relabeled for a private label distributor:

(a) The NDC number, assigned by us under § 207.33, for each drug; the NDC number must be provided for the drug to be considered listed;

(b) The registration number of each establishment where the repacking or relabeling is performed for the drug;

(c) With respect to foreign establishments only, unless previously provided under § 207.25(h), the name address, telephone and fax numbers, and e-mail address of each importer of such drug in the United States that is known to the establishments, and of each person who imports or offers for import such drug to the United States;

(d) *Labeling*—(1) *Human prescription drugs.* If any change in labeling is made to the drug repacked or relabeled, a copy of all changed labeling for each human prescription drug that is repacked or relabeled;

(2) *Human OTC drugs*—(i) *Manufacturer regards as subject to section 505 of the act or section 351 of the Public Health Service Act.* If any change in labeling is made to the drug repacked or relabeled, a copy of all changed labeling for each human OTC drug that is repacked or relabeled;

(ii) *Manufacturer regards as not subject to section 505 of the act or section 351 of the Public Health Service Act.* A copy of the current label, a copy of any changes made to the package insert, if there is one, and a representative sampling of any other labeling for each human OTC drug that the manufacturer of the drug regards as not subject to section 505 of the act or section 351 of the Public Health Service Act;

(3) *Animal drugs.* A copy of the current label, a copy of changes made to each animal drug labeling, and a representative sampling of any other labeling for each animal drug;

(e) *Advertisements.* (1) A representative sampling of advertisements for human prescription drugs that the repacker or relabeler regards as not subject to section 505 of the act or section 351 of the Public Health Service Act;

(2) If we request it for good cause, a copy of all advertisements for a particular drug described in paragraph (e)(1) of this section, including those described in § 202.1(l)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after our request; and

(f) If the drug is repacked or relabeled for a private label distributor, the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor.

§ 207.54 What listing information is required for drug product salvagers who are not repackers or relabelers?

(a) Drug product salvagers who also repack and relabel the drugs they salvage must list those drugs as a repacker or relabeler in accordance with § 207.53.

(b) Drug product salvagers who do not otherwise repack or relabel drugs they salvage must provide all of the following listing information to us for each drug they list, including a drug salvaged for a private label distributor:

(1) The NDC number assigned to the drug immediately before the drug is received by the drug product salvager; the NDC number must be provided for the drug to be considered listed;

(2) The lot number and expiration date of the salvaged drug product;

(3) The registration number of each establishment where the drug product salvager salvages the drug;

(4) With respect to foreign establishments only, unless previously provided under § 207.25(h), the name address, telephone and fax numbers, and e-mail address of each importer of such drug in the United States that is known to the establishment, and of each person who imports or offers for import such drug to the United States; and

(5) If the drug is salvaged for a private label distributor, the name, address, labeler code, telephone and fax numbers, and e-mail address of the private label distributor.

§ 207.55 What additional drug listing information may be required?

For a particular drug product, upon our request, the manufacturer, repacker, relabeler, or drug product salvager must briefly state the basis for its belief that the drug product is not subject to section 505 or 512 of the act or section 351 of the Public Health Service Act.

§ 207.57 What are the requirements for reviewing and updating listing information?

Manufacturers, repackers, relabelers, and drug product salvagers must review and update their drug listing information required under §§ 207.49, 207.53, 207.54, and 207.55.

(a) Manufacturers, repackers, relabelers, and drug product salvagers must provide listing information, during the annual review and update of registration information, for any drug that has not been previously listed.

(b) Manufacturers, repackers, relabelers, and drug product salvagers must review and update their listing information each June and December of every year. They must:

(1) Provide listing information, in accordance with §§ 207.49, 207.53, 207.54, and 207.55, for any drug manufactured, repacked, relabeled, or salvaged for commercial distribution that has not been previously listed;

(2) Submit the date that they discontinued the manufacture, repacking, relabeling, or salvaging for commercial distribution of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled, or salvaged;

(3) Submit the date that they resumed the manufacture, repacking, or relabeling for commercial distribution of a drug previously discontinued and provide any other listing information not previously required or submitted;

(4) Submit any material changes in any information previously submitted

pursuant to §§ 207.49, 207.53, 207.54, 207.55, or this section; or

(5) Certify that no changes have occurred if no changes have occurred since the last review and update. If a drug is discontinued and we have received the information required under paragraph (b)(2) of this section, no further certifications are necessary for the discontinued drug.

Subpart E—Electronic Format for Registration and Listing

§ 207.61 How is registration and listing information provided to FDA?

(a) *Electronic format.* (1) Manufacturers, repackers, relabelers, and drug product salvagers that are subject to the registration and listing requirements of this part must provide the following information to us by using our electronic drug registration and listing system, in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30:

(i) Establishment registration information in §§ 207.25 and 207.29;

(ii) Information required for an NDC number in § 207.33; and

(iii) Drug listing information in §§ 207.49 (except paragraphs (g) and (h)), 207.53 (except paragraphs (d) and (e)), 207.54, 207.55, and 207.57.

(2) The content of labeling required under § 207.49(g)(1) through (g)(3) must be provided to us in an electronic format, in accordance with part 11 of this chapter, except for the requirements in § 11.10(a), (c) through (h), and (k) and the corresponding requirements in § 11.30. The NDC number must also be provided with the content of labeling for each drug.

(3) Advertisements and labeling (other than the content of labeling) required under §§ 207.49(g) and (h) and 207.53(d) and (e) may be provided to us in paper or electronic format in accordance with part 11 of this chapter, except for the requirements in § 11.10(a), (c) through (h), and (k) and the corresponding requirements in § 11.30. The NDC number must also be provided with such advertisements and labeling for each drug.

(4) The information provided in electronic format must be in a form that we can process, review, and archive. We may periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation and organization of files).

(b) *English language.* Registration and listing information must be provided in the English language. Labeling must also be provided in the English language, except as provided in § 201.15(c) of this chapter.

§ 207.65 How is a waiver from the electronic format requirement requested?

(a) If the information under § 207.61(a) cannot be submitted electronically, a waiver may be requested. We may grant a waiver request if the manufacturer, repacker, relabeler, or drug product salvager does not have an e-mail address and access to a computer and an Internet service provider that can access our electronic drug registration and listing system.

(b) Waiver requests must include a telephone number and/or mailing address where we can contact the manufacturer, repacker, relabeler, or drug product salvager.

(c) If we grant the waiver request, we will provide information on how to submit registration and/or listing information.

Subpart F—Miscellaneous

§ 207.69 What are the requirements for an official contact and a United States agent?

(a) *Official contact.* Manufacturers, repackers, relabelers, and drug product salvagers that are subject to the registration requirements of this part must designate an official contact for each establishment. The official contact is responsible for:

(1) Ensuring the accuracy of registration and listing information; and

(2) Reviewing, disseminating, routing, and responding to communications from us.

(b) *United States agent.* (1) Each foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager must designate a single United States agent. The United States agent is responsible for:

(i) Helping us communicate with the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager;

(ii) Responding to questions concerning those drugs that are imported or offered for import to the United States; and

(iii) Helping us schedule inspections.

(2) The United States agent must reside or maintain a place of business in the United States.

(3) A United States agent may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present.

(4) If we are unable to contact a foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager directly or expeditiously, we may provide information or documents to the United States agent. We will consider such an action to be equivalent to providing the same information or documents to the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager.

§ 207.77 What legal status is conferred by registration and listing?

(a) Registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing is misleading and constitutes misbranding.

(b) Assignment of an establishment registration number, inclusion of a drug in our database of drugs, or assignment of an NDC number does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed. Any representation that creates an impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned a NDC number, or the establishment has been assigned an establishment registration number, is misleading and constitutes misbranding. Failure to comply with § 207.37 also constitutes misbranding.

(c) Neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the act. Registration and listing may, however, be evidence that a facility is manufacturing, repacking, relabeling, or salvaging drugs or that a product is a drug.

§ 207.81 What registration and listing information will we make available for public disclosure?

(a) Except as provided in paragraphs (b) and (c) of this section, the following information will be made available for public disclosure upon request or at our own discretion:

(1) All registration information; and

(2) After a drug is listed, all information obtained for that drug under §§ 207.33, 207.49, 207.53, and 207.54, except for that information obtained under 207.33(d)(1)(ii) and 207.54(b)(1).

(b) Unless information is publicly available or we find that confidentiality would be inconsistent with the protection of the public health, we will

not make publicly available any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the act.

(c) We may determine, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health and the Freedom of Information Act to exempt from public disclosure specific information in paragraph (a) of this section. In such instances, a manufacturer, repacker, relabeler, or drug product salvager must demonstrate that specific information is exempt or is otherwise prohibited by law from public disclosure. If we agree, we will not make such information publicly available.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

8. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

9. Section 314.81 is amended by revising paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Withdrawal of approved drug product from sale.* (*a*) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are manufacturers, repackers, or relabelers subject to part 207 of this chapter must submit the following information about the drug in electronic format, in accordance with the applicable requirements described in § 207.61(a):

(*1*) The National Drug Code (NDC) number;

(*2*) The identity of the drug by established name and by proprietary name, if any;

(*3*) The new drug application number or abbreviated application number;

(*4*) The date of withdrawal from sale. We request that the reason for withdrawal of the drug from sale be included with the information.

(*b*) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are not subject to part 207 of this chapter must submit the information listed in paragraphs (*a*)(*1*) through (*a*)(*4*) of this section. The information must be submitted on the appropriate form, which must be submitted to the Drug Listing Branch, Food and Drug Administration, CDER Central Document Room, 5901B Ammendale Rd., Beltsville, MD 20705–1266.

* * * * *

§ 314.125 [Amended]

10. Section 314.125 is amended in paragraph (b)(11) by removing the words ''or processed''.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

11. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

12. Section 330.1 is amended by revising paragraph (b) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

* * * * *

(b) The establishment(s) in which the drug is manufactured is registered, and the drug is listed, in compliance with part 207 of this chapter. The appropriate National Drug Code (NDC) number must appear on the drug's label in accordance with §§ 201.2, 207.33, and 207.37 of this chapter.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

13. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e, 381.

14. Section 514.111 is amended by adding paragraph (a)(12) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(12) The drug will be produced in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and part 207 of this chapter.

* * * * *

PART 515—MEDICATED FEED MILL LICENSE

15. The authority citation for 21 CFR part 515 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 515.10 [Amended]

16. Section 515.10 is amended in paragraph (b)(8) by removing the phrase ''§§ 207.20 and 207.21'' and by adding in its place the phrase ''part 207''.

PART 601—LICENSING

17. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

18. Section 601.2 is amended by adding paragraph (f) to read as follows:

§ 601.2 Applications for biologics licenses; procedures for filing.

* * * * *

(f) *Withdrawal from sale of approved biological products.* A holder of a biologics license application (BLA) must report to FDA, electronically in accordance with part 207 of this chapter, the withdrawal from sale of an approved biological product. The information must be submitted to FDA within 30 working days of the biological product's withdrawal from sale. The following information must be submitted: The holder's name; product name; BLA number; the National Drug Code number, if applicable; and the date of withdrawal from sale. The reason for the withdrawal of the biological product is requested but not required to be submitted.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

19. The authority citation for 21 CFR part 607 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

20. Section 607.3 is amended by revising the second sentence in paragraph (b), and by adding new paragraph (k) to read as follows:

§ 607.3 Definitions.

* * * * *

(b) * * * For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act, as well as licensed biologic components used in the manufacture of a licensed device.

* * * * *

(k) *Importer* means a company or individual in the United States that is the owner, consignee, or recipient of the foreign establishment's blood product that is imported into the United States.

21. Section 607.7 is revised to read as follows:

§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products shall comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.

22. Section 607.22 is revised to read as follows:

§ 607.22 How to register blood product establishments and list blood products.

Initial and subsequent registrations and product listings by a blood product establishment for blood products must be on Form FDA 2830 (Blood Establishment Registration and Product Listing). Manufacturers may obtain, complete, and submit the form in the following ways:

(a) Complete the form online and submit electronically at *http://www.fda.gov/cber/blood/bldreg.htm*; this information must be submitted in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30; or

(b) Download the form from the Internet at *http://www.fda.gov/cber/blood/bldreg.htm*, and mail the completed form to the address in § 607.22(e); or

(c) Request the form by mail using the address in § 607.22(e), or by e-mail at *bloodregis@cber.fda.gov*, and mail the completed form to the address in § 607.22(e).

(d) For subsequent annual registration renewals, FDA will furnish the establishment's most recent Form FDA 2830 before November 15 of each year. The updated Form FDA 2830 must be submitted to FDA before December 31 of that year.

(e) Forms may be requested from and mailed to: Center for Biologics Evaluation and Research (HFM–370), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

23. Section 607.25 is amended by revising paragraph (b)(1) to read as follows:

§ 607.25 Information required for establishment registration and blood product listing.

* * * * *

(b) * * *

(1) A list of blood products by established name as defined in section 502(e) of the act and by proprietary name, if any, which are being manufactured for commercial distribution and which have not been included in any list previously submitted on Form FDA 2830 (Blood Establishment Registration and Product Listing).

* * * * *

24. Section 607.35 is revised to read as follows:

§ 607.35 Blood product establishment registration number.

A permanent registration number will be assigned to each blood product establishment registered in accordance with this part.

25. Section 607.37 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) Information submitted on the Form FDA 2830 (Blood Establishment Registration and Product Listing) will be available for inspection under section 510(f) of the act, on the Internet at *http://www.fda.gov/cber/blood/bldregdata.htm*, and at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

* * * * *

26. Section 607.39 is revised to read as follows:

§ 607.39 Misbranding by reference to establishment registration, validation of registration, or to registration number.

Registration of an establishment, validation of registration, or assignment of a registration number does not in any way denote approval of the firm or its products nor does it mean that the products may be legally marketed. Any representation that creates an impression of official approval because of establishment registration, validation of registration, or possession of a registration number is misleading and constitutes misbranding.

27. Section 607.40 is amended by revising paragraphs (a), (b), (c), the introductory text of (d), and (d)(3), and by adding new paragraphs (e) and (f) to read as follows:

§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

(a) Every foreign blood product establishment must comply with the requirements for domestic blood product establishments in subpart B of this part, unless exempt under subpart D of this part.

(b) No blood product may be imported or offered for import into the United States unless it complies with the blood product listing requirements in subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. Blood products imported or offered for import under the investigational use provisions of part 312 of this chapter are not subject to the requirements in subpart B of this part. All establishment registration and blood product listing information must be in the English language.

(c) Each foreign establishment required to register under paragraph (a) of this section must, as part of the establishment registration and blood product listing, submit the name and address of the establishment, the name of each importer of the foreign establishment's blood products that is known to the establishment, the name of each person who imports or offers for import such blood products to the United States, and the name of the individual responsible for submitting establishment registration and blood product listing information. Any changes in this information must be reported to FDA at the intervals specified for updating establishment registration information in § 607.26.

(d) Each foreign establishment required to register under paragraph (a) of this section must submit the name, address, telephone and fax numbers, and e-mail address of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment must designate only one United States agent.

* * * * *

(3) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone and fax numbers, and e-mail address to FDA within 30 calendar days of the change.

(e) Each foreign establishment required to register under paragraph (a) of this section must register and list blood products using the electronic registration and listing system, in accordance with § 607.22(a).

(f)(1) If the foreign establishment cannot submit the information electronically under § 607.40(e), the

establishment may request a waiver. FDA may grant a waiver request if the foreign establishment does not have an e-mail address and access to a computer and an Internet service provider that can access the electronic registration and listing system.

(2) Waiver requests must include a telephone number and/or mailing address where the agency can contact the foreign establishment.

(3) If the agency grants the waiver request, the foreign establishment must register and list blood products in accordance with § 607.22(b) or (c).

28. Section 607.65 is amended by redesignating paragraph (f) as paragraph (g) and by adding new paragraph (f) to read as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(f) Persons who engage solely in the production of any plasma derivative, such as albumin, Immune Globulin, Factor VIII and Factor IX, bulk product substances such as fractionation intermediates or pastes, or recombinant versions of plasma derivatives or animal derived plasma derivatives. This paragraph does not exempt such persons from registration and listing under part 207 of this chapter.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

29. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

30. Section 610.60 is amended by revising paragraph (a)(2) to read as follows:

§ 610.60 Container label.

(a) * * *

(2) The name, address, license number of the manufacturer, and the NDC number in accordance with part 207 of this chapter.

* * * * *

31. Section 610.61 is amended by revising paragraph (b) to read as follows:

§ 610.61 Package label.

* * * * *

(b) The name, address, license number of the manufacturer, and the NDC number in accordance with part 207 of this chapter.

* * * * *

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

32. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

§ 1271.1 [Amended]

33. Section 1271.1 is amended in paragraphs (a) and (b)(2) by removing ''207.20(f)'' and by adding in its place ''207.9(c)(2)''.

34. Section 1271.3 is amended by adding paragraphs (mm) and (nn) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(mm) Importer means a company or individual in the United States that is the owner, consignee, or recipient of the foreign establishment's HCT/P that is imported into the United States.

(nn) United States agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

§ 1271.20 [Amended]

35. Section 1271.20 is amended by removing ''207.20(f)'' and by adding in its place ''207.9(c)(2)''.

36. Section 1271.22 is added to read as follows:

§ 1271.22 How do I register and submit an HCT/P list?

(a) You must use the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm* in accordance with § 1271.25 for:

(1) Establishment registration,

(2) HCT/P listings, and

(3) Updates of registration and HCT/P listing.

(b) FDA will periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation, and organization of files).

(c) You must provide the information under paragraph (a) of this section in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30.

37. Section 1271.23 is added to part 1271 to read as follows:

§ 1271.23 How is a waiver from the electronic format requirements requested?

(a) You may request a waiver from the requirement in § 1271.22 that information must be provided to FDA in electronic format if you do not have an e-mail address and access to a computer and an Internet service provider that can access the Web-based FDA registration and listing database.

(b) Requests for a waiver must include a telephone number and/or mailing address where FDA can contact the person making the request.

(c) If FDA grants the request for a waiver, FDA will inform you how to submit your registration and/or listing information.

38. Section 1271.25 is amended by revising introductory paragraph (a), paragraphs (a)(2) and (a)(3), and by adding new paragraphs (a)(5), (a)(6), and (d) to read as follows:

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration must include:

* * * * *

(2) Each location, including the street address, telephone and fax numbers, email address, and the postal service zip code of the establishment;

(3) The name, address, telephone and fax numbers, e-mail address, and title of the reporting official;

* * * * *

(5) Each foreign establishment must also submit the name, address, telephone and fax numbers, and e-mail address of each importer that is known to the establishment, and the name of each person who imports or offers for import such HCT/P to the United States for purposes of importation; and

(6) Each foreign establishment must also submit the name, address, telephone and fax numbers, and e-mail address of its United States agent. Each foreign establishment must designate only one United States agent.

(i) The United States agent must reside or maintain a place of business in the United States.

(ii) Upon request from FDA, the United States agent must assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action must be considered

to be equivalent to providing the same information or documents to the foreign establishment.

(iii) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone and fax numbers, and e-mail address to FDA within 30 calendar days of the change.

* * * * *

(d) In addition, if your HCT/P is described under § 1271.20, you must submit the information required under part 207 of this chapter using the procedures under this subpart.

39. Section 1271.26 is revised to read as follows:

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, or if there is a change in the United States agent's name, address, telephone and fax numbers, and e-mail address, you must submit an amendment to registration within 30 calendar days of the change.

§ 1271.37 [Amended]

40. Section 1271.37 is amended in the introductory text of paragraph (a) by removing the phrase ''Form FDA 3356'' and adding in its place the phrase ''registration and listing information''.

Dated: August 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–7172 Filed 8–23–06; 3:48 pm]

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Federal Register

Tuesday,
August 29, 2006

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Part 93
Congestion Management Rule for LaGuardia Airport; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No. FAA–2006–25709; Notice No. 06–13]

RIN 2120–AI70

Congestion Management Rule for LaGuardia Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA is proposing a rule to address the potential for increased congestion and delay at New York's LaGuardia Airport (LaGuardia) when the High Density Rule (HDR) expires there on January 1, 2007. The rule, if adopted, would establish an operational limit on the number of aircraft landing and taking off at the airport. To offset the effect of this limit, the proposed rule would increase utilization of the airport by encouraging the use of larger aircraft through implementing an airport-wide, average aircraft size requirement designed to increase the number of passengers that may use the airport within the overall proposed operational limits.

DATES: Send your comments on or before October 30, 2006.

ADDRESSES: You may send comments [identified by Docket Number FAA–2006–25709] using any of the following methods:

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Molly W. Smith, Office of Aviation Policy and Plans, APO–001, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3275; e-mail *molly.w.smith@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also review the docket using the Internet at the Web address in the **ADDRESSES** section.

Privacy Act: Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov.*

Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(2) Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/*; or

(3) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

Authority for This Rulemaking

The FAA has broad authority under 49 U.S.C. 40103 to regulate the use of the navigable airspace of the United States. This section authorizes the FAA to develop plans and policy for the use of navigable airspace and to assign the use that the FAA deems necessary for its safe and efficient utilization. It further directs the FAA to prescribe air traffic rules and regulations governing the efficient utilization of the navigable airspace. The FAA interprets its broad statutory authority to ensure the efficient use of the navigable airspace to encompass management of the nationwide system of air commerce and air traffic control.

In addition to the FAA's authority and responsibilities with respect to the efficient use of airspace, the Secretary of Transportation is required to consider several other objectives as being in the public interest, including: Keeping available a variety of adequate, economic, efficient, and low-priced air services; placing maximum reliance on competitive market forces and on actual and potential competition; avoiding airline industry conditions that would tend to allow at least one air carrier unreasonably to increase prices, reduce services, or exclude competition in air transportation; encouraging, developing, and maintaining an air transportation system relying on actual and potential

competition; encouraging entry into air transportation markets by new and existing air carriers and the continued strengthening of small air carriers to ensure a more effective and competitive airline industry; maintaining a complete and convenient system of scheduled air transportation for small communities; ensuring that consumers in all regions of the United States, including those in small communities and rural and remote areas, have access to affordable, regularly scheduled air service; and acting consistently with obligations of the U.S. Government under international agreements. See 49 U.S.C. 40101(a)(4), (6), (10)–(13) and (16), and 40105(b).

I. Background

A. The High Density Traffic Airports Rule at LaGuardia

The FAA manages congestion and delay at LaGuardia by means of the HDR, which is codified under 14 CFR part 93, subpart K. The HDR took effect in 1969 as a temporary rule, but since it was effective in reducing congestion and delays, it became permanent in 1973.

The HDR establishes limits on the number of take-offs and landings during certain hours at five airports, including LaGuardia.[1] In order to operate during the restricted hours, a carrier needs a reservation, commonly known as a ''slot.'' Slots were initially allocated through airline scheduling committees, operating under then-authorized antitrust immunity, and the airlines would agree to the allocation. After the Airline Deregulation Act in 1978, new entrant airlines formed, and the pre-existing legacy carriers sought to expand their operations. This increased competition made it even more difficult for airlines to reach agreement, and the scheduling committees began to deadlock.

In 1985, a new Subpart S was added to Part 93 by the Department of Transportation that established allocation procedures for slots, including Use-or-Lose provisions and permission to buy and sell slots in a secondary market (50 FR 52195, December 20, 1985). These procedures replaced the scheduling committees.

On April 5, 2000, Congress enacted the Wendell H. Ford Aviation Investment and Reform Act of the 21st Century (AIR–21 or the Act). The Act phases out the HDR at three of the covered airports, with the rule scheduled to terminate at LaGuardia on January 1, 2007. Additionally, AIR–21 expanded existing operations at LaGuardia by directing the Secretary of Transportation to grant exemptions for certain flights from the HDR's operational limits prior to the HDR's termination at that airport. Specifically, AIR–21 authorized exemptions for flights operated by new entrant carriers or certain flights that would serve Small-Hub and Non-Hub Airports as long as the aircraft being used has fewer than 71 seats.

In phasing out the HDR, Congress recognized the possibility that there could be an increase in congestion and delay at the affected airports. Therefore, under the section that phases out the rule, the Act states that ''[n]othing in this section * * * shall be construed * * * as affecting the Federal Aviation Administration's authority for safety and the movement of air traffic.'' 49 U.S.C. 41715(b).

B. Resurgence of Unacceptable Levels of Congestion at LaGuardia

As a result of the AIR–21 legislation, the DOT approved more than 600 exemption requests for flights at LaGuardia. By fall 2000, air carriers had added over 300 new scheduled flights at LaGuardia, with plans to operate more in the coming months.

With no new airport infrastructure or air traffic control procedures, overall airport capacity remained the same while the number of aircraft operations and delays soared. The average minutes of delay for all arriving flights at LaGuardia increased 144%: From 15.52 minutes in March 2000 (the month before AIR–21 was enacted) to 37.86 minutes in September 2000.[2] The increase in delay as a result of AIR–21 was not limited to delays at LaGuardia. Flights that arrived and departed late at LaGuardia affected flights at other airports and in adjacent airspace as well, and by September 2000, flight delays at LaGuardia accounted for 25 percent of the nation's delays, compared to 10 percent for the previous year.[3]

Concerned about the accelerating levels of congestion, flight delays, and cancellations and the prospects of reaching gridlock, the Port Authority of New York and New Jersey (Port Authority) attempted to impose a temporary moratorium on new flights at LaGuardia and requested the assistance of the FAA. Using its authority under 49 U.S.C. 40103, and pending the development of a longer term solution, the FAA published a Notice of Intent in the **Federal Register** on November 15, 2000, announcing its intention to temporarily cap AIR–21 slot exemptions at LaGuardia and to allocate them via a lottery (65 FR 69126, November 15, 2000). The lottery, which was conducted on December 4, 2000, was premised on the imposition of an airfield and airspace capacity management limit of 75 scheduled operations per hour (plus 6 unscheduled operations primarily used by the general aviation community) beginning January 31, 2001 (65 FR 75765, December 4, 2000). This limit still allowed a significant increase in operations at the airport above the regulatory limits, thus serving Congressional objectives while stretching capacity to its practical limits. The number of AIR–21 slot exemptions at LaGuardia was restricted to a total of 159 a day between the hours of 7 a.m. and 9:59 p.m. As a result of the hourly restrictions, the average number of aircraft delays at LaGuardia fell from 330 per day in October 2000 to 98 per day in April 2001.

The December 4, 2000, limits on AIR–21 slot exemptions and the lottery allocation has been extended several times to allow the FAA to explore other options to control delay at the airport. Most recently, the FAA announced in the **Federal Register** a fourteen months extension to the current limits and allocation of slot exemptions at LaGuardia through December 31, 2006 (70 FR 36998, June 27, 2005).

Because LaGuardia airport is relatively close to mid-town Manhattan, many travelers prefer it, and airlines wish to meet that demand by operating many flights to LaGuardia. LaGuardia Airport consistently has been one of most congested airports in the nation. These facts, coupled with the inability to expand the physical airspace and airfield capacity of the airport, makes LaGuardia one of the most constrained airports in our national system. Passenger demand for access to LaGuardia exceeds available airspace and airfield capacity at the airport. This proposed rule aims to maximize the utilization of this airport, without generating unacceptable congestion and delay.

C. Research Into Market-Based and Administrative Alternatives at LaGuardia

Over the past several years, the FAA and the DOT's Office of the Secretary of Transportation (OST) have taken a number of steps to identify and develop a market-based mechanism to allocate limited capacity at LaGuardia.

[1] The limits at Newark were suspended in 1970 and were eliminated at Chicago O'Hare International Airport in July 2002.

[2] Source: FAA's Aviation System Performance Metrics (ASPM).

[3] Calculated from FAA's Air Traffic Operations Network Database (OPSNET).

On June 12, 2001, the FAA published a variety of congestion management alternatives in the **Federal Register**, including the use of auctions, congestion pricing and administrative alternatives, and sought the public's views on the potential use of each of these mechanisms at LaGuardia (66 FR 31731). Due to the September 11, 2001, terrorist attacks, the immediate need to develop a solution at LaGuardia was tempered because of the corresponding decrease in passenger demand. The FAA still received a substantial number of comments. The comments varied—some supported market-based measures, such as congestion pricing, while others recognized that the best solution might incorporate administrative allocation mechanisms. The FAA and OST have evaluated the comments and considered them in our research initiatives. We also have incorporated the views of the industry in the development of both this proposal and the legislation we intend to seek that would permit a market-based means of controlling congestion and delay at LaGuardia.

1. Auction Roundtable

In July 2004, the FAA held a roundtable to discuss the use of auctions to allocate capacity at LaGuardia. The purpose of the roundtable was twofold. First, the roundtable exposed senior FAA and OST officials to auctions and the issues surrounding their potential implementation at LaGuardia. Second, it served as an initial stakeholder meeting to seek comment on the possible use of auctions.

Several participants pointed to issues that would need to be addressed prior to implementing an auction of take-off or landing authorizations at LaGuardia, including the notion of incumbency; associated property rights and their duration, if any; the impact that auctions may have on airport revenues; predictability of the auction outcome; the impact on small communities; and the financial impact on the air carriers and their customers. Because of these concerns, the air carriers that participated in the roundtable appeared largely unenthusiastic about the potential use of auctions at LaGuardia.

However, several advantages to an auction also were noted. For example, auctions effectively allocate scarce resources under market conditions and thus seem less arbitrary in nature than allocating slots under an administrative solution (such as a lottery). Another benefit to auctions is that they rely on markets, which are more robust and responsive to industry changes than administrative regulations. These potential benefits have been echoed by the Department of Justice in its comments on another congestion management rulemaking involving operations at Chicago's O'Hare International Airport. In its comments, the Department stated that, ''a well-designed slot auction would both assign prices and allocate efficiently scarce airport resources, and limit the maintenance or accumulation of market power by individual carriers.'' [4]

Thus, if the complexities associated with implementing an auction at LaGuardia can be resolved, an auction could provide an economically efficient mechanism for allocating ''Operating Authorizations'' [5] at the airport in the future.

2. Congestion Pricing Forum

The FAA arranged a forum in February 2005 to explore the use of congestion pricing at airports. The series of presentations addressed the applicability of congestion pricing to control aviation capacity, with a focus on LaGuardia, and included presentations on the Massachusetts Port Authority's (Massport) congestion pricing proposal for Logan International Airport, as well as highway and energy peak period pricing programs. Several participants believed that Massport's model could not be successfully deployed at LaGuardia because the level of demand at LaGuardia is perceived to be too high to implement a revenue-neutral congestion pricing policy, as adopted at Boston Logan Airport. However, other participants believed a congestion pricing mechanism was feasible and would provide benefits associated with allowing the market to allocate capacity without the need for government imposed slot restrictions.

3. National Center of Excellence for Aviation Operations Research

The FAA and OST also contracted with the National Center of Excellence for Aviation Operations Research (NEXTOR) to conduct research on various proposals to implement at LaGuardia upon the expiration of the HDR. As part of that research, NEXTOR has conducted a number of strategic simulations with industry in an effort to design and assess the potential effectiveness of various allocation mechanisms. These mechanisms include auctions, congestion pricing, and various administrative measures.

In November 2004, NEXTOR conducted a 2-day simulation of congestion pricing and various administrative measures at LaGuardia. The FAA, OST, several industry stakeholders and airlines attended the workshop. The simulation measured airline responses to a variety of congestion pricing fees and administrative rules.

In February 2005, NEXTOR conducted a second strategic simulation in which it demonstrated how an auction model could be used to allocate capacity. The simulation was structured around a mock auction for arrival and departure slots at LaGuardia. The purpose of this simulation was to familiarize the relevant industry and government communities with auction processes and the specifics of modern slot auction design. The exercise also elicited views from industry and government representatives on the overall policy of using auctions to allocate arrival and departure capacity. The feedback gathered during this simulation exercise has generated further FAA and OST research on auctions. In particular, more work has been done to better anticipate the impact of aligning ''slots'' with necessary gate space. Additionally, the FAA and OST have worked with NEXTOR to develop auction rules that could incorporate exemptions for service to small communities.

This information will also be incorporated in a legislative proposal to Congress that will seek authority to utilize market-based mechanisms at LaGuardia in the future. Such legislation would be necessary to employ market-based approaches such as auctions or congestion pricing at LaGuardia because the FAA currently does not have the statutory authority to assess market-clearing charges for a landing or departure authorization. If Congress approves the use of market-based mechanisms as we plan to propose, a new rulemaking would be necessary to implement such measures at LaGuardia.

II. Continued Need To Limit Operations at LaGuardia

Today's proposal anticipates the complete phase-out of the HDR at LaGuardia on January 1, 2007, as required by AIR–21. In response, the FAA could simply allow the HDR to expire and to let events run their course without FAA intervention. This approach would permit each individual airline to manage (and potentially

[4] Comments of the United States Department of Justice in Docket No. FAA–2005–20704. May 24, 2005, pp. 11–13.

[5] As proposed, an Operating Authorization is the operational authority assigned to an air carrier by the FAA to conduct one scheduled IFR arrival or departure operation each week on a specific day of the week during a specific 15-minute period at LaGuardia.

increase) its own flights. Air traffic control procedures and traffic management initiatives such as ground delay programs, miles-in-trail restrictions, and aircraft re-routing, would help to ensure that any additional flights did not affect air safety. However, the congestion and delays experienced in the wake of AIR–21 flight additions would likely recur if limitations on the hourly operations at LaGuardia were not adopted. Indeed, because the delays in late 2000 resulted from just two types of operations, it is likely that a complete expiration of the HDR would lead to even greater delays absent a regulation designed to avert precipitous growth in operations.

Because the cost of delays is not fully internalized by any individual carrier, both experience and theory suggest that without any constraint, each carrier would, at least initially, continue adding flights despite an unacceptable level of congestion and delay. This was precisely the situation in 2000, and the airport cannot accommodate, nor can the FAA permit, such unrestrained growth at LaGuardia. Delays at LaGuardia have a significant detrimental impact on the rest of the national airspace system, leading to nationwide delay and inefficiency. Because simply allowing the HDR to expire is not a desirable option at LaGuardia, the FAA believes that some regulatory action to limit congestion at the airport is necessary.

LaGuardia cannot realistically expand its runway infrastructure because it borders on Bowery Bay and Flushing Bay. Thus, an airport expansion project like that proposed for Chicago's O'Hare International Airport is not feasible. Because of these groundside constraints, air traffic management improvements such as airspace redesign or changes to separation standards would permit minimal capacity increases at most. Even if these efficiencies can be realized, operating constraints likely still will be needed at LaGuardia because of its physical limitations, including runway and taxiway constraints.

The FAA is committed to ensuring that excessive delays and congestion do not return at LaGuardia after the HDR expires. The FAA and OST are evaluating appropriate market-based mechanisms, such as auctions or congestion pricing, for allocating capacity at LaGuardia over the long-term. The FAA currently does not have full legislative authority to employ such mechanisms at LaGuardia or at other airports, although the Port Authority could currently implement revenue-neutral congestion pricing or other mechanisms regarding operating rights so long as such changes did not require a fee or assessment by the Federal Government and the Port Authority's program otherwise would be reasonable, nonarbitrary and nondiscriminatory; would not create an undue burden on interstate or foreign commerce; would maintain the safe and efficient use of the navigable airspace; would not conflict with any existing Federal statute or regulation including Federal grant agreements; and would not create an undue burden on the national aviation system. As discussed above, Massport has developed a revenue-neutral congestion pricing program for use at Boston's Logan airport;[6] however, we do not believe that a revenue-neutral policy would be effective at LaGuardia. The demand for access at LaGuardia is so high that carriers may simply pay any fee imposed in a revenue-neutral model rather than changing their practices.

Consequently, we are seeking the legislative authority to conduct auctions or congestion pricing at LaGuardia in the future. If Congress approves the use of market-based mechanisms, a new rulemaking would be necessary to implement such measures at LaGuardia.

The FAA has broad authority under 49 U.S.C. 40103 to regulate the use of the navigable airspace of the United States. This authority is exclusive to the FAA. Section 40103 authorizes the FAA to develop plans and policy for the use of navigable airspace and to assign the use that the FAA deems necessary to its safe and efficient utilization. It further directs the FAA to prescribe air traffic rules and regulations governing the efficient utilization of the navigable airspace. The FAA interprets its broad statutory authority to ensure the efficient use of the navigable airspace to encompass management of the nationwide system of air commerce and air traffic control. AIR–21, while phasing out the HDR, did not strip the FAA of its authority to place operating limitations on air carriers to preserve the efficient utilization of the National Airspace System (NAS). Indeed, the FAA has, out of necessity, restricted the number of exemptions to the HDR since 2001 at LaGuardia, and no one has challenged its authority to do so at that airport.

In addition to the FAA's authority and responsibilities over the efficient use of airspace, the Secretary of Transportation is required to consider several other objectives as being in the public interest, including: Keeping available a variety of adequate, economic, efficient, and low-priced air services; placing maximum reliance on competitive market forces and on actual and potential competition; avoiding airline industry conditions that would tend to allow at least one air carrier unreasonably to increase prices, reduce services, or exclude competition in air transportation; encouraging, developing, and maintaining an air transportation system relying on actual and potential competition; encouraging entry into air transportation markets by new and existing air carriers and the continued strengthening of small air carriers to ensure a more effective and competitive airline industry; maintaining a complete and convenient system of scheduled air transportation for small communities; ensuring that consumers in all regions of the United States, including those in small communities and rural and remote areas, have access to affordable, regularly scheduled air service; and acting consistently with obligations of the U.S. Government under international agreements. See 49 U.S.C. 40101(a)(4), (6), (10)–(13) and (16), and 40105(b).

[6] The FAA has not had the occasion to issue a final opinion on Massport's program since the program has not yet been implemented.

III. Summary of Proposed Rule

The FAA proposes to cap hourly operations at LaGuardia. Under the proposed rule, the FAA would limit the number of scheduled flight arrivals and departures at LaGuardia Monday through Friday from 6:30 a.m. to 9:59 p.m. and Sunday from noon to 9:59 p.m. Similar limits would be placed on unscheduled arrivals and departures, excluding helicopters, conducted under instrument flight rules (IFR). The FAA would create ''Operating Authorizations'' according to the hourly limit on operations of 75 scheduled operations and 6 ''Reservations'' for unscheduled operations. The Operating Authorizations would be allocated to carriers at the airport based on historic usage subject to adjustments required to meet the proposed limits. The Operating Authorizations would be allocated in 15-minute increments (i.e., 6:30 a.m. through 6:44 a.m., 6:45 a.m. through 6:59 a.m.), with specified arrivals and departures, in order to minimize congestion from schedule peaking. The FAA believes that the relationship of schedule peaks and delays at LaGuardia is particularly significant since the current airport demand approaches the airport's optimal, good weather capacity. Reservations would be allocated on a half-hourly basis using a reservation system similar to the one currently in effect for unscheduled flights at the high density airports, Chicago O'Hare International Airport,

and at airports under special traffic management programs, whereby an operator may obtain a Reservation beginning 72 hours in advance of the proposed operation.

To encourage efficient use of scarce airspace, holders of Operating Authorizations would be required to meet an airport-wide average aircraft size target annually. Passenger demand for access to LaGuardia airport exceeds the number of passengers being accommodated today. Although the airport cannot currently, or in the foreseeable future, accommodate a greater number of flight operations, the airport's terminal and other groundside facilities could accommodate a greater number of passengers on the existing number of flights.

The use of commuter equipment (aircraft with fewer than 71 seats) arriving at LaGuardia from medium and large hub airports has increased by more than 50 percent since August 2001.[7] This trend has resulted in the underutilization of airport facilities at LaGuardia.

For example, on April 19, 2005, there were 16 flights to Baltimore, MD (a large hub) on aircraft with an average of 38 seats. Similarly, on the same day, there were 44 operations to Raleigh-Durham, NC (medium hub) on aircraft with an average of 50 seats, and 20 flights to Philadelphia, PA (large hub) on aircraft with an average of 58 seats. While we recognize that service to non-hub and Small-Hub Airports may only support commuter aircraft, serving medium and large hub airports repeatedly throughout the day with the smaller gauge aircraft does not maximize passenger throughput or the use of a constrained resource. For this reason, the proposed rule explicitly encourages the use of larger aircraft within the constrained operating environment.

Through this rule the FAA therefore proposes to encourage airlines to use larger aircraft, on average, than are being operated at the airport now (and in the recent past) so that a larger share of consumer demand will be satisfied. Compliance with the airport-wide target would be enforced through a Use-or-Lose provision, which would require carriers to report the average number of seats offered on all non-exempt Operating Authorizations each year.[8] Each carrier's annual ''average seat size'' would have to be equal to or greater than the airport-wide target or the FAA would withdraw Operating Authorizations from the carrier. The FAA first would withdraw the Operating Authorization(s) operated using the smallest aircraft. The number of Operating Authorizations withdrawn would depend on how far off the target the carrier's operations were over the preceding year. If removing one Operating Authorization was sufficient to raise the carrier's average seat size to the target level, only that Operating Authorization would be withdrawn. If more withdrawals were needed in order to meet the target, additional Operating Authorizations would be withdrawn until the target was met.[9]

While an important goal of this rule is to promote efficiency at LaGuardia, another objective is to avoid the elimination of service to the small and non-hub communities that rely on service at the airport. Accordingly, the FAA proposes that Operating Authorizations used for service to certain small and non-hub communities are exempt from the target aircraft size requirement.

The proposed rule would assign expiration dates to all Operating Authorizations. Operating Authorizations would be allocated in 2007 with expiration dates ranging from 2010 through 2019. As Operating Authorizations expire they would be reallocated with a renewed life span of ten years. Establishing a finite lives for Operating Authorizations can improve efficiency at LaGuardia over time by encouraging all airlines to maximize the use of a scarce resource and to maximize their investment at the airport. The authorization's finite life would influence carriers to recognize the present value of operating at LaGuardia because an Operating Authorization ultimately expires, at which point it would be worth nothing to the existing holder. If a carrier is not able to use an Operating Authorization profitably, the carrier may sell the authorization on the secondary market rather than hold the authorization and operate it at a loss. This incentive, coupled with the Use-or-Lose provision which enforces usage of Operating Authorizations, would promote efficient use of scarce airport resources because the carriers that value them the most will use the Operating Authorizations.[10]

IV. The Proposal To Limit Operations at LaGuardia

A. Initial Allocation of Operating Authorizations

Upon expiration of the HDR on January 1, 2007, slots will no longer exist at LaGuardia. Under today's proposed rule, the FAA would place an hourly cap on operations at LaGuardia to prevent unacceptable delay that would impact the National Airspace System. The proposed number of operations is consistent with the cap that has been in place since January 2001—75 scheduled operations per hour. The FAA's procedures for allocating AIR–21 slot exemptions since January 31, 2001, accommodate some new entrant carriers' operations above the hourly limit. Under this proposed rule, these operations would be ''grandfathered'' within the allocated hour. However, any Operating Authorizations that revert to the FAA in those hours would be moved to an hour with fewer than 75 operations prior to reallocation and assigned within the adopted 15 and 30 minute limits. Arrival and departure authorizations would be distributed in fifteen-minute time increments, and Reservations would be limited to six per hour.

The existing cap at LaGuardia represents the FAA's estimate of the maximum number of operations that can be accommodated at the airport with its current configuration and without causing excessive additional congestion and delay. The FAA is not proposing to increase the cap at this time, because it is premised on favorable weather conditions. Furthermore, even with the existing cap of 75 scheduled and 6 unscheduled operations per hour, LaGuardia has consistently been one of the top five delayed airports in the United States. In fiscal year 2005, LaGuardia ranked as the third most delayed airport in the

[7] Source: OAG, August 2001 and August 2005.

[8] Average seat size would be equal to the total number of seats offered over the year divided by the total Operating Authorization days in the year. For further detail on the average seat size calculation see the ''Use or Lose Requirements'' section in the pages below.

[9] For example, if the airport-wide target was 100, and a carrier's average seat size over all its Operating Authorizations was 99 seats then the air carrier would not have met the ''target'' and FAA would withdraw the Operating Authorization(s) that used the smallest aircraft. If one Operating Authorization was withdrawn and the air carrier's average aircraft size was re-calculated to equal 100 seats or more, that carrier would only lose a single Operating Authorization. If the re-calculation did not result in an average aircraft size of 100 seats or more, the FAA would withdraw a second Operating Authorization. This process would be repeated until the carrier's average aircraft size was equal to or greater than the ''target.''

[10] The FAA has also proposed a congestion management rule at Chicago O'Hare (Docket No. FAA–2005–20704). This proposed rule differs from that which was proposed at O'Hare because the operational characteristics at LaGuardia and O'Hare are significantly different. The primary differences between these two proposed rules are (1) that the rule at LaGuardia would not be temporary (as is anticipated at O'Hare) because increased capacity is not expected at LaGuardia, (2) Operating Authorizations at LaGuardia would expire and be reallocated, and (3) air carriers would be required to meet an airport-wide ''target'' aircraft size at LaGuardia.

nation, with only 71 percent of operations arriving on time.[11]

Operating Authorizations and Reservations would not be required on Saturdays or Sunday mornings, as there is a significant drop in traffic on those days, and we have not experienced nor do we expect to experience excessive congestion during those times. However, the FAA would consider additional rulemaking to cap operations on those days if traffic and delays become unacceptable.

Although operations would be kept at the current level of service at LaGuardia, the FAA would have the authority under this proposal to retain expired and returned Operating Authorizations, or to retime them to less congested periods, if necessary to reduce congestion and delays. Operational or navigational improvements could mitigate the need to retain or retime expired or returned Operating Authorizations, and the FAA believes that such efficiency enhancements may be possible. However, this authority would enable the FAA to take appropriate action against growing delay and to manage capacity over the life of this rule.[12]

1. ''Grandfather'' Provision

Operating Authorizations initially would be grandfathered to each carrier at LaGuardia operating slots and slot exemptions based on schedules as of October 1–6, 2006, provided that the published schedules are consistent with the 15 and 30 minute limits in this proposal. Since carriers are currently able to schedule flights anytime within the 30-minute slot window, these schedules may contribute to the current congestion and delays at the airport because this practice occasionally allows operations to exceed the airport's capacity. This is particularly apparent in the peak morning and early evening periods. Further, because we will use October 1–6, 2006, schedules, which are not currently finalized, there is potential for the 15-minute schedule peaks to increase. One objective of this rule is to improve operational performance at the airport, and we do not believe it would be prudent to grant historic status to schedule levels that are not realistic.

While one way to improve performance would be to reduce the permitted number of hourly scheduled and/or unscheduled operations, we are proposing instead to spread demand in certain peak periods. If it is necessary to de-peak the October 1–6, 2006 schedules to meet the 15 and 30 minute limits in this proposal, we do not propose to require any carrier to reduce overall hourly operations below its initial base or to operate in a different hour from the hour allocated under the HDR. To achieve the necessary de-peaking, the FAA proposes to call for voluntary measures to reallocate the grandfathered Operating Authorizations to less congested time periods within the same hour or proposes an administrative mechanism such as a lottery. We seek comment on these options.

In the event that the HDR expires prior to the publication of a Final Rule, the FAA would continue to rely on the October 1–6, 2006 timeframe as the basis for future grandfathering of aircraft Operating Authorizations. If a carrier were using a slot that is ''held'' by another carrier, the Operating Authorization would be grandfathered to the carrier that actually holds the slot.[13] Alternatively, if a carrier were using a slot that is held by an entity that is not a certificated carrier, the operating carrier would be grandfathered the Operating Authorization. The FAA proposes grandfathering operating rights to carriers in an effort to preserve service to communities with existing service at LaGuardia and to minimize disruption at the airport and to the traveling public. Although the initial ''grandfathering'' of Operating Authorizations to incumbent carriers does not provide new entrant carriers with immediate access to the airport, other aspects of this rule, such as finite Operating Authorization lives, would give those carriers not already operating at LaGuardia access to the airport as Operating Authorizations expire and are reallocated.

2. Finite Operating Authorizations

Under the proposed rule, Operating Authorizations would have finite lives. Operating Authorizations would be allocated initially in 2007 with an expiration date ranging from the year 2010 through 2019. The initial authorizations would be distributed based on actual operations and FAA slot allocation records for LaGuardia by scheduled carriers as of the week October 1–6, 2006. Operating Authorizations would then be divided into regular Operating Authorizations and Operating Authorizations that are exempt from the minimum airport seat targets. Each authorization would then be assigned an expiration date using the method discussed below (see ''Schedule of Expiration Dates for Grandfathered Operating Authorizations''). The method for determining when initial allocations expire would ensure that the expiration of Operating Authorizations is evenly distributed among all carriers so that no carrier loses a disproportionate number of Operating Authorizations at any one time.

Operating Authorizations that are initially allocated in 2007 would be granted a life of three to thirteen years. The fourth year after the rule is in effect (2010), 10 percent of the authorizations would expire and be reallocated with a renewed ten-year life. Each year thereafter, 10 percent of the Operating Authorizations would expire and be reallocated for 10 years.

This reallocation approach should encourage dynamic access to air services at LaGuardia. Determining the percentage of capacity that should be subject to reallocation annually requires establishing a balance between exposing airport access to market forces, providing access for new entrants, and preserving stability at the airport. The first three years after the initial grandfathering in 2007 would provide incumbent carriers with a degree of certainty regarding operations at the airport. The FAA believes that after 2009, use of ten-year operating lives would strike an appropriate balance between very large annual withdrawals of Operating Authorizations (which could make it less attractive for carriers to develop service at the airport) and very slow (or no) turnover of Operating Authorizations (which could result in barriers to entry to the airport). Operating Authorizations need to expire at varying times so that air service at LaGuardia remains stable even as some authorizations are subject to reallocation. We expect that any

[11] Source: ASPM. The Inspector General's FY 2006 Top Management Challenges also recently highlighted the fact that LaGuardia Airport is severely delayed. The report points out that in the summer of 2005 LaGuardia Airport ranked as the fifth most delayed airport in terms of percentage of delayed flights and had the longest average minutes of delay, with an average of 70.03 minutes of delay (p. 23).

[12] The FAA has determined that delays are not so excessive that it is necessary to reduce the hourly cap at the airport at the outset of this proposed rule but there would be some schedule depeaking required to meet the proposed 15-minute limits. If the FAA reduced hourly operations, this would impede current service levels and disadvantage the carriers as well as the traveling public.

[13] A slot ''holder'' is the air carrier that has operational authority, assigned by the FAA, to conduct scheduled arrival or departure operations at LaGuardia on a particular day of the week during a specific time of the day. Each FAA slot under the HDR has both a ''holder'' status and an ''operator'' status. The ''holder'' status typically reflects long-term slot rights and does not need to be an air carrier. The ''operator'' status reflects which particular carrier is authorized to utilize a slot on a particular day. Operator status commonly differs from holder status to reflect the assignment of slots to a commuter affiliate or partner airline, the lease or transfer of slots for a defined period of time, or one for one trades or swaps of slots with other carriers to accommodate schedule changes.

reallocation process adopted through subsequent rulemaking would provide sufficient lead time for an orderly schedule planning process by the impacted carrier(s). We invite comments and analysis on the appropriate lifespan of Operating Authorizations.

If carriers were granted perpetual operating rights they may not have sufficient incentive to sell or lease Operating Authorizations on the secondary market to a competitor placing a higher value on their use. The expiration and reallocation of Operating Authorizations should drive carriers to maximize the value of their authorization because the authorization would no longer represent an infinite investment interest. The revolving allocation process also would provide new entrant airlines and incumbent airlines wishing to expand service at LaGuardia the opportunity to acquire Operating Authorizations at LaGuardia because there would be a new stock of authorizations available each year after 2010. Establishing finite life for Operating Authorizations also meets the Department's mandate of ''placing maximum reliance on the competitive market forces and on the actual and potential competition in airline markets.'' [14]

The first Operating Authorizations would not expire at LaGuardia until 2010. The FAA is planning to seek legislative authority to provide the opportunity for market-based solutions to address congestion at LaGuardia. Should the agency receive this authority, a market-based process would be the agency's preferred reallocation methodology, and we would issue a proposed rule to implement measures for redistributing expired Operating Authorizations at that time.

3. Schedule of Expiration Dates for Grandfathered Operating Authorizations

On January 1, 2007, when the Operating Authorizations initially are allocated to the carriers, the FAA also would establish a schedule for when each Operating Authorization would expire. This procedure for assigning rolling expiration dates would only occur one time, at the initial grandfathering of Operating Authorizations, because as the grandfathered Operating Authorizations expire each one would be reallocated with a 10-year life.

All ''grandfathered'' Operating Authorizations would have a minimum life of 3 years. Beginning in 2010, 10 percent of the total Operating Authorizations allocated to all carriers would be withdrawn annually and then redistributed. The life of each ''grandfathered'' Operating Authorization, anywhere from three to 13 years, would be determined using the methodology explained below.

Under the expiration schedule, each carrier's holdings of Operating Authorizations would satisfy two conditions: (1) The average ''life'' of the Operating Authorizations would be approximately the same for all carriers; and (2) expiration of Operating Authorizations would be staggered so that no carrier would lose a disproportionate number of Operating Authorizations in a given time period.

In order to assign expiration dates to ''grandfathered'' Operating Authorizations the FAA would segregate each carrier's schedule. Non-hub and Small Community Operating Authorizations (service to Small-Hub or Non-Hub Airports) would be separated from the other Operating Authorizations. All Operating Authorizations would be assigned a scheduled expiration date, but segregating the authorizations should ensure that a disproportionate number of Small Community Operating Authorizations do not expire any given year.

Each carrier would be entitled to authorization life (beyond 2009) on average equal to 5.5 years for the Operating Authorizations that they hold. The average life of Operating Authorizations would be equal to 5.5 years because that is the arithmetic mean between one and ten years of life beyond 2009. (If Operating Authorizations expired over 20 years then 5 percent of the Operating Authorizations would expire each year and the average ''life'' of an Operating Authorization would be 10.5 years.) [15] The expiration dates of the authorizations in each quarter-hour would be assigned as follows:

(1) The number of Operating Authorizations is equal to the average number of ''slot and slot exemption'' operations held under the HDR in each quarter-hour time period;

(2) The average remaining years of life (beyond 2009) for all authorizations is roughly 5.5 years; and

(3) The total years of remaining life among all authorizations would be distributed so that 10 percent of the total Operating Authorizations at the airport expire each year.

The following example illustrates how an individual carrier's Operating Authorizations would be assigned expiration dates in each quarter-hour time period.

ALLOCATION CARRIER A'S COMMERCIAL OPERATING AUTHORIZATION EXPIRATION DATES

Time window	9:00–9:14	. . .	14:00–14:14
Carrier A's Operating Authorization (OA) Holdings	4 OAs		2 OAs
Expiration Dates	OA 1—expiration in 2 years. OA 2—expiration in 3 years. OA 3—expiration in 8 years. OA 4—expiration in 9 years. Average = 5.5 years.		OA 1—expiration in 2 years. OA 2—expiration in 9 years. Average = 5.5 years.

In this example, Carrier A has 4 slots in the 9:00 to 9:14 time period and 2 slots in the 14:00–14:14 time period. The carrier would initially be grandfathered these 6 operations (in the same time periods) as Operating Authorizations under this rule. On average, these new authorizations would have 5.5 years of life remaining after 2009. An equitable allocation for this carrier's 9:00–9:14 Operating Authorizations that would average 5.5 years of life would be the following years of remaining life beyond 2009: 2, 3, 8, and 9. In this case the four

[14] **Federal Register**, Vol. 70, No. 57 page 15523: ''Congestion, Delay Reduction and Operating Limitations at Chicago O'Hare Airport.''

[15] For 10 year Operating Authorizations the average ''life'' would be 5.5 years. The average ''life'' is calculated as follows: (Year 1*10%) + (year 2*10%) + (year 3*10%) + (year 4*10%) + (year 5*10%) + (year 6*10%) + (year 7*10%) + (year 8*10%) + (year 9*10%) + (year 10*10%) = 5.5 years (the first Operating Authorizations expire in 2010 so their ''life'' after 2009 is zero years. The last Operating Authorizations to expire from the initial grandfathering will expire in 2019 so their ''life'' is ten years.

operating authorizations would expire at the end of 2011, 2012, 2017, and 2018. Likewise, an equitable allocation for Carrier A's 14:00–14:14 Operating Authorizations would be 2 years and 9 years; therefore these Operating Authorizations would expire in 2011 and 2018.[16] It should be noted that the allocation in this case would depend on: (1) Satisfying this carrier's existing number of both arrival and departure authorizations in each quarter-hour of the day; (2) satisfying all other carriers' existing operations in that quarter-hour; and (3) ensuring that 10 percent of all authorizations expire each year. The FAA is developing a programming tool to solve this allocation process.[17]

The same process would be repeated in order to assign expiration dates to the Non-hub and Small Community Operating Authorizations.

The programming tool would use two objective functions to guide the allocation process. The first measures the discrepancy between the total of all authorization lifetimes allocated to each carrier in a quarter-hour and a presumed preferred distribution based on that carrier's current holdings. The second measures the discrepancy between the total of all authorization lifetimes allocated to each carrier over the entire day and the presumed preferred total for the day. By defining two objective functions the procedure is able to compensate in a later period for any discrepancies from the ideal in an earlier period.

B. Congestion Management Upgauging Rule at LaGuardia

1. Average Aircraft Size

To encourage efficient use of scarce air traffic system capacity at LaGuardia, the FAA, in consultation with the Port Authority, intends to set an airport-wide target for the average aircraft size used by carriers on scheduled Operating Authorizations. The size of an aircraft would be measured by the number of seats that are offered for sale on the aircraft. The target for average fleet seat capacity would be based on a passenger throughput target for the airport, based on the limitations on various terminal and ground facilities to handle passengers. Thus, the target would be based on engineering measures of the capacities of the ground facilities. The target would be phased in so that carriers at LaGuardia would have sufficient time to make adjustments to their fleets and service routes. The target also needs to be consistent with safety issues associated with runway length, takeoff performance, and landing performance.

The proposed target would range from 105 seats to 122 seats per aircraft depending on which alternatives for the proposed exemptions for Non-Hub and Small-Hub Airport services is adopted, as explained below in the discussion of more options. On January 1, 2008, one year after the Final Rule is in effect, carriers would have to report their use of Operating Authorizations over the preceding year.[18] However, the ''target'' would not be enforced until the following year, January 1, 2009. At that point, any carrier that fails to meet the ''target'' would be subject to the provisions outlined in the Use-or-Lose requirement. The FAA believes that this phase-in period provides carriers a sufficient amount of time after publication of the Final Rule to adjust their operations as necessary to meet the airport-wide target. An FAA required average aircraft size target would encourage efficient use of the airport facilities by increasing passenger throughput at LaGuardia and by providing incentives for more efficient use of the airport's physical infrastructure.

The preference for larger aircraft is a special approach to a unique situation at LaGuardia. Demand at LaGuardia exceeds the airport's capacity for flight operations throughout the day, and there is no prospect for any significant increase in capacity for aircraft operations at the airport because of its physical limitations. On the other hand, the airport's groundside facilities can handle more passengers than now use the airport.[19] Promoting larger aircraft is the only means to increase passenger access to LaGuardia. Accordingly, in these limited circumstances, the increase in passenger throughput can be considered as a measure of efficiency of the use of airspace, and is within the FAA's authority under 49 U.S.C. 40103(b) to establish regulations for the efficient use of airspace.

The upgauging policy proposed for LaGuardia is based on the FAA's authority for efficient management of airspace under 49 U.S.C. 40103. This limited application of an upgauging policy under the FAA's airspace management authority is unrelated to airport proprietary authority. The FAA's exercise of its statutory authority for efficient airspace management does not affect the obligation of airport sponsors under Airport Improvement Program (AIP) sponsor assurances to provide access to all types, kinds, and classes of aeronautical use on reasonable and not unjustly discriminatory terms.

The average aircraft size target would be monitored on an annual basis, which would afford carriers the business flexibility to meet the overall average fleet goal with whatever combination of aircraft they determine is right for each route and service over the course of the year. Each year, carriers would be required to operate, on average, aircraft with at least as many seats as specified by the target aircraft size or they would lose one or more Operating Authorizations.

Every twelve months, the FAA, after consultation with the Port Authority, would re-evaluate the target and modify it as necessary to account for changes in the airport's operations or modifications to the capacity at the airport. For example, if gate usage requirements change or airport infrastructure is developed that allows more efficient use (e.g., terminal modifications), the target could be adjusted upward. In fact, the effectiveness of this rule could be augmented by sponsor gate use policies that maximize the potential of the infrastructure. Alternatively, if the operations at the airport were negatively impacted due to an overly optimistic target, the FAA would have the ability to adjust the target downward. Because the target affects carrier planning of fleet mix, routes, staffing requirements, and gate usage, the FAA would limit target increases to no greater than a 3-seat increase in any year.[20] On the other hand, a decrease in the ''target'' would likely only occur if it were necessary to correct unforeseen problems that result from an inflated ''target.'' Carriers would not be penalized from operating aircraft that are larger than the airport-wide target, so a decrease in the target

[16] This illustration provides one possible distribution of expiration dates for the given Operating Authorizations although not the only possible expiration schedule; several combinations of expiration dates could generate the same ''remaining life'' outcome of 5.5 years.

[17] Anomalies could occur in order to balance these criteria. Rather than 10% of Operating Authorizations expiring in a particular quarter hour it might be 10% plus or minus 1% in order to get the proper total integrated number of Operating Authorizations.

[18] Reporting requirements are discussed in the Use-or-Lose section in the pages below.

[19] According to the Port Authority's 2004 Airport Traffic Report, 24.5 million domestic and international passengers flew through LaGuardia in 2004. In various forums the Port Authority has indicated that approximately 28.5 million passengers could be accommodated at the airport on existing facilities and infrastructure.

[20] An annual increase to the target aircraft size of up to 3 seats per year provides sufficient flexibility to adjust the target, if necessary. If it were determined that a more significant target increase were appropriate in any given year, FAA would publish the proposed target increase in the **Federal Register** and seek comments on the proposed target.

is not expected to have a negative impact on carriers.

To assess the impact of upgauging at LaGuardia, NEXTOR has conducted simulations that examine the behavior of the airport runway, taxiway, and gate operations in the presence of a ''high-demand'' schedule when 25 percent of the regional jets are upgauged to narrow-body jets. By extending several Official Airline Guide (OAG) schedules to a representative ''high-demand'' arrival and departure schedule, NEXTOR analyzed the impact of upgauging using Total Airport & Airspace Modeler (TAAM) for LaGuardia. Experts from the FAA air traffic control tower and representatives from the Port Authority validated the operational assumptions regarding gate, taxiway, and runway utilization parameters used in the TAAM simulation model. Results show that representative upgauging by the airlines from regional jets to narrow-body jets could result in increased passenger throughput without negative impact on LaGuardia airport operations, flight delays or passenger delays.

2. Services Not Subject to the Average Aircraft Size Target

a. *Baseline Operations.* Each carrier would be granted a ''baseline'' of up to 10 Operating Authorizations per day that would not be subject to the target aircraft size requirement in this proposed rule.[21] The FAA has tentatively determined that each carrier should be assessed a minimum number of takeoffs and landings that are not at risk should its overall operations not meet the airport-wide target. While that number should be sufficiently large to permit minimal fleet and route flexibility, it should not overshadow the goal of increased throughput. A baseline of 10 Operating Authorizations per day should provide carriers with a stable base of operations, minimizing the disruption on carrier schedules and operations at the airport while not compromising the goal of increased passenger throughput at the airport. Each year, carriers would notify FAA which of their Operating Authorizations they intend to designate as ''baseline'' operations, and these operations would not be subject to the target and Use-or-Lose provisions of the rule based on average aircraft size target.

A baseline is particularly important for carriers that have operated at LaGuardia for decades and developed their networks to include service at the airport. Similarly, carriers with limited ability to adjust their fleet size would be assured that their baseline operations would not be at risk of being withdrawn for non-compliance with the target aircraft size requirement. New entrants and carriers with a limited number of Operating Authorizations at LaGuardia may not have much fleet versatility at the airport, particularly if they do not have excess over-night parking and gate space that can be used to interchange aircraft. Although the airport target would not bind baseline operations, carriers would not be restricted from operating aircraft equal to or larger than the target aircraft size with these baseline Operating Authorizations.

b. *Non-Hub and Small-Hub Airport Services.* While a primary goal of this rule is to promote efficient use of the airport, the DOT's mandate to consider the public interest requires us to encourage the maintenance of scheduled services to small communities. Congress recognized this public interest when it required exemptions from the HDR in AIR–21 for small community service. Because regular demand to and from LaGuardia from these communities may not be sufficient for a carrier to meet the airport-wide target,[22] some type of relief may be needed.

In an effort to preserve service to these communities, the FAA is proposing to create a separate pool of Operating Authorizations, to be used to provide service to non-hub and small-hub communities, that would be excepted from the target aircraft size requirement. Unlike the HDR or the AIR–21 slot exemption provisions, air carriers would not be limited to operating aircraft of a certain size.[23] Instead, carriers with Non-Hub and Small-Hub Airport operations would have the flexibility to fly aircraft of whatever size they want to these communities.

The FAA requests comments on the relative merits of three non-hub and small-hub options, as well as any combination of the three:

(1) The FAA would create a pool of Operating Authorizations for service to Non-Hub Airports. These Operating Authorizations would be excused from the target aircraft size requirement. The pool of non-hub Operating Authorizations would be based on the service level to Non-Hub Airports during the week of October 1–6, 2006; although any Non-Hub Airport would be eligible for service under this target exemption.[24]

(2) The FAA would create a pool of Operating Authorizations for service to Non-Hub Airports and all Small-Hub Airports within 300 miles of LaGuardia [25] (''Local Small Communities''). These Operating Authorizations would not be subject to the target aircraft size requirement. The pool of Non-Hub and Local Small Community Operating Authorizations would be based on the service level to Non-Hub and Local Small Communities during the week of October 1–6, 2006. However, any Non-Hub Airport Small-Hub Airport within 300 miles of LaGuardia would be eligible for service under this target exemption.

(3) The FAA would create a pool of Operating Authorizations for service to Non-Hub Airports, Small-Hub Airports that have existing service at LaGuardia, and Small-Hub Airports within 300 miles of LaGuardia (''Local Small Communities''). The pool of Non-Hub and Local Small Community Operating Authorizations would be based on the service level to Non-Hub and Small-Hub Airports during the week of October 1–6, 2006. However, any Non-Hub Airport or Small-Hub Airport would be eligible for service under this target exemption.

Under the first option, the FAA would exclude operations arriving and departing from Non-Hub Airports from the proposed target aircraft size requirement. The number of Operating Authorizations that would be excluded from the target for Non-Hub Airport service would be based on level of operations to non-hub cities during the week of October 1–6, 2006.[26] Although we cannot fully anticipate what may be the level of operations for October 1–6, 2006, we believe the levels during the twelve month period of April 2004 through March 2005 are representative. Over the twelve-month period of April 2004 through March 2005 there was an

[21] Carriers that have 10 or fewer Operating Authorizations would not be subject to the airport target since all their Operating Authorizations would be considered ''baseline'' operations.

[22] Operations to these communities are typically on smaller-sized aircraft.

[23] There are several HDR slot categories that limit aircraft size. For example, Commuter Turboprop Slots require aircraft with less than 75 seats; Commuter Turbojet Slots limit seats to 55 or less; and AIR–21Small Hub/Non-Hub Airport exemptions require aircraft with 70 seats or less.

[24] A Non-Hub Airport is a commercial service airport that has more than 10,000 annual passenger boardings but less than 0.05% of the total United States annual passenger boardings.

[25] Small-Hub Airports are locations with at least .05%, but less than .25% of annual passenger boardings. Small Hub Airports that are within 300 miles of LaGuardia and have existing service include: Albany, Burlington, Portland, Richmond, Rochester, Syracuse, and Newport News/Williamsburg. Source: T–100 Data, April 2004–March 2005.

[26] Nantucket, Bangor, Charlottesville, Hyannis, Wilmington, Ithaca, Lebanon, and Martha's Vineyard are Non-Hub Airports with existing service at LaGuardia. Source: T–100 Data, April 2004–March 2005.

average of forty-five operations arriving and departing to Non-Hub Airports per day.[27] Although the pool of Operating Authorizations that would be excluded from the target aircraft size requirement would remain fixed, any Non-Hub Airport could be served through these target exclusions. Additional flights to or from these non-hub cities (beyond the fixed number of Operating Authorizations that are excluded from the target) would be subject to the target aircraft size requirement. This approach maintains a level of service to Non-Hub Airports (that typically do not support operations on large aircraft) while preserving the possibility for other Non-Hub Airports that do not currently have service at LaGuardia to gain this same access to the airport.

The pool of Operating Authorizations that would be excluded from the target for service to non-hub communities would be allocated in the same manner as the other Operating Authorizations. Air carriers currently providing service to non-hub communities would be allocated Operating Authorizations for ''Non-hub'' service at the October 1–6, 2006, level. If an air carrier with a Non-hub Operating Authorization wanted to sell or lease the Operating Authorization in the secondary market, it could do so, but the Operating Authorization would have to be sold or leased as a ''Non-hub'' Operating Authorization. Therefore, the pool of ''Non-hub'' exemptions would remain fixed throughout the life of the rule.

The second option is similar to the first; however, it provides a larger pool of Operating Authorizations that would be excused from the average aircraft size target. The pool of Operating Authorizations in this option would be equivalent to the October 1–6, 2006, level of service to Non-Hub Airports and to Small-Hub Airports within 300 miles of LaGuardia.[28] Over the twelve-month period of April 2004 through March 2005 there was an average of 121 operations arriving and departing to these airports per day.[29] Although the pool of exempt Operating Authorizations would be fixed to October 1–6, 2006, level of service, air carriers could use these Non-hub and Local Small Community Operating Authorizations to provide service to any Non-Hub Airport or any Small-Hub airport within 300 miles of the airport; they would not be restricted to serving just the non-hub and small-hub cities that have service at LaGuardia as of October 1–6, 2006.[30]

However, as under the first option, the number of target-exempt flights to Non-hubs and Local Small Communities would be limited to the number of Operating Authorizations in the Non-hub and Local Small Community pool. Additional flights to or from these cities would be subject to the seat size requirement of this rule.

Because the pool of Non-hub and Local Small Community Operating Authorizations would remain fixed, if an air carrier wanted to start new service to a qualified Small or Non-Hub Airport it could do so using these excluded Operating Authorizations, but it would have to forego another Non-Hub or Small-Hub Airport. As a result, the amount of service to or from a particular non-hub or small-hub community might vary over time, but the total number of exempt operations to such communities would remain the same.[31]

Operating Authorizations for service to non-hub and Local Small Communities would be allocated in the same manner as described in the first option. Similarly, if an air carrier wishes to sell or lease a Non-hub and Small Community Operating Authorization on the secondary market, it would be leased or sold as such.

The third exemption option would provide the greatest number of exemptions to small and non-hub communities. The FAA would exempt flights to all Non-Hub Airports, all Small-Hub Airports that have service at LaGuardia as of October 1–6, 2006, and any Small-Hub Airports within 300 miles of LaGuardia.[32] Operating Authorizations would be ''grandfathered'' to carriers that provide service to these airports as October 1–6, and the transfer of these Non-hub and Local Small Community Operating Authorizations in the secondary market would be subject to the same type of restrictions as described in the two previous alternatives. The total number of such exemptions would be fixed but the number of operations to any one Non-Hub or Small-Hub Airport might vary over time.

The pool under this third exemption option would be equal to the October 1–6, 2006, level of service from LaGuardia to Non-Hub and Small-Hub Airports. Over the twelve-month period of April 2004 through March 2005 there was an average of 200 operations arriving and departing to these airports per day.[33] This approach would maximize service to small communities, but could remove as much as 30 percent of the overall fleet from the population of aircraft required to meet a minimum average seat size.[34] In order to increase passenger throughput, the airport-wide target may be so large as to be impractical because the higher the airport-wide target, the more gate limitations (certain gates can only accommodate small to medium sized aircraft). Additionally, the FAA is aware that fewer markets support operations on large aircraft than on small-medium sized aircraft.

The FAA seeks comment on the merits and practicality of the three non-hub and small-hub exemption alternatives outlined above. We want to make clear in any event that we are not proposing to limit service to non-hub or small communities with aircraft meeting the targeted size.

3. Calculation of the Average Aircraft Size Target

The airport-wide target for the average aircraft size at LaGuardia is dependent on which of the Non-hub and Small-hub alternatives is ultimately adopted in the Final Rule. The target would vary because the number of exempt Operating Authorizations is different in each scenario. The first scenario, which only provides target exemptions for Non-Hub Airports, would produce the lowest airport-wide target since there would only be a limited number of

[27] Source: T–100 Data, April 2004–March 2005.

[28] Small Hub Airports that are within 300 miles of LaGuardia and have existing service include: Albany, Burlington, Portland, Richmond, Rochester, Syracuse and Newport News/Williamsburg. (Non-Hub Airports with existing service are listed in footnote above). Source: T–100 Data, April 2004–March 2005.

[29] Source: T–100 Data, April 2004–March 2005.

[30] FAA believes that there is merit in preserving nonstop service to non and small hub cities within 300 miles of LaGuardia. If passengers in these cities had to make a connection in order to fly into LaGuardia, they likely would fly further away from LaGuardia to reach the connecting airport.

[31] Non Hub and Small Hub Operating Authorizations could only be used for service to qualifying airports; service to medium and large hubs would not be permitted with this pool of Operating Authorizations.

[32] The following non hub and small hub airports have existing service to and from LaGuardia: Nantucket, MA; Bangor, ME; Charlottesville, VA; Hyannis, MA; Wilmington, NC; Ithaca, NY; Lebanon, NH; Martha's Vineyard, MA; Albany, NY; Burlington, VT; Portland, ME; Richmond, VA; Rochester, NY; Syracuse, NY; Newport News/Williamsburg, VA; Birmingham, AL; Columbia, SC; Akron/Canton, OH; Charleston, SC; Dayton, OH; Greensboro, NC; Greenville-Spartanburg, SC; Lexington Blue Grass, KY; Myrtle Beach, SC; Roanoke, VA; Savannah, GA; Knoxville, TN; and Fayetteville, AR. Source: T–100 Data, April 2004–March 2005.

[33] Source: T–100 Data, April 2004–March 2005.

[34] This Non Hub and Small Hub option would provide the greatest number of target-exemptions for service to small communities (approximately 200 per day). These Non Hub and Small Community Operating Authorizations combined with the target-exemptions for ''baseline'' operations would equate to approximately 30% of the Operating Authorizations at the airport.

Operating Authorizations exempt from the target. Alternatively, the third scenario, which would also exempt all Small-Hub Airports that have existing service at LaGuardia and Local Small Communities, produces the largest target because roughly 30 percent of the daily operations would be removed from the target requirement at the airport. The targets under each of these three scenarios are presented in the table below.

The FAA computed the target aircraft size for LaGuardia using an airport passenger throughput target, as determined by the Port Authority, of 28.5 million passengers per year.[35] T–100 data from April 2004 through March 2005 reports roughly 372,000 commercial operations over the twelve-month period.[36] In order to calculate the target size, the FAA assumed the number of commercial operations at LaGuardia would remain constant at 75 per hour. Using T–100 data to track historic usage patterns and service routes, the FAA has tentatively determined that the following airport-wide targets are appropriate, depending on which small community exemption alternative is ultimately adopted. Currently, aircraft operating at LaGuardia have 98 seats, on average.

Option 1: Non-Hub Airports and up to 10 Baseline Operations per Carrier would be Exempt

Target Average Aircraft Size = 105 Seats

Option 2: Non-Hub Airports, Small-Hub Airports < 300 Miles and up to 10 Baseline Operations per Carrier would be Exempt

Target Average Aircraft Size = 116 Seats

Option 3: Non-Hub Airports, Small-Hub Airports with Existing Service, Small-Hub Airports < 300 Miles and up to 10 Baseline Operations per Carrier would be Exempt

Target Average Aircraft Size = 122 Seats

The FAA seeks comments on each of the non-hub and small-hub exemption alternatives and the corresponding airport-wide targets.

4. Use-or-Lose Requirements

a. *Use-or-Lose Requirement Based on Average Aircraft Size.* The FAA is proposing a requirement to obtain compliance with the ''target'' aircraft size requirement at the airport. The FAA would administer the requirement on an annual basis. Carriers would be required to submit annual reports of usage, including a record of (1) the FAA assigned priority number, time, and arrival or departure designation; (2) the operating carrier; (3) the aircraft-type; (4) the number of passenger seats on the aircraft for each operation; (5) the date and time of each of its operations using an Operating Authorization, including flight number, and origin/destination; and (6) the average number of seats flown for all operations over the year. Statistics on the use of baseline authorizations and target exclusions for service to Non-Hub and Small-Hub Airports would be required in the report, although the number of seats flown on these operations would not be included in the carrier's average seat size calculation. The annual report would be due to the FAA no later than March 1st of each year, starting March 1, 2008.

The average seat size would be computed by totaling the number of seats flown over the year (on each Operating Authorization, excluding baseline operations and operations that serve Non-Hub and Small-Hub Airports), divided by the total number Operating Authorization days.[37] Operating Authorizations that are not used on any given day would be presumed to have a zero seat capacity.[38] A carrier's average number of seats on all Operating Authorizations combined during the year must meet the annual airport-wide for the carrier to be in compliance with the utilization requirement.[39]

If a carrier fails to meet the average seat size requirement for the year, it would be required to give up sufficient Operating Authorization(s) beginning with those that use the smallest average aircraft size until the remainder meet the target from the preceding year. (If two or more Operating Authorizations have the same average aircraft size and are tied as having the smallest average seat size, the carrier could chose which of those Operating Authorization(s) would be withdrawn unless the FAA determines that there is an operational need to withdraw one Operating Authorization over another.) The FAA would provide 45 days notice to the carrier prior to withdrawing Operating Authorization(s). The Use-or-Lose requirement would be waived during the Thanksgiving, Christmas, and New Year's holiday periods. The Use-or-Lose requirement could also be waived during a strike, or in other circumstances outside a carrier's control, as determined by the FAA.

b. *Use-or-Lose Requirement for ''Baseline'' and '' Small Community'' Operating Authorizations.* The FAA believes that a minimum usage requirement is appropriate for Operating Authorizations excluded from the target aircraft requirement. Although these operations are not subject to the upgauging aspect of the rule, these resources should be used effectively. Depending on which non-hub and small-hub exemption scenario is selected in the final rule, a significant number of Operating Authorizations may not be subject to the airport-wide target. Therefore, the omission of a Use-or-Lose requirement on these exempt Operating Authorizations as well as the Baseline Operations would pose a risk that a sizable number of Operating Authorizations could be used inadequately.[40]

[35] The Port Authority has indicated that passenger demand for access to the airport is forecasted at 30 million annual passengers (FAA's Terminal Area Forecast (TAF) concurs that passenger demand at LaGuardia will reach 30 million annual passenger in the next couple of years). However, landside limitations on the terminals and roadways of the airport restrict passenger throughput to approximately 28.5 million passengers per year.

[36] Part 121 and scheduled Part 135 departure data is submitted by carriers to the Office of Airline Information (OAI) within the Bureau of Transportation Statistics (BTS) under 14 CFR Parts 241 and 298, respectively. The airlines submit the data on Form 41, Schedule T–100 '' U.S. Air Carrier Traffic and Capacity Data By Nonstop Segment and On-flight Market and Form 41, Schedule T–100 (f)—Foreign Air Carrier Traffic and Capacity Data by Nonstop Segment and On-flight Market.

[37] Operating Authorization days would be Monday through Friday and Sunday afternoons.

[38] Because unused Operating Authorizations must be included in the average seat size calculation the Use-or-Lose requirement ensures Operating Authorizations are used and not sitting idle.

[39] The following example illustrates the average seat size computation for an air carrier that holds three evening Operating Authorizations that are not excluded from the target.

Each year there would be approximately 313 Operating Authorization days for each of the Operating Authorizations (365 days − 52 Saturdays).

*If the carrier offered a total of 33,000 seats over the year on the first Operating Authorization the average seat size on that Operating Authorization would be: 33,000/313 days = 105 seats per aircraft;

*If the carrier offered a total of 40,000 seats over the year on the second Operating Authorization the average seat size on that Operating Authorization would be: 40,000/313 days = 128 seats per aircraft; and

*If the carrier offered 27,000 seats over the year on the third Operating Authorization the average seat size on that Operating Authorization would be: 27,000/313 days = 86 seats per aircraft.

*The air carrier's average seat size over all three Operating Authorizations would be equal to: 100,000 seats/939 Operating Authorization Days = 107 seats per aircraft.

[40] It should be noted that several airlines that responded to the Chicago O'Hare Notice of Proposed Rulemaking (Docket No. FAA–2005–20704) supported a Use-or-Lose requirement at O'Hare when presented with the option of not having a usage requirement at the airport. It was generally suggested that a minimum usage requirement should be included to prevent carriers from retaining Arrival Authorizations for which they have no use.

The FAA proposes to adopt a Use-or-Lose provision that would require air carriers to utilize each authorization they hold at least 80 percent of the time over a two-month reporting period. Any Operating Authorization used less frequently would be withdrawn after notice to the holder. Under this alternative, the 80 percent usage requirement would apply only during the restricted hours (*i.e.* Saturdays and Sunday mornings would be excluded from the usage requirement). The Thanksgiving, Christmas, and New Year's holiday periods could also be excluded. The Use-or-Lose requirement would also be waived during a strike, or in other circumstances as determined by the FAA.

This proposed Use-or-Lose requirement mirrors one of the minimum usage alternatives presented in the Chicago O'Hare NPRM and widely supported by the commenters. Nevertheless, FAA seeks comment regarding the appropriate minimum usage requirement for Operating Authorizations that are not subject to the aircraft size target at LaGuardia.

5. Lottery for the Reallocation of Certain Operating Authorizations

The FAA is proposing to implement a weighted lottery for reassigning authorizations that are returned to the FAA, withdrawn as a result of failing to meet the usage requirements under the Use-or-Lose provision of the rule, or not assigned by the FAA as part of the initial allocation. Under this system, each carrier's weight in the lottery would be inversely proportional to the carrier's share of total operations at LaGuardia. If a potential new entrant wishes to participate in the lottery, its weight would equal that of a carrier with a single roundtrip flight at the airport.

An inversely weighted lottery would provide preferences to carriers that do not have a presence at LaGuardia and to those carriers with a limited number of Operating Authorizations at the airport.[41] This approach meets the Secretary of Transportation's public interest objectives by keeping available a variety of adequate, economic, efficient, and low-priced air services; placing maximum reliance on competitive market forces and on actual and potential competition; encouraging entry into air transportation markets by new and existing air carriers; and continuing to strengthen small air carriers to ensure a more effective and competitive airline industry. See 49 U.S.C. 40101(a)(4), (6), (10)–(13) and (16), and 40105(b). To further these goals and to assure efficient and effective use of the authorizations, Operating Authorizations obtained through a weighted lottery may not be bought, sold, leased, or otherwise transferred until one year has elapsed from their assignment.

An inverse lottery disadvantages those carriers with the largest presence at LaGuardia because they will always be less likely to win an Operating Authorization than other carriers with a smaller presence. However, an inverse lottery is appropriate in this limited circumstance because under our proposal the incumbent carriers at the airport would have already received numerous Operating Authorizations in the initial allocation process.

This lottery approach is limited to Operating Authorizations that are lost via the Use-or-Lose provision or are otherwise returned to the FAA for non-use and to any Operating Authorizations that are not assigned by the FAA as part of the initial allocation. Those Operating Authorizations that revert back to the FAA as a function of the Operating Authorizations' finite life are not impacted by this lottery. The method for reallocating expired Operating Authorizations has not been decided; however, the FAA preliminarily finds that an inverse lottery would not be appropriate for reallocation. The FAA believes it may be unfair to impose an inverse lottery on those withdrawals because the incumbent carriers would repeatedly be penalized as the lowest weighted lottery participant.

The following provides an illustration of how weights would be assigned to each carrier in the lottery if there were three carriers participating in the lottery. Assume Carrier A has 50 Operating Authorizations, Carrier B has 20 Operating Authorizations, and Carrier C has 10 Operating Authorizations, for a total of 80 Operating Authorizations.

Carrier A's share is 50/80 = 0.600
Carrier B's share is 20/80 = 0.250
Carrier C's share is 10/80 = 0.125

The inverse of each carrier's market share determines each carrier's weight in the lottery. Thus:

Carrier A's weight in the lottery is: 1 / 0.6 = 1.67
Carrier B's weight in the lottery is: 1 / 0.25 = 4.0
Carrier C's weight in the lottery is: 1 / 0.125 = 8.0

Each carrier's odds of winning the lottery are a function of their weight in the lottery. In this example, Carrier A holds the greatest number of Operating Authorizations at LaGuardia, and therefore has the lowest odds of winning the lottery. The odds that each carrier would win are as follows:

Carrier A's chances of winning are 1.67 / 13.67 = 12.22%
Carrier B's chances of winning are 4 / 13.67 = 29.26%
Carrier C's chances of winning are 8 / 13.67 = 58.52%

If a new entrant carrier, Carrier D, also enters the lottery it would be assigned a weight as if it had one round trip flight (2 Operating Authorizations) at the airport. The odds that each carrier would win are adjusted as follows:

Total weight in the lottery would be increased to 13.67 + 40 = 53.67[42], so:

A's chances of winning are 1.67 / 53.67 = 3.1%
B's chances of winning are 4 / 53.67 = 7.5%
C's chances of winning are 8 / 53.67 = 14.9%
D's chances of winning are 40 / 53.67 = 74.5%

Alternatively, the FAA is considering permitting the sale of Operating Authorizations that would otherwise be withdrawn or returned in a blind secondary market. This approach has the benefit of not penalizing, even marginally, carriers with sizeable Operating Authorizations because their acquisition opportunity would not be hampered by their existing holdings. However, this mechanism would not provide any advantage for new carriers or for those carriers with only a few Operating Authorizations.

Under the blind secondary market scenario, if a carrier did not meet the target aircraft size requirement, the FAA would provide 45 days advance notice to the carrier that it has failed to meet the usage requirement and an Operating Authorization(s) was to be withdrawn. The Operating Authorization would then be posted for sale in the blind

[41] This lottery differs from that which was proposed in the congestion management rule at Chicago's O'Hare. The lottery to reallocate withdrawn operations at O'Hare would consist of two rounds. In the first round, only new entrants and limited incumbents would be permitted to participate. In the second round any remaining Arrival Authorizations would be assigned by lottery to incumbent carriers at O'Hare.

The lottery proposed herein for LaGuardia also provides a preference for limited incumbents and new entrants, but does not preclude incumbent carriers from participating in the first round of the lottery. Since this proposed rule is expected to have a longer duration than that which was proposed at O'Hare, the FAA determined that it is important to implement a lottery that provides all carriers access to reallocated/withdrawn Operating Authorizations.

[42] Carrier D's weight in the lottery is calculated as follows:

Carrier D's share = 2 Operating Authorizations/ 80 Operating Authorizations = .025.

Carrier D's weight in the lottery = 1/.025 = 40.

auction (see details of Alternative 1 in the Secondary Market discussion below). Proceeds of a sale would go to the airline that lost the Operating Authorization and any unsold Operating Authorizations would revert to the FAA and be reallocated in a lottery.

The FAA requests comments on the relative merits of these two reassignment methodologies for withdrawn Operating Authorizations.

C. Commercial Options for Carriers

1. Secondary Market

Under the HDR, the Department received complaints about the buy/sell process as it was implemented. The rule permitted the buyer and seller to deal directly with each other. Incumbent carriers would refuse to sell to a new entrant or a competitive airline according to the reports received by the Department, raising concerns with the ''transparency'' [43] of the existing secondary market. There was no requirement for the seller to advise parties that slots were available, limiting opportunity for other carriers to make an offer for the slot. Finally, the terms of a transaction were not disclosed making it more difficult to develop future bidding strategies, which may have included cash and non-cash assets.

The Department of Justice submitted comments in the O'Hare rulemaking, which supported the use of a blind market or a non-transparent market, because the secondary markets at LaGuardia and O'Hare under the HDR have not been ''sufficiently liquid.'' [44] A blind secondary market effectively eliminates non-cash assets to be bid. We acknowledge that a proposal to prohibit the use of non-monetary considerations in transactions involving Operating Authorizations may be unpopular.[45] Cash equivalent consideration allows the buyer of an Operating Authorization to offer items that may be mutually beneficial and less ''cost'' than cash. Perhaps, given the industry's liquidity problems and the operational needs of carriers at various airports, an airline selling or buying an Operating Authorization ought to be able to accept or offer non-monetary consideration (i.e. services, ground handling) as part of the bid. By opening the auction to pledges of assets other than money, we would widen the auction market to cash-strapped airlines.

Nevertheless, we are concerned that the uniqueness of non-monetary assets, such as baggage handling and marketing arrangements, would effectively undermine any form of a ''blind'' secondary market. The inclusion of non-monetary assets would make it virtually impossible to hide identities during the bid evaluation process. In order for the buyer to put together an attractive package and assign a value to non-cash assets, the seller must be known. Similarly, a seller cannot assess the value of an asset if it does not know who is specifically offering the asset and how the asset would be transferred. Furthermore, if non-cash assets are pledged, the parties would want to negotiate terms, including but not limited to, the terms of any warranties, approval and agreement enforceability, and damages for any breach of the agreement. It is unreasonable to assume that the FAA, or any other entity, could independently appraise the value of a package for the buyer or seller. In fact, the FAA would not be in a position to judge the value of an offer to the selling carrier since that involves access to the carrier's strategic plan and internal documents that would not be readily available.

We are seeking comment on three alternative secondary market provisions for this proposed rule. Differences under each proposed alternative include whether the sale or lease is blind and whether non-cash assets could be included in the buyers' bids.

- Alternative 1 would be a blind, cash-only secondary market. The identity of the seller and the bidders would be maintained until the seller accepts the highest bid at the close of the auction. Sellers would be expected to close the sale in good faith regardless of whom the buyer may be.
- Alternative 2 would permit non-cash assets to be bid, and the parties identities would be known throughout the process. When the FAA posted notice of the sale of an Operating Authorization, the seller would be identified. As each bid was posted, the identity of the bidders would be disclosed. Consideration for the transaction could be any combination of money, real property and non-monetary assets. An estimated value of these assets would have to be provided under each bid. Because the FAA would not be in a position to deem what bid is of highest value to the seller, all bids would be posted at the close of each day. Within five business days of the close of the auction, the seller, in good faith, would have to identify to the FAA which bid is most competitive. The seller and buyer then would have 10 business days to negotiate the provisions of the sale.
- Alternative 3 is a hybrid of the first two alternatives described above. This option provides for up-front anonymity and cash-only bids, but it would eventually allow the parties to negotiate non-cash terms. During the posting of the sale or lease and the subsequent bidding of an Operating Authorization, the party's identities would not be known. Once the auction closed, the FAA would forward the highest bid to the seller without any bidder identification. The seller would have three business days to accept the bid. The parties' identities would then be revealed, and they would have 10 business days to negotiate the possibility of non-cash assets in lieu of money as consideration for the sale or lease. If, however, the parties did not come to agreement on the non-cash assets, sale or lease of the Operating Authorization would have to proceed on a cash-only basis.

The advantage of Alternative 3 is that it responds to concerns that the buy/sell arrangements that currently occur under the HDR are too transparent; thereby allowing incumbent carriers to fence out new entrants or other airlines that could pose a competitive threat. At the same time, it releases restrictions on the use of non-monetary considerations. Again, because of the uniqueness of non-monetary assets, the identity of the buyer and seller eventually have to be disclosed so that they can come to terms on the possible non-cash aspects of the package. If, however, the parties cannot come to agreement on non-monetary consideration, both parties are fully expected to follow through on the transaction on a cash-only basis. While this may mean that cash-strapped carriers without the credit-worthiness to obtain liquidity on a secured or unsecured basis would not be able to participate in the process because they risk having to come up with 100% cash, it does allow for some flexibility.

Under either Alternatives 2 or 3, we would preclude the direct trading in gate leasehold interests. Under the terms of the FAA-airport grant assurances, airports have agreed to make their facilities available for public use under reasonable terms and conditions.[46] This assurance obligates an airport to make its facilities available to a requesting carrier, whether an incumbent carrier that is seeking to expand at the airport

[43] ''Transparency means that the identity of buyers and sellers is known. Transparency in the secondary market permits strategic sales, leases, and purchases by incumbents to prevent new entry.'' Comments of the United States Department of Justice in Docket No. FAA–2005–20704. May 24, 2005, pp. 5–9.

[44] *Id.*

[45] We learned under the O'Hare rulemaking that most commenters believe that each carrier should be allowed to consider the value of specific gates, baggage handling, marketing arrangements, and other potential offers in lieu of cash.

[46] 49 U.S.C. 47107(a).

or a new entrant seeking access. By facilitating requested accommodations, an airport is able to provide opportunities for airline competition and thereby confer benefits on the traveling public and help to stimulate economic growth. Since gates are a necessary part of access, the FAA expects airports to assert and maintain control over each airline's use of and leasehold interests in the gates and to notify all interested carriers when a gate is underutilized or otherwise becomes available. Implementing fair and transparent procedures for gate access assures that dominant carriers do not control access to the airport to the exclusion of competitors. We believe that permitting a carrier to trade its gate leasehold rights for an operating authorization at LaGuardia would diminish the control of the airport operator over its facilities and could denigrate competitive opportunities at the airport served by the bidding airline.

The general process under any of the alternatives would be as follows:

The FAA would serve as the clearinghouse through which sales and leases of Operating Authorizations are completed, which would address complaints by some airlines and other entities that under the HDR, they were not even aware of opportunities to purchase or lease slots.[47] A carrier wishing to sell, lease or buy an Operating Authorization would notify the FAA of the relevant details—the Operating Authorization number, time, frequency, expiration date and effective date the Operating Authorization would transfer to the winning bidder—and the FAA would post advance notice of the opening and closing dates for bids to all airlines and afford all airlines an equal opportunity to bid. A Small Community Operating Authorization must be sold, bought and leased as a Small Community Operating Authorization. Selling carriers may also provide the FAA with a minimum bid price, which the FAA would post.

Carriers would be permitted to continue bidding until the closing date of the auction. To insure against participants bidding at the last moment (known as ''bid-sniping''), the ''winning'' bidder must participate in the bidding from the first day of the auction, rather than submitting a bid in the final minutes before the bidding is closed.[48] In order to qualify, bids must meet the minimum price if one is specified. The FAA proposes that each auction would last for 3 business days. Upon acceptance of a bid and ratification of the sale or lease, both airlines would have to submit the necessary information to the FAA for transfer of the Operating Authorization in a timely manner. A record of each sale and lease would be kept on file by the FAA and be available to the public upon request. Only airlines would be allowed to participate in this market. The FAA welcomes comments from the public on these or other appropriate auction design features.[49]

2. One-for-One Trades

In addition, the proposed rule would permit the one-for-one exchange of Operating Authorizations between airlines so long as no additional consideration was provided. Under the proposal, these exchanges must be publicly disclosed and could take place outside of the secondary market because many of these arrangements are for operational reasons and could be accomplished only through multi-carrier trades. Such exchanges would be an effective way to deal with variations in seasonal demand and airline business strategies. The authorizations could not be used until written confirmation of the transaction is received from the FAA. Both parties would have to attest that no other consideration or promise of consideration was provided by either party to the trade.

D. Unscheduled Operations

The FAA is proposing to implement a Reservation system for unscheduled operations to ensure that demand is spread reasonably throughout the day to support the FAA's established operational cap for scheduled and unscheduled flights.[50] Therefore, the FAA proposes a limit of 6 unscheduled operations per hour between the hours of 6:30 a.m. and 9:59 p.m. The FAA recognizes that there is often greater flexibility in the timing of these flights and there are many factors that impact the proposed time of these unscheduled flights. The FAA believes that a half-hour allocation period would be appropriate and proposes to limit Reservations in each half-hour period to no more than 3 operations (arrivals and departures).

The allocation mechanism for unscheduled operations proposed in this NPRM is similar to the procedures the FAA currently follows in allocating unscheduled reservations for airports subject to the provisions of the HDR (particularly LaGuardia Airport and John F. Kennedy International Airport). The proposed procedures are also similar to the measures that were implemented at Chicago O'Hare in Special Federal Aviation Regulation (SFAR) 105.

A Reservation would be allocated on a 30-minute basis during the peak hours for which the restrictions would be in place. The FAA's Airport Reservation Office (ARO) would receive and process all Reservations. The Reservations would be allocated on a first-come, first-served basis, determined by the time the request is received by the ARO. Operators can obtain a Reservation: (1) through the Internet; or (2) by calling the ARO's interactive computer system via touch-tone telephone. Operators would provide the date and time of the proposed operation and other identifying information concerning the aircraft and the intended flight. Reservations could be made no more than 72 hours in advance of the proposed flight time. The assigned Reservation number would be included in the ''Remarks'' section of the flight plan. Reservations must be cancelled if they will not be used as assigned so that another operator has an opportunity to operate to or from the airport. The FAA would not permit a secondary market in Reservations in order to prevent abuse of the system or the bundling of airport Reservations with other flight-related services.

The FAA is not proposing to include a limited exception to the 72-hour window for public charter operators to obtain a Reservation, as was adopted under SFAR 105 for Chicago's O'Hare International Airport. There is more connecting and international passenger

[47] The DOT has docketed three petitions on this subject in recent years. Dockets OST–2004–18586, OST–2002–13650, and FAA–2001–9156. The petitions are available for review on the DOT's Web site.

[48] Requiring the winning bidder to participate in all rounds of the auction encourages sincere bidding.

[49] The secondary market that is being proposed for use at LaGuardia differs somewhat from the blind secondary market that was proposed at Chicago O'Hare because the proposed rule at LaGuardia will be permanent and the O'Hare rule is scheduled to sunset in 2008. We believe that it is appropriate to implement a more sophisticated auction-style secondary market at LaGuardia considering the long-term nature of the rule.

[50] Unscheduled operations are operations other than those regularly conducted by a carrier between LaGuardia and another service point. The unscheduled operations include general aviation, public aircraft, military, charter, ferry, and positioning flights. (An air carrier also could use an Operating Authorization for a ferry, positioning, or other non-revenue flight. An air carrier may choose to do so if a Reservation is not available.) Helicopter operations are excluded from the reservation requirement. Reservations for unscheduled flights operating under visual flight rules (VFR) are granted when the aircraft receives clearance from air traffic control to land or depart LaGuardia. Reservations for unscheduled VFR flights are not included in the limits for unscheduled operators.

traffic at O'Hare than at LaGuardia, which has more point-to-point, short-haul traffic. Therefore, it is important that public charter operations flying into O'Hare be able to connect to commercially scheduled flights (domestic or international) and arrive at O'Hare at their intended arrival time so passengers can make their flight. Also, many of these public charter flights at O'Hare operate to international destinations, representing key access for service to those points from the Chicago area. However, charter operations that fly to the New York City area to connect to international or long-haul domestic flights, or to serve international destinations more on a origin/destination basis, are more likely to fly into Newark Liberty International or John F. Kennedy International (which house those operations in the New York area), rather than LaGuardia. Consequently, the nature of public charter operations at LaGuardia does not warrant treatment different than any other unscheduled operation.

The allocation of a Reservation does not constitute an Air Traffic Control clearance nor does it replace the need to file an IFR flight plan. The FAA would accommodate declared emergencies without regard to reservations. Non-emergency flights in direct support of national security, law enforcement, military operations, or public-use aircraft operations may be accommodated above the reservation limits with the prior approval of the FAA. The FAA may authorize additional Reservations for unscheduled operations if permitted by operating conditions or if there are temporarily available Operating Authorizations.

E. Administrative Reversion of Operating Authorizations

Operating Authorizations are temporary operating privileges. As such, they remain subject to FAA control. We propose allowing them to be bought and sold, subject to FAA secondary market restrictions, in order to promote their most efficient use. However, they may be withdrawn at any time to fulfill operational needs such as eliminating operations due to reduced capacity. If the FAA determines that capacity must be reduced for a specified period of time, for example if a runway were temporarily closed, Operating Authorizations would be withdrawn. Once the capacity is resumed, the withdrawn Operating Authorizations would be returned to the carriers from which they were withdrawn provided they continued to conduct scheduled service at the airport. The FAA would assign, by random lottery, priority numbers for withdrawal of Operating Authorizations, if necessary to reduce capacity for operational reasons. If it was necessary to withdraw Operating Authorizations, they would be withdrawn in the specified 15-minute time periods in accordance with the priority list. Carriers with a limited presence at the airport would be protected from the withdrawal of Operating Authorizations. Carriers with fewer than 10 Operating Authorizations would not have authorizations withdrawn from them under these provisions of the rule.

The proposal also provides that all of the Operating Authorizations held by any carrier would revert to the FAA if that carrier ceases all operations at LaGuardia for any reason other than a strike or labor dispute.[51]

Paperwork Reduction Act

This proposal contains the following new information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted the information requirements associated with this proposal to the Office of Management and Budget for its review.

Title: Congestion Management Rule for LaGuardia Airport.

Summary: The FAA is proposing a new rule to address the potential for increased congestion and delay at New York's LaGuardia Airport (LaGuardia) when the High Density Rule (HDR) expires there on January 1, 2007. The rule, if adopted, would establish an operational limit on the number of aircraft landing and taking off at the airport. To offset the effect of this limit, the proposed rule would increase utilization of the airport by encouraging the use of larger aircraft through implementing an airport-wide, average aircraft size requirement designed to increase the number of passengers that may use the airport within the overall proposed operational limits.

Use of: The information is reported to the FAA by operators holding Operating Authorizations. The FAA logs, verifies, and processes the requests made by the operators.

This information is used to allocate, track usage, withdraw, and confirm transfers of Operating Authorizations among the operators and facilitates the buying and selling of Operating Authorizations in the secondary market. The FAA also uses this information in order to maintain an accurate base of operations to ensure compliance with the operations permitted under the rule and those actually conducted at the airport.

Respondents (including number of:) The likely respondents to this proposed information requirement are scheduled carriers with existing service at LaGuardia, carriers that plan to enter the LaGuardia market (and participate in the lottery or secondary market), and carriers that enter the LaGuardia market in the future. There are currently fourteen (14) carriers with existing scheduled service at LaGuardia.

Frequency: The information collection requirements of the rule involve scheduled carriers notifying the FAA of their use of Operating Authorizations. The carriers must notify the FAA of: (1) Requests to be included in a lottery for available Operating Authorizations; (2) requests for confirmation of one-for-one Operating Authorization trades; (3) usage of Operating Authorizations that are subject to the airport-wide upgauging target, and compliance with that target (on an annual basis); (4) usage of Operating Authorizations that are not subject to the airport-wide target (on a bi-monthly basis); and (4) participation in the secondary market.

Annual Burden Estimate: The annual reporting burden for each subsection of the rule is presented below.

The reporting burden was calculated by the following formula:

Annual Hourly Burden = (# of respondents) * (time involved) * (frequency of the response).

Section 93.67(c) Sale and Lease of Operating Authorizations

(16 carriers) * (1.5 hours per submittal) * (4 occurrences per year) = 96 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours for each occurrence of a sale or lease of an Operating Authorization. For each operator, we assumed that a sale or lease of an Operating Authorization would occur quarterly.

Section 93.68(b) One-for-One Trades of Operating Authorizations

(16 carriers) * (1.5 hours per submittal) * (4 occurrences per year) = 96 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours for each occurrence of a one-for-one trade of an Operating Authorization. For each

[51] An air carrier could sell off its Operating Authorizations as part of a liquidation strategy, if it does so before failing to meet the Use-or-Lose requirements of the rule. However, if an air carrier ceases all operations and subsequently fails to meet the Use-or-Lose requirement, the Operating Authorizations would revert to the FAA and they could not be sold.

operator, we assumed that a one-for-one trade of an Operating Authorization would occur quarterly.

Section 93.72(a) Reporting Requirements

(16 carriers) * (1.5 hours per submittal) * (1 occurrence per year) = 24 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours for each annual occurrence of the data required in § 93.72(a)(1) and § 93.72(a)(2).

Section 93.72(b) Reporting Requirements

(16 carriers) * (1.5 hours per submittal) * (6 occurrences per year) = 144 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours every two months of the data required by § 93.72(b).

Section 93.72(c) Reporting Requirements

(16 carriers) * (1.5 hours per submittal) * (1 occurrence per year) = 24 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours for each annual occurrence of the data required in § 93.72(c).

Section 93.73(d) Weighted Lottery

(16 carriers) * (1.5 hours per submittal) * (4 occurrence per year) = 96 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours every quarter for participation in a lottery for an Operating Authorization.

Section 93.74(d) Administrative Provisions

(16 carriers) * (1.5 hours per submittal) * (4 occurrence per year) = 96 hours

We assumed that the 16 marketing carriers operating at LaGuardia expend one and one half hours every quarter for administrative provisions.

Summary—Total Annual Hourly Reporting Burden—576 Hours

The agency is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may submit comments on the information collection requirement by October 30, 2006, and should direct them to the address listed in the **ADDRESSES** section of this document. Comments also should be submitted to the Office of Information and Regulatory Affairs, OMB, New Executive Building, Room 10202, 725 17th Street, NW., Washington, DC 20053, Attention: Desk Officer for FAA.

According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number. The OMB control number for this information collection will be published in the **Federal Register**, after the Office of Management and Budget approves it.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

Economic Assessment, Regulatory Flexibility Determination, Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 4 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to be the basis of U.S. standards. Fourth, the Unfunded Mandate Reform Act of 1995 (Public Law 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

In conducting these analyses, FAA has determined this proposed rule (1) has benefits that justify its costs, is a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is ''significant'' as defined in DOT's Regulatory Policies and Procedures; (2) would not have a significant economic impact on a substantial number of small entities; (3) would not adversely affect international trade; and (4) would not impose an unfunded mandate on State, local, or tribal governments, or on the private sector. These analyses, set forth in this document, are summarized below.

Total Costs and Benefits of This Rulemaking

FAA estimates that this proposed rule would result in about a 37% decrease in the average delay per operation at LaGuardia. Present value net benefits are estimated at $4.3 billion from 2007–2019; net benefits over an infinite time horizon total about $7.5 billion. The benefits are estimated by comparing the no-rule scenario (similar to the situation at LaGuardia in 2001) with the proposed upgauging scenario.

There are almost no costs associated with the proposed rule. The only exception is for the cost of designing and carrying out periodic lotteries that may be required to assign unused operating authorizations. These present value costs total about $11.3 million through 2019, and $19.4 million over an infinite time horizon.

Who Is Potentially Affected by This Rulemaking

- Operators of scheduled and non-scheduled, domestic and international flights, and new entrants who do not yet operate at New York's LaGuardia Airport (LaGuardia).
- All communities, including small communities with air service to LaGuardia.
- Passengers of scheduled, domestic flights to LaGuardia.
- New York and New Jersey Port Authority.
- FAA Air Traffic Control.

Key Assumptions

- Base Case Flight Operations and Delay-Adjusted Official Airline Guide (OAG) Schedule, December 2000 (1,373 daily operations).

• Current Scenario Case Flight Operations and Delay—OAG Schedule, April 19, 2005 (1,194 daily operations).

• Delay improvements are about 9.2 minutes per flight, equivalent to a 37% improvement in delay. This delay improvement estimate was derived from GRA's [52] Delay Model.

• For this evaluation, the proposed rule's effective date is January 1, 2007.

Other Important Assumptions

• Discount Rate—7%.

• Period of Analysis—2007 through 2019.

• Assumes 2005 Current Year Dollars.

• Passenger Value of Travel Time—$30.86 per hour.[53]

• For this evaluation, all flights to Non-Hub Airports with existing service at LaGuardia, as well as a baseline exemption of 10 flights for each carrier would be exempt from the aircraft upgauging target.

Alternatives We Have Considered

• Alternative #1—This alternative would have let the High Density Rule order expire on January 1, 2007. Based on history, under this alternative, we expected operators would most likely continue to expand operations, and therefore further worsen airport delays. We are presenting this alternative as the base case for calculation of costs and benefits associated with this rulemaking.

• Alternative #2—This alternative would exempt operations to Non-Hub Airports with existing service at LaGuardia from the target aircraft size calculation.

• Alternative #3—This alternative would exempt operations to Non-Hub Airports with existing service at LaGuardia and Small-Hub Airports within 300 miles of LaGuardia from the target aircraft size calculation.

• Alternative #4—This alternative would exempt operations to Non-Hub Airports with existing service at LaGuardia, Small-Hub Airports within 300 miles of LaGuardia, and Small-Hub Airports with existing LaGuardia service from the target aircraft size calculation.

We are seeking comment from industry on alternatives #2 through #4 to promote efficient use of the airspace through equipment type upgauging, but not at the expense of removing service to small and non-hub communities.

[52] GRA Inc. of Jenkintown, Pennsylvania.

[53] ''Draft Economic Value for FAA Investment and Regulatory Decisions, A Guide'' December 31, 2004, weighted using LaGuardia shares of 51% leisure and 49% business travel.

Benefits of This Rulemaking

The primary benefits of this rule would be the airline and passenger delay cost savings. The benefits reflect a prorating of the 5.5 days per week the operational limits are in effect. The total estimated net benefits in present value dollars are about $4.3 billion when compared to 2001 delays over the 13-year analysis interval.

Costs of This Rulemaking

The major costs of this proposed rule cover the costs of implementing a lottery system for unutilized operating authorizations. The estimated present value cost of this final rule is about $11.3 million over the 13-year analysis interval.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation''. To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

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

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear. The basis for such FAA determination follows.

The proposed rule affects all scheduled operators at LaGuardia. A review of the number of employees for each operator shows that the following are ''small entities'' (defined as firms with 1,500 or fewer employees):

Carrier	Employees
Commutair	340
Colgan Air	546

Under the proposed rule, all operators' Operating Authorizations would be ''grandfathered'' for at least three years. Further, service to Non-Hub Airports would be exempt from the upgauging incentive where smaller entities are operating. Thus most of the LaGuardia markets operated by existing small entities would be exempt from upgauging.

The FAA has also reviewed whether there would be interruptions to service to communities with a population of less than 50,000. Because of the exemption from the upgauging incentive Non-Hub Airports would receive, only one such community is exposed. Burlington, Vermont has a population less than 50,000, but because it is a small-hub community [54] it would not be eligible for the exemption. But, Burlington is a dynamic economy, has existing service from both Newark and JFK airports, and service from LaGuardia may well be viable at this airport even without the exemption.

Therefore, the FAA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that it would impose the same costs on domestic and international entities and thus have a neutral trade impact.

Unfunded Mandate Assessment

The Unfunded Mandate Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation)

[54] *http://www.faa.gov/arp/planning/stats/index.cfm?nav=cargo#apttype.*

in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $128.1 million in lieu of $100 million. This final rule does not contain such a mandate. The requirements of Title II do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action would not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore would not have federalism implications.

Environmental Analysis

FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312d ''Issuance of regulatory documents (e.g., Notices of Proposed Rulemaking and issuance of Final Rules) covering administration or procedural requirements (does not include Air Traffic procedures; specific Air Traffic procedures that are categorically excluded are identified under paragraph 311 of this Order.)''. It has been determined that no extraordinary circumstances exist that may cause a significant impact and therefore no further environmental review is required.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this NPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order because it is not a ''significant regulatory action'' under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 14 CFR Part 93

Air traffic control, Airports, Alaska, Navigation (air), Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 93—SPECIAL AIR TRAFFIC RULES

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

Authority: 49 U.S.C. 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44719, 46301.

2. Subpart C is added to read as follows:

Subpart C—Performance Based Upgauging Rule for New York LaGuardia Airport

Sec.

93.61 Applicability.
93.62 Definitions.
93.63 Operating Authorizations for Scheduled Arrivals and Departures.
93.64 Initial Allocation and Reallocation of Operating Authorizations.
93.65 Duration of Operating Authorizations.
93.66 Reversion and Withdrawal of Operating Authorizations.
93.67 Sale and Lease of Operating Authorizations.
93.68 One-for-One Trades of Operating Authorizations.
93.69 Average Aircraft Size Target.
93.70 Minimum Usage Requirements for Small and Community and Baseline Operating Authorizations.
93.71 Unscheduled Operations.
93.72 Reporting Requirements.
93.73 Weighted Lottery.
93.74 Administrative Provisions.

Subpart C—Performance Based Upgauging Rule for New York LaGuardia Airport

§ 93.61 Applicability.

(a) This subpart prescribes the air traffic rules for the arrival and departure of aircraft, other than helicopters, operating at New York's LaGuardia Airport (LaGuardia).

(b) This subpart also prescribes procedures for the assignment, transfer, sale, lease, reversion and withdrawal of Operating Authorizations issued by the FAA for Scheduled Operations by Carriers at LaGuardia.

(c) The provisions of this subpart apply to LaGuardia during the local hours of 6:30 a.m. through 9:59 p.m., Monday through Friday, and 12 p.m. through 9:59 p.m. on Sunday. No person shall conduct a Scheduled Operation to or from LaGuardia during such hours without obtaining an Operating Authorization. No person shall conduct an Unscheduled Operation to or from LaGuardia during such hours without obtaining a Reservation.

(d) Carriers that have Common Ownership shall be considered a single U.S. air carrier or foreign air carrier for purposes of this subpart.

§ 93.62 Definitions.

For purposes of this subpart the following definitions apply:

Airport Reservation Office (ARO) is an operational unit of the FAA's David J. Hurley Air Traffic Control System Command Center. It is responsible for the administration of Reservations for Unscheduled Operations at LaGuardia.

Average Aircraft Size Target is the required average number of passenger seats per aircraft offered for sale for each Scheduled Operation at LaGuardia. The target is calculated as the annual passenger seats divided by the total number of Operating Authorizations held over the year excluding all Baseline Operations and Small Community Operating Authorizations.

Baseline Operations are Operating Authorizations excluded from the Average Aircraft Size Target. Annually, each Carrier may designate up to 10 Operating Authorizations per day as its Baseline Operations.

Carrier is a U.S. air carrier or foreign air carrier with authority to conduct scheduled service at LaGuardia under Parts 121, 129, 135 of this Chapter and has economic authority to operate scheduled service under 14 CFR chapter II and 49 U.S.C. chapter 411.

Carrier's Average Aircraft Size is the total number of passenger seats offered under all Operating Authorizations (excluding Baseline Operations and Small Community Operating Authorizations) over the calendar year, divided by the total number of Operating Authorizations held over the year.

Common Ownership with respect to two or more air carriers or foreign air carriers means having in common at least 50 percent beneficial ownership or control by the same entity or entities.

Enhanced Computer Voice Reservation System (e-CVRS) is the system used by the FAA to make arrival and/or departure Reservations for Unscheduled Operations at LaGuardia and other designated airports.

Non-Hub Airport is a commercial service airport that has more than 10,000 annual passenger boardings but less than 0.05% of the total annual United States passenger boardings.

Operating Authorization is the operational authority assigned by the FAA to a Carrier to conduct one

scheduled instrument flight rules (IFR) arrival or departure operation at LaGuardia on a particular day of the week during a specific 15-minute period during the hours of 6:30 a.m. through 9:59 p.m., Monday through Friday, and 12 p.m. through 9:59 p.m. on Sunday.

Reservation is an authorization received by a Carrier or other operator of an aircraft, excluding helicopters, in accordance with procedures established by the FAA to operate an unscheduled arrival or departure to or from LaGuardia on a particular day of the week during a specific 30-minute period during the hours of 6:30 a.m. through 9:59 p.m., Monday through Friday, and 12 p.m. through 9:59 p.m. on Sunday.

Scheduled Operation is the arrival or departure segment of any operation regularly conducted by a Carrier between LaGuardia and another point regularly served by that Carrier.

Small Community Operating Authorizations are the designated Operating Authorizations excluded from the Average Aircraft Size Target but subject to the minimum usage requirement. These Operating Authorizations are designated by the FAA effective January 1, 2007 and may only be used to operate to a Non-Hub and Small-Hub Airports.

Small-Hub Airport is a commercial service airport with at least 0.05% but less than .25% of total annual United States passenger boardings.

Unscheduled Operation is an arrival or departure segment of any operation that is not regularly conducted by a Carrier or other operator of an aircraft, excluding helicopters, between LaGuardia and another service point. The following types of Carrier operations shall be considered Unscheduled Operations for the purposes of this rule: Public, on-demand, and other charter flights; hired aircraft service; extra sections of scheduled flights; ferry flights; and other non-passenger flights.

Weighted Lottery is a lottery conducted by the FAA to reassign to Carriers' Operating Authorizations that are initially unassigned, returned to the FAA or withdrawn as a result of the Average Aircraft Size Target requirements or minimum use requirements. A weighted lottery assigns Operating Authorizations to a Carrier based on its inverse proportion of the Carrier's share of total Operating Authorizations at LaGuardia.

§ 93.63 Operating Authorizations for Scheduled Arrivals and Departures.

(a) During the hours of 6:30 a.m. through 9:59 p.m., Monday through Friday, and 12 p.m. through 9:59 p.m. on Sunday, no person may operate an aircraft other than a helicopter, as a Scheduled Operation to or from LaGuardia unless he or she has received an Operating Authorization for that operation.

(b) Seventy-five (75) Operating Authorizations are available per hour at LaGuardia. The number of Operating Authorizations may not exceed 19 in any 15-minute period; 38 in any 30-minute period; and 75 in any 60-minute period. The number of arrival and departure Operating Authorizations in any period may be adjusted by the FAA if necessary based on the actual or potential delays created by such number or other considerations relating to congestion, airfield capacity and the air traffic control system.

§ 93.64 Initial Allocation and Reallocation of Operating Authorizations.

(a) Except as provided for under paragraphs (b) and (c) of this section, any Carrier allocated operating rights under 14 CFR part 93, subpart K, and 49 U.S.C. 41716 during the week of October 1–6, 2006, as evidenced by the FAA's records, will be assigned corresponding Operating Authorizations, by hour, effective January 1, 2007. The FAA will assign Operating Authorizations in 15-minute periods consistent with the limits under § 93.63(b) of this section. If necessary, the FAA may utilize administrative measures such as voluntary measures or a lottery to re-time the grandfathered Operating Authorizations within the same hour to meet the 15-minute and 30-minute limits under § 93.63(b) of this section. The FAA Vice President, System Operations Services, is the final decision-maker for determinations under this section.

(b) If a carrier was allocated operating rights under 14 CFR part 93, subpart K, and 49 U.S.C. 41716 during the week of October 1–6, 2006, but the operating rights were held by another carrier, then the corresponding Operating Authorizations will be assigned to the carrier that held the operating rights for that period, as evidenced by the FAA's records.

(c) If a carrier was allocated operating rights under 14 CFR part 93 during the week of October 1–6, 2006, and those operating rights were held by an entity other than a certificated carrier, then corresponding Operating Authorizations will be assigned to the operating carrier, as evidenced by the FAA's records.

(d) Any Operating Authorizations that are returned to the FAA or withdrawn as a result of the Average Aircraft Size Target requirement under § 93.69 of this subpart or the minimum use requirement for Operating Authorizations to or from Non-Hub and Small-Hub Airports under § 93.70 of this subpart will be reallocated by a Weighted Lottery.

§ 93.65 Duration of Operating Authorizations.

(a) Operating Authorizations initially assigned to Carriers on January 1, 2007, have a minimum term of three years unless withdrawn or returned in accordance with this subpart.

(b) By January 1, 2007, the FAA will establish the expiration schedule for all Operating Authorizations assigned to Carriers on January 1, 2007. Ten percent of these Operating Authorizations will expire annually beginning on December 31, 2009.

(c) Each expired Operating Authorization will be reallocated and thereafter shall carry a 10-year operating term.

§ 93.66 Reversion and Withdrawal of Operating Authorizations.

(a) A Carrier's Operating Authorizations revert automatically to the FAA 30 days after the Carrier has ceased all operations at LaGuardia for any reasons other than a strike.

(b) The FAA may retime, withdraw or temporarily suspend Operating Authorizations at any time to fulfill operational needs.

(1) Operating Authorizations will be withdrawn in accordance with the priority list established under § 93.74 of this subpart.

(2) Except as otherwise provided in paragraph (a) of this section, the FAA will notify the affected Carrier before withdrawing or temporarily suspending an Operating Authorization and specify the date by which operations under the authorizations must cease. The FAA will provide at least 45 days' notice unless otherwise required by operational needs.

(3) Any Operating Authorization that is temporarily withdrawn under this paragraph will be reassigned, if at all, only to the Carrier from which it was withdrawn, provided that the Carrier continues to conduct Scheduled Operations at LaGuardia.

(c) The FAA shall not withdraw or temporarily suspend any Operating Authorizations under paragraph (b) of this section from any Carrier if the result would reduce the Carrier's total number of Operating Authorizations below ten per day.

§ 93.67 Sale and Lease of Operating Authorizations.

(a) Carriers may buy, sell or lease Operating Authorizations in accordance with this section.

(b) Only monetary consideration may be provided in any transaction conducted under this section.

(c) A Carrier must provide notice to the FAA to sell or lease an Operating Authorization. Such notice must contain: the Operating Authorization number and time, effective dates and, if appropriate, the duration of the lease and the minimum size aircraft that must be used for the operation. The Carrier also may provide the FAA with a minimum bid price.

(d) The FAA will post a notice of the sale or lease of the Operating Authorization and relevant details on the FAA Web site at *http://www.faa.gov*. An opening date, closing date and time by which bids must be received will be provided. Information identifying the seller or lessor of the Operating Authorization will not be released until after the transfer of the Operating Authorization.

(e) The FAA must receive all bids electronically, via the FAA Web site, by the closing date and time. Eligibility requires a bidding Carrier to participate on the first day of the bidding process. Late bids will not be considered. All bids will be held confidential, with each bidder certifying to the FAA that its bid has not been disclosed to any person.

(f) The FAA will forward the highest bid to the seller or lessor without any information about the identity of the bidder. The seller or lessor has three business days to accept or reject the bid.

(g) Upon acceptance, the FAA will notify the buyer/lessee.

(h) Written evidence of each Carrier's consent to the transfer must be provided to the FAA, and each Carrier must certify that only monetary consideration will be exchanged.

(i) The Operating Authorization may not be used until the conditions of paragraph (h) of this section have been met, and the FAA provides notice of its approval of the transfer.

(j) A Carrier may transfer an Operating Authorization to another Carrier that conducts operations at LaGuardia solely under the transferring Carrier's marketing control, including the entire inventory of the flight. Each party to such transfer must provide written evidence of its consent to the transfer. The FAA Vice President, System Operations Services, is the final decision maker for any determinations under this subsection. The recipient Carrier of the transfer may not use the Operating Authorization until the FAA has provided written confirmation.

§ 93.68 One-for-One Trades of Operating Authorizations.

(a) A Carrier may trade an Operating Authorization with another Carrier on a one-for-one basis.

(b) Written evidence of each Carrier's consent to the transfer must be provided to the FAA.

(c) The recipient of the transfer may not use the Operating Authorization until written confirmation has been received from the FAA.

(d) Carriers participating in a one-for-one transfer must certify to the FAA that no consideration or promise of consideration was provided by either party to the trade.

§ 93.69 Average Aircraft Size Target.

(a) On an annual basis, beginning in 2008, each Carrier's Average Aircraft Size must meet or exceed the Average Aircraft Size Target established by the FAA for LaGuardia. The FAA will publish the target in the **Federal Register** at least 90 days before the beginning of the calendar year.

(b) Baseline Operations and Small Community Operating Authorizations are excluded from the Carrier's Average Aircraft Size calculation.

(c) Beginning January 1, 2009, if a Carrier's Average Aircraft Size does not meet the Average Aircraft Size Target over the preceding year, the FAA will withdraw Operating Authorization(s) from the Carrier until the target is met.

(1) The FAA will withdraw the Operating Authorization(s) that used the aircraft with the smallest seating capacity.

(2) Unless there is an operational need identified by the FAA, the Carrier may designate which Operating Authorization is withdrawn.

(d) Paragraph (a) of this section does not apply to Operating Authorizations that are not used by a Carrier because of a strike.

(e) The FAA may waive the requirements of paragraph (a) of this section in the event of a highly unusual and unpredictable condition that is beyond the control of the Carrier and that persists for a period of 5 consecutive days or more. Examples of conditions which could justify a waiver under this paragraph are weather conditions that result in the restricted operation of an airport for an extended period of time or the grounding of any aircraft type.

(f) Paragraph (a) of this section does not apply to Operating Authorizations that are held by a Carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Sunday in January.

(g) Paragraph (a) of this section does not apply to the first 90-day period after assignment of Operating Authorizations obtained in a Weighted Lottery or through a sale.

§ 93.70 Minimum Usage Requirements for Small Community and Baseline Operating Authorizations.

(a) Any Small Community or Baseline Operating Authorization that is not used at least 80 percent of the time over a consecutive two-month period will be withdrawn by the FAA.

(b) Paragraph (a) of this section does not apply to the first 90-day period after assignment of Operating Authorizations obtained in a Weighted Lottery or through a sale.

(c) Paragraph (a) of this section does not apply to Operating Authorizations that are not used by a Carrier because of a strike.

(d) The FAA may waive the requirements of paragraph (a) of this section in the event of a highly unusual and unpredictable condition that is beyond the control of the Carrier and that persists for a period of 5 consecutive days or more. Examples of conditions which could justify a waiver under this paragraph are weather conditions that result in the restricted operation of an airport for an extended period of time or the grounding of any aircraft type.

(e) The FAA will treat as used any Operating Authorization held by a Carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Sunday in January.

§ 93.71 Unscheduled Operations.

(a) During the hours of 6:30 a.m. through 9:59 p.m., Monday through Friday, and 12 p.m. through 9:59 p.m. on Sunday, no person may operate an aircraft other than a helicopter to or from LaGuardia unless he or she has received, for that Unscheduled Operation, a Reservation that is assigned by the Airport Reservation Office (ARO). Additional information on procedures for obtaining a Reservation will be available on the Internet at *http://www.fly.faa.gov/ecvrs*.

(b) Six (6) Reservations are available per hour. The ARO will assign Reservations on a 15-minute basis.

(c) The ARO will receive and process all Reservation requests for unscheduled arrivals and departures at LaGuardia. Reservations are assigned on a ''first-come, first-served'' basis determined by the time the request is received at the ARO. Reservations must be cancelled if they will not be used as assigned.

(d) The filing of a request for a Reservation does not constitute the

filing of an IFR flight plan as required by regulation. The IFR flight plan must be filed only after the Reservation is obtained, include the Reservation number in the ''Remarks'' section, and be filed in accordance with FAA regulations and procedures.

(e) Air Traffic Control will accommodate declared emergencies without regard to Reservations. Non-emergency flights in direct support of national security, law enforcement, military aircraft operations, or public-use aircraft operations may be accommodated above the Reservation limits with the prior approval of the Vice President, System Operations Services, Air Traffic Organization. Procedures for obtaining the appropriate waiver will be available on the Internet at *http://www.fly.faa.gov/ecvrs*.

(f) Notwithstanding the limits in paragraph (b) of this section, if the Air Traffic Organization determines that air traffic control, weather and capacity conditions are favorable and significant delay is not likely, the FAA may determine that additional Reservations may be accommodated for a specific time period. Unused Operating Authorities may also be temporarily made available for Unscheduled Operations. Reservations for additional operations must be obtained through the ARO.

(g) Reservations may not be bought, sold, or leased.

§ 93.72 Reporting Requirements.

(a) *Carrier's Aircraft Size Target.* (1) Annually, beginning March 1, 2008, each Carrier holding an Operating Authorization must report, in a format specified to the FAA, the following information for each Operating Authorization held during the previous calendar year:

(i) The Operating Authorization number, time, and arrival or departure designation;

(ii) The operating Carrier;

(iii) The aircraft-type;

(iv) The number of passenger seats offered on the aircraft for each operation; and

(v) The date and time of each of its operations using an Operating Authorization, including flight number, and origin/destination.

(2) Annually, beginning March 1, 2008, each Carrier holding an Operating Authorization must report, in a format specified by the FAA, the average number of seats flown over all Operating Authorizations that are subject to the Average Aircraft Size Target.

(b) Minimum Usage Requirements for Small Community and Baseline Operating Authorizations. Each Carrier holding a Small Community or Baseline Operating Authorization must, within 14 days after the last day of the 2-month period beginning January 1, 2007, and every 2 months thereafter report, in a format acceptable to the FAA, the following for each Operating Authorization held:

(1) The Operating Authorization number, time, and arrival or departure designation;

(2) The operating Carrier;

(3) The aircraft-type;

(4) The number of passenger seats offered on the aircraft for each operation; and

(5) The date and time of each of its operations using an Operating Authorization, including flight number, and origin/destination.

(c) Annually, by March 1, 2008, each Carrier must designate ten Operating Authorizations as its Baseline Operations and report to the FAA the Operating Authorization number, time, and arrival or departure.

(d) The FAA may withdraw the Operating Authorizations of any Carrier that does not report its utilization of Operating Authorizations in accordance with this section.

§ 93.73 Weighted Lottery.

(a) The FAA will reassign by Weighted Lottery Operating Authorizations not assigned by the FAA as part of the initial allocation and those returned to the FAA or withdrawn, as described under § 93.66 of this subpart or withdrawn under § 93.69 and § 93.70 of this subpart.

(b) Each Carrier's weight in the lottery is inversely proportional to its share of total Operating Authorizations at LaGuardia. Any Carrier that does not hold or operate Operating Authorizations under its own name as of the announced date of a Weighted Lottery, and has not held or operated Operating Authorizations at LaGuardia since [EFFECTIVE DATE OF FINAL RULE], its weight is equal to that of a Carrier with two Operating Authorizations (a single roundtrip flight).

(c) The FAA will publish a notice in the **Federal Register** announcing the lottery dates and any special procedures for the lotteries.

(d) Any Carrier seeking to participate in a lottery must notify the FAA in writing, and such notification must be received by the FAA 15 days prior to the lottery date. The Carrier must report—

(1) If it currently operates scheduled service at LaGuardia or has operated scheduled service at LaGuardia since [EFFECTIVE DATE OF FINAL RULE];

(2) The number of Operating Authorizations it holds (if any); and

(3) If there is common ownership with any other Carrier, and if so, the identify of such Carrier.

(e) Operating Authorizations obtained under this section may not be bought, sold, leased, or otherwise transferred until one year has elapsed from their assignment.

§ 93.74 Administrative Provisions.

(a) The FAA will assign priority numbers by random lottery for Operating Authorizations at LaGuardia. Each Operating Authorization will be assigned a withdrawal priority number, and the 15-minute time period for the Operating Authorization, frequency, and the arrival or departure designation.

(b) If FAA determines that operations need to be reduced for operational reasons, the lowest assigned priority number Operating Authorization will be the last withdrawn.

(c) Any Operating Authorizations available on a temporary basis may be assigned by the FAA to a Carrier on a non-permanent, first-come, first-served basis subject to permanent assignment under this subpart. Any remaining Operating Authorizations may be made available for Unscheduled Operations on a non-permanent basis and will be assigned under the same procedures applicable to other Operating Reservations.

(d) All transactions under this subpart must be in a written or electronic format approved by the FAA.

Issued in Washington, DC on August 23, 2006.

Nan Shellabarger,

Director of Aviation Policy and Plans.

[FR Doc. 06–7207 Filed 8–25–06; 9:00 am]

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Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Part 93

Congestion and Delay Reduction at Chicago O'Hare International Airport; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No.: FAA–2005–20704; Amendment No. 93–85]

RIN 2120–AI51

Congestion and Delay Reduction at Chicago O'Hare International Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting regulations to address persistent flight delays from overscheduling at O'Hare International Airport (O'Hare). This final rule is intended to be an interim measure only, and the FAA anticipates that the rule will yield to longer term solutions to traffic congestion at the airport. Such solutions include plans by the City of Chicago to modernize the airport and reduce levels of delay, both in the medium term and long term. For this reason, the final rule includes provisions allowing for the limits it imposes to be gradually relaxed, and in any event the regulation will sunset in 2008.

DATES: This amendment becomes effective October 29, 2006. Affected parties, however, do not have to comply with the information collection requirements in §§ 93.23, 93.25, 93.27, 93.28, 93.29, 93.30, 93.31, and 93.32 until the FAA publishes in the **Federal Register** the control number assigned by the Office of Management and Budget (OMB) for this information collection requirement. Publication of the control number notifies the public that OMB has approved this information collection requirement under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Jeffrey Wharff, Office of Policy and Plans, APO–200, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3274.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

Visiting the Office of Rulemaking's Web page at *http://www.faa.gov/avr/arm/index.cfm*; or

Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the amendment number or docket number of this rulemaking.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at *http://www.faa.gov/avr/arm/sbrefa.cfm.*

Authority for This Rulemaking

The FAA has broad authority under 49 U.S.C. 40103 to regulate the use of the navigable airspace of the United States. This section authorizes the FAA to develop plans and policies for the use of navigable airspace and to assign the use we deem necessary to its safe and efficient utilization. It further directs the FAA to prescribe air traffic rules and regulations governing the efficient utilization of the navigable airspace. The FAA interprets this broad statutory authority to encompass management of the nationwide system of air commerce and air traffic control.

In addition to the FAA's authority and responsibilities with respect to the efficient use of airspace, the Secretary of Transportation is required to consider several other objectives as being in the public interest, including: Keeping available a variety of adequate, economic, efficient, and low-priced air services; placing maximum reliance on competitive market forces and on actual and potential competition; avoiding airline industry conditions that would tend to allow at least one air carrier unreasonably to increase prices, reduce services, or exclude competition in air transportation; encouraging, developing, and maintaining an air transportation system relying on actual and potential competition; encouraging entry into air transportation markets by new and existing air carriers and the continued strengthening of small air carriers to ensure a more effective and competitive airline industry; maintaining a complete and convenient system of scheduled air transportation for small communities; ensuring that consumers in all regions of the United States, including those in small communities and rural and remote areas, have access to affordable, regularly scheduled air service; and acting consistently with obligations of the U.S. Government under international agreements. See 49 U.S.C. 40101(a)(4), (6), (10)–(13) and (16), and 40105(b).

Background

On March 25, 2005, the FAA published a notice of proposed rulemaking (NPRM) (70 FR 15521) which would limit the number of scheduled arrivals at O'Hare during peak operating hours and establish an allocation system, including transfer and usage requirements.

Since publishing the NPRM in March 2005, the FAA twice has extended the Order published in August 2004 that set operation limits on domestic and Canadian scheduled arrivals into O'Hare International Airport. The Order most recently was extended to October 29, 2006, which coincides with the effective date of this rule (71 FR 16405; March 31, 2006).

History

The High Density Traffic Airports Rule at O'Hare

Until July 2002, the FAA managed congestion and delay at O'Hare by means of the High Density Rule (HDR), which was codified in 14 CFR part 93, subpart K. The FAA adopted the HDR under its broad authority to ensure the efficient use of the nation's navigable airspace (49 U.S.C. 40103). The HDR took effect in 1969, and while it originally was a temporary rule, it became permanent in 1973.

The HDR established limits on the number of all take-offs and landings during certain hours at five airports, including O'Hare. In order to operate a flight during the restricted hours, an airline needed a reservation, commonly known as a slot. Slots were initially allocated through scheduling committees, operating under then-authorized antitrust immunity, where all the airlines would agree to the allocation. After the Airline Deregulation Act in 1978, new entrant

airlines formed and the pre-existing, or legacy carriers, sought to expand. This increased competition made it increasingly difficult for airlines to reach agreement, and the scheduling committees began to deadlock.

In 1984, the FAA amended the HDR to increase the hours in which limitations at O'Hare would apply and to increase the number of take-offs and landings permitted at that airport (49 FR 8237, March 6, 1984). The next year, a new Subpart S was added to Part 93 that established allocation procedures for slots including use-or-lose provisions and permission to buy and sell slots in a secondary market (50 FR 52195, December 20, 1985). These procedures replaced the scheduling committees.

Statutory Changes Ending the High Density Rule at O'Hare

In 2000 Congress relaxed the slot rules at the high density airports and phased out the specific regulations then in place at three of them, including O'Hare (49 U.S.C. 41715, 41717). With respect to O'Hare, Congress directed that:

(1) Beginning May 1, 2000, exemptions be granted to airlines to provide air service to small airports with 70-seat or smaller aircraft;

(2) 30 slot exemptions be granted to new entrant or limited incumbent air carriers;

(3) After May 1, 2000, slots no longer be required to provide international air service;

(4) Beginning July 1, 2001, the slot control restrictions be limited to the period between 2:45 p.m. and 8:14 p.m.; and

(5) Slot restrictions be lifted entirely after July 1, 2002.

In phasing out the HDR, however, Congress recognized the possibility that there could be an increase in congestion and delays at the affected airports. Therefore, in the section that phased out the rule, it made clear that ''[n]othing in this section * * * shall be construed * * * as affecting the Federal Aviation Administration's authority for safety and the movement of air traffic.'' (49 U.S.C. 41715(b).)

Resurgence of Unacceptable Levels of Congestion

As a result of the 2000 legislation, the slot restrictions of the HDR lapsed at O'Hare as of July 1, 2002. The absence of these restrictions allowed airlines operating at the airport to add flights, which over time led to a dramatic increase in airline delays. These delays reverberated throughout the national air transportation system.

Initially, lifting the HDR had a minimal impact on delays due to the lingering effects of the 9/11 terrorist attacks on airline passenger traffic. But by 2003, the two air carriers operating hubs at O'Hare, American Airlines (''American'') and United Airlines (''United''), had added a large number of operations and retimed other flights, resulting in congestion during peak hours of the day. From April 2000 through November 2003, American increased its scheduled operations at O'Hare between the hours of 12 p.m. and 7:59 p.m. by nearly 10.5 percent. Over the same period, United increased its scheduled operations at O'Hare by over 41 percent.

The increases in operations by American and United did not result in a corresponding increase in seat capacity. During the peak period, these two carriers added 375 regional jet operations per day. Overall, American and United added over 600 regional jet operations per day. At the same time as they added regional jet operations, they reduced mainline jet operations. The result was actually a decrease in seat capacity by each carrier at O'Hare of more than 5.5 percent from April 2000 to November 2003 while flights increased by an average of 150 per day. In November 2003, more than 40 percent of American's and United's O'Hare flights were operated with regional jets, many to large and medium hubs. The significant increases in scheduled operations during this time period resulted in excessive delays and congestion at O'Hare.

By November 2003, O'Hare had the worst on-time performance of any major airport. O'Hare arrivals were on time only 57 percent of the time, well below the FAA goal of 82 percent. Departures were little better. They were on time only 67 percent of the time, well below the average of 85 percent at other major airports. These delays averaged about an hour in duration. Published schedules for February 2004 indicated that the problem would be exacerbated by the addition of even more flights.

Recognizing congestion was again becoming a significant issue, Congress enacted legislation that included a mechanism to help reduce delays and improve the movement of air traffic at congested airports (49 U.S.C. 41722). That statutory provision authorized the Secretary of Transportation (Secretary) to request that scheduled air carriers meet with the FAA to discuss flight reductions at severely congested airports to reduce over-scheduling and flight delays during hours of peak operation, if the Administrator determines that it is necessary to convene such a meeting and the Secretary determines that the meeting is necessary to meet a serious transportation need or achieve an important public benefit.

In early 2004, the Secretary and the FAA Administrator determined that a schedule reduction meeting was necessary to deal with congestion-related delays at O'Hare. Before such a meeting could be convened, however, United and American each agreed in separate discussions with agency officials to reduce their scheduled flights voluntarily. Accordingly, the schedule reduction meeting was deferred. Instead, the FAA issued an order implementing the voluntary agreement of the two air carriers, Docket FAA–2004–16944–55; 69 FR 5650 (2004). The FAA order required a 5 percent reduction in the two carriers' scheduled operations. This reduction was to be effective between 1 p.m. and 8 p.m. for six-months, beginning no later than March 4, 2004.

The FAA again reviewed O'Hare's on-time performance in March 2004 in light of the ordered schedule reductions. That review showed that the total delay minutes would have been as much as 30 percent higher without the reductions but that delays still remained more than double the level of a year earlier and represented more than a third of the total delays in the national airspace system.

In light of the continued problems at O'Hare, the agency officials again discussed the situation with American and United to consider additional flight reductions to improve on-time performance at the airport. As a result, on April 21, 2004, the FAA issued an amendment to the previous order in Docket FAA–2004–16944. This amendment required additional flight reductions. Specifically, beginning no later than June 10, 2004, it required (1) An additional schedule reduction of 2.5 percent of each carrier's total operations in the 1 p.m. through 7:59 p.m. hours including arrival reductions during specific times; (2) a reduction in the number of scheduled arrivals in the 12 p.m. hour; and (3) reductions to continue through October 30, 2004.

Prior to the implementation of the June flight reductions, delays at O'Hare continued. In May, there were a record 14,495 total delays. While the numbers in June and July improved, as the last round of cutbacks by American and United took effect, the FAA determined that the overall trend of delays remained unacceptably high.

Meanwhile, some airlines that were not party to the agreement involving American and United continued to add

flights, making it unlikely that those two carriers would extend their voluntary schedule reductions without similar commitments by other carriers. Published schedules for November indicated that during several times of the day scheduled arrivals would approach or exceed the airport's highest arrival capacity. Accordingly, in July, the Secretary and FAA Administrator determined that the scheduling reduction meeting that had previously been deferred now needed to be held (69 FR 46201, August 2, 2004).

The meeting between DOT and the carriers convened on August 4, 2004, and was followed by meetings between Federal officials and individual airlines. As a result, United and American agreed to reschedule and further reduce scheduled arrivals by about 5 percent during peak hours and other airlines agreed to some flight re-timings and not to increase the number of their scheduled arrivals. New entrants and limited incumbents were permitted to add a small number of scheduled flights. Based on the information provided through the meetings and submissions filed in the docket, the FAA issued a comprehensive order on scheduled arrivals at O'Hare on August 18, 2004, limiting scheduled arrivals by U.S. and Canadian air carriers to 88 during most hours of the day and implementing the above agreement (August 2004 Order). The Order took effect November 1, 2004, and was to expire on April 30, 2005. The FAA extended this Order on three separate occasions to permit full consideration of the issues and comment on the NPRM.[1] On each occasion the agency sought the views of interested persons on the advisability of extending the August 2004 Order in Docket FAA–2004–16944. As indicated in the October 2, 2005, extension of the Order, significant operational benefit has been achieved since the voluntary schedule reductions took effect on November 1, 2004. The subsequent extensions of the Order were necessary to maintain the scheduling limits set in August 2004 and achieve delay—reduction and operational benefits pending completion of this rulemaking.

Related Activity

On July 8, 2005, the FAA published in the **Federal Register** Special Federal Aviation Regulation (SFAR) 105, ''Reservation System for Unscheduled Operations at Chicago's O'Hare International Airport,'' (70 FR 39610). This SFAR limits unscheduled arrivals at the airport to four per hour and provides an allocation mechanism for operators to obtain reservations for those operations. SFAR 105 was extended through March 31, 2006 (70 FR 66253).

On September 30, 2005, the FAA issued the Record of Decision for O'Hare Modernization providing final agency determinations and unconditional approval of the revised Airport Layout Plan and other certain Federal actions by the FAA necessary for the proposed improvement of O'Hare, as provided in Alternative C presented to the agency (the O'Hare Modernization Plan and other components of the City's Airport Master Plan.). The O'Hare Modernization Plan (OMP) provides for certain capacity enhancement actions to result in new capacity by 2008.

Phased implementation of the OMP will provide incrementally increasing operational benefits. The FAA's analysis projects that the addition of the first new OMP runway will, by 2008, allow the airfield to accommodate over 50,000 additional forecast operations with an average annual delay per aircraft no higher than exists today. With the completion of Phase 1 of the OMP, the FAA's analysis projects that the airfield will accommodate, by the 2010 time frame, approximately 90,000 additional forecast operations (over today's activity level) with a decrease in average annual delay per aircraft of approximately 33% below today's delay per aircraft at O'Hare. Finally, with the completion of OMP Phase 2 in 2013, the FAA's analysis projects that the airfield will accommodate approximately 1.12 million annual forecast operations (an increase of more than 140,000 annual operation over today's activity level) with an average annual delay per aircraft nearly 70% below today's delay per aircraft.

Summary of Comments

The FAA published the NPRM, ''Congestion and Delay Reduction at Chicago O'Hare International Airport,'' on March 25, 2005. The comment period closed on May 24, 2005. During that period, we received 22 comments from interested parties including airlines, industry organizations, individuals, members of Congress and the City of Chicago (City). We also received five additional comments after the close of the comment period.

In the NPRM, we requested comment on several specific aspects of the proposed rule, as well as any general comments. Comments to the NPRM are addressed below by topic. Only one commenter supported the proposal entirely; he is a student and pilot.

Overall, most commenters agreed that before the recent schedule reductions at O'Hare, congestion and delays had become intolerable. Some clearly disliked the proposal and questioned whether less intrusive methods were available to address short-term congestion and delay. Nearly all commenters agreed that governmental limits on flights are not the preferred approach and increasing air traffic capacity at O'Hare is the best way to solve the problem of congestion and delays. Some commenters suggested that the Order only accomplished what market forces ultimately would have dictated carriers to do if given appropriate time.

Comments expressing concern that the NPRM amounted to a reimposition of the HDR were received from Senators Richard Durbin and Barack Obama, and Representatives Dennis Hastert, Jesse Jackson, Jr., Jerry Costello, John Shimkus, Jerry Weller, Melissa Bean, Danny K. Davis, Henry Hyde, Judy Biggert, Timothy Johnson, Daniel Lipinski, Luis V. Gutierrez, Lane Evans, Bobby L. Rush, Rahm Emanuel, Mark Kirk, and Donald A. Manzullo (Members of Congress). The Members did not oppose a short-term limit on flights, with certain modifications, provided that the rule sunset (as proposed) no later than April 2008.

Expiration of the August 2004 Order (No Further Governmental Action)

We questioned in the NPRM whether the limitations established in the August 2004 Order should be allowed to expire of their own accord with no governmental intervention to address the operational environment at the airport. Under this approach, carriers would be free to determine the number and timing of flights at O'Hare.

The Department of Justice (DOJ) and the Air Carrier Association of America (ACAA) objected to allowing the Order to expire with no mechanism in place to manage demand at O'Hare. DOJ argued that allowing the Order to expire with no plan in place to deal with the airport's limited capacity would lead to more congestion and significant delays for passengers throughout the country. ACAA contended that both American and United would add flights to block competition at any cost and that smaller carriers have fewer options to cancel flights or re-route passengers through other airports and consequently suffer disproportionate delays.

The City argued the opposite. The City requested that the FAA accelerate the OMP approval process, allow the Order to expire, and let free market forces manage flight levels. The City

[1] *See* 71 FR 16405, March 31, 2006; 70 FR 59798, October 13, 2005; and 70 FR 15540, March 25, 2005.

also countered that the airlines have learned their lesson from past overscheduling and are not likely to repeat that practice. However, if delays were to reach unacceptable levels again, the City suggested that the FAA negotiate a new temporary scheduling agreement like the one that resulted in the August 2004 Order. The Airports Council International-North America (ACI–NA) supported the comments filed by the City.

The FAA has determined that a rule limiting arrivals at O'Hare is necessary. After the phase-out of the HDR at O'Hare, carriers had the opportunity to add flights and adjust schedules as they saw appropriate, which resulted in extensive delays for all operators at O'Hare and wide-ranging effects on the NAS. In contrast, since the limits on scheduled and unscheduled arrivals took effect on November 1, 2004, air traffic delays have decreased and on-time arrival performance has increased. Through October 2005, the average minutes of arrival delay at O'Hare decreased by approximately 24 percent when compared to the same 12-month period the year before. The longest arrival delays lasting more than one hour have decreased by 28 percent. Overall, the on-time arrival performance at O'Hare has increased by almost 7 percentage points. As a result, O'Hare is now performing near the average of the rest of the major airports in the NAS, a dramatic improvement from the airport's bottom-tier performance during much of 2004.

The FAA could permit the current scheduling limits to expire and allow carriers to individually determine the number and timing of their flights at O'Hare as advocated by some of the commenters. Safety would be maintained through air traffic control (ATC) procedures and congestion would be managed as needed through various traffic management initiatives. However, based on the history of scheduled demand, we forecast that flights would increase and that delays, cancellations, and disruptions at O'Hare and other airports are likely and would be unacceptable to the industry and the flying public. As indicated by the previous statistics, the limits imposed by the August 2004 Order have resulted in measurable reductions in delay. We are mindful that other factors have contributed to the decrease in delay, including additional flight reductions by some carriers beyond those specified in the Order, and increased operational capacity in some periods due to improved weather and other system efficiency gains.

We are not persuaded by the City's argument that the carriers at O'Hare will be able to resist the short-term marketplace incentives to add flights during peak hours, particularly if one or more of the hub carriers significantly changes its schedule or the other carriers introduce new service to O'Hare. Carriers typically respond to competition by matching frequency and/or fares. At O'Hare, the hubbing carriers have reduced flights significantly since November 2003, and if the Order expired, might resume previous flight frequencies or enter new markets to respond to other carriers' schedules.

In the event that flights were added and delays increased significantly, we could initiate schedule discussion meetings similar to the August 2004 discussions while continuing to manage delays on a daily basis. This process, however, would be counterproductive to our mandate to manage the use of the navigable airspace efficiently, particularly since it is very likely that carriers would launch new operations once the August 2004 Order expired. Furthermore, our ability to secure a new voluntary schedule reduction agreement is at best uncertain in view of the comments submitted in this rulemaking. Consequently, we dismissed this option as a feasible solution.

American noted that other airports experience more delay than O'Hare and that the FAA has not intervened there. American questions why O'Hare was singled out for such action. United commented that the operational limits at O'Hare, which is its primary hub, limit its ability to increase operations for new market opportunities or high passenger load factors.

The agency is addressing congestion at other delay prone airports. A single approach to manage congestion and delay at all airports cannot be realistically achieved at present. As articulated previously and elsewhere in the document, the deteriorating situation at O'Hare had impacts far beyond that airport. Delays at other airports on the other hand, generally do not lead to delays throughout the nation's air transportation system. Given the competitive stance of the major carriers, we believe that it was unlikely to be solved without government intervention. Our preference is to use whichever methods for addressing congestion are best suited for a particular airport. These methods may include increasing airport capacity and system efficiencies, or in the case at O'Hare, addressing through regulatory limits the impact of schedule adjustments by the largest operators at the airport.

Extend the August 2004 Order

No commenter specifically recommended that we simply extend the August 2004 Order until 2008. The City did suggest this action as an alternative if the current Order were allowed to expire and operations grew causing the airport to return to a critical state. DOJ stated that this option would be better than doing nothing; but it would lead to inefficient use of the airport's limited capacity and is not likely to result in any significant new entry or expansion by smaller carriers.

After considering this option, we concluded that it would be difficult to maintain the current agreement or negotiate yet another voluntary schedule reduction agreement that would limit operations until new airport capacity is in place. We agree with DOJ that while the continuation of the Order would achieve the objective of limiting overall operations at the airport, it would not necessarily result in any new entry by smaller carriers for the duration of the proposal. Also, this option would not necessarily promote the most efficient use of the operating authorities at O'Hare, given that the existing Order does not include provisions for usage, allocation, or market-based transfer mechanisms.

Any future scheduling discussions would start with current operational levels and the FAA's scheduling targets proposed for those discussions would apply.[2] As indicated in the comments, carriers of all sizes have expressed a desire to expand their operations at O'Hare, or at least preserve their option to grow. A scheduling meeting would confront us with complex and controversial determinations as to which carriers would have access to new capacity as it became available and how any new capacity would therefore be allocated. This is a complicated obstacle to overcome in the context of attempting to obtain a voluntary agreement from competing air carriers.

The FAA and the Office of the Secretary of Transportation are continuing the evaluation of market-based mechanisms, such as auctions or congestion pricing that may improve on prior methods of allocating available capacity at constrained airports. This evaluation includes an assessment of the research conducted by the

[2] The City comments that each carrier could be returned to November 2004 flight levels to ensure that there are not incentives for carriers to overschedule. However, if the August 2004 Order expires, we expect the target and the base schedules would be issues during the negotiations.

Department's contractor, National Center of Excellence for Aviation Operations Research (NEXTOR),[3] in conjunction with various air carriers and the Port Authority of New York and New Jersey, on options to manage demand at LaGuardia upon the expiration of the HDR at that airport. A market-based approach represents a much longer-term option that is not needed at this point in time at O'Hare, given the expectation of capacity improvement through the OMP.

As it would be unwise to let the limits simply expire, we find it necessary to invoke our authority to manage the efficient use of the navigable airspace and to impose peak hour scheduling limits at O'Hare so as to prevent overscheduling given the airport's current capacity. Even with the FAA approval of the OMP, there are no viable capacity enhancement efforts (procedural or technological) expected during the effective period of this rule that will result in sufficient capacity gains to completely meet the airport demand experienced during 2003 and 2004. Moreover, the uniqueness of O'Hare (as a major, dual hub airport) and its critical role in the National Airspace System (NAS) warrant special attention and careful measures to manage operations at that airport until new capacity comes on-line.

We stress that as a policy matter the Department promotes the efficient utilization of existing system capacity and the development of new capacity to meet aviation demand. We also prefer to address operational and airport congestion issues on a local level with airport operators and customers to the greatest extent practicable. This rule provides a temporary regulatory solution necessary to maintain an acceptable level of operations at O'Hare without congestion and delay impacting the entire NAS.

Authority To Cap Arrivals at the Airport

America West and Continental opposed all government-imposed restrictions on airport access. These carriers, along with others, argued that the NPRM is contrary to Congressional intent in the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR–21), which phased out the slot regulations at O'Hare. They also argue that as the HDR has been eliminated at O'Hare, the FAA may not implement a rule that is substantially similar to the HDR.

In carrying out our plenary authority to manage the safe and efficient use of the navigable airspace,[4] we properly may impose limits on flights at O'Hare to reduce delays and congestion. The HDR, which was also promulgated under this authority, addressed delays and congestion at five main airports.[5] While AIR–21 provided for the termination of the HDR at O'Hare and the New York airports, it also included a proviso that the FAA's ''authority for safety and the movement of air traffic'' was not to be affected by the phase out and termination of the HDR at O'Hare[6] or other HDR airports. There is no indication that Congress intended to narrow the FAA's authority to manage the use of the navigable airspace or to prohibit its use of this authority at O'Hare. AIR–21 by its terms only terminated the HDR then in place and did not restrict the FAA's authority to regulate the use of the airspace. The legislative history to the House version of AIR–21 (H.R. 1000), 106th Cong., Rpt. 106–167 indicates Congress' intent simply to place O'Hare on the same ''playing field'' as other airports.

Since AIR–21 the FAA has exercised its authority to manage the efficient use of the navigable airspace by capping the flood of AIR–21 slot exemptions filed for LaGuardia Airport (in November 2000), and by ordering schedule reductions in August 2004 at O'Hare.[7] In Vision 100—Century of Aviation Reauthorization Act (Pub. L. 108–176), Congress gave the Secretary and Administrator new authority to convene industry-wide scheduling meetings at O'Hare and elsewhere; these meetings, however, can only result in effective action if implemented through orders limiting flight operations. This basis for this new authority would not make sense if Congress had intended to take away the Administrator's authority to restrict operations at O'Hare. In all of these matters, as with the HDR in 1969, the agency was faced with delays at certain key airports that transcended those airports and disrupted the efficiency of the NAS. We conclude that the FAA retains its full authority to adopt this rule limiting flights at O'Hare.

Operational Cap

The FAA proposed to limit the number of scheduled arrivals at O'Hare to 88 per hour, between the hours of 7 a.m. and 7:59 p.m. Monday through Friday and 12 p.m. and 7:59 p.m. Sunday.[8] The limit on scheduled arrivals would increase to 98 arrivals per hour in the 8 p.m. hour, Monday through Friday. These are the same hourly quotas imposed by the August 2004 Order. In setting the hourly arrival cap under the Order and proposing the same for the NPRM, the FAA relied on analyses of actual, weekday, hourly arrivals and departures at O'Hare in late 2003 and in 2004. (This is when scheduled demand at O'Hare was at its peak and pressure on the ATC system to accommodate that demand is reflected in actual airport hourly traffic counts.) We also relied on analyses preformed by MITRE Corporation's Center for Advanced Aviation System Development (CAASD), which ran computer modelling on behalf of the FAA to simulate the effect of hypothetical schedule reductions on the level of flight delays at O'Hare given the established air traffic control procedures and airport capacity.[9]

The models predicted that constraints used in the August 2004 Order and the NPRM would reduce delays at the airport by approximately 20 percent from the levels attributed to schedules in effect at the time the August 2004 Order was imposed. MITRE/CAASD also simulated the results of a completely unconstrained schedule, using the industry's proposed November 2004 schedules and calculated that delays under the Order would be approximately 43 percent less than would be experienced if no action were taken and schedules similar to the November 2003 schedules were allowed to take effect.

The City commented that the proposed hourly limits do not take advantage of present available capacity at the airport. The City contended that the airport could accommodate 92 scheduled arrivals per hour and accommodate international and unscheduled arrivals above that level. ACI–NA supports the City's comments.

We have reviewed the operational performance of O'Hare, including the percentage of flights arriving and

[3] NEXTOR is a consortium of universities contracted by the FAA to research various aviation issues.

[4] 49 U.S.C. 40103.

[5] 33 FR 17896; December 3, 1968.

[6] 49 U.S.C. 41715(b)(1).

[7] The schedule reduction meeting was convened under 49 U.S.C. 41722.

[8] During this period, scheduled arrivals are not to exceed 50 during each half-hour beginning at 7 a.m. and ending at 7:59 p.m. Scheduled arrivals are not to exceed 88 within any two consecutive 30-minute periods.

[9] There were 89 arrivals modeled during the 1 p.m., 3 p.m., and 6 p.m. hours and 98 arrivals in the 8 p.m. hour. Four arrivals per hour were added for unscheduled flights. The modeled results also included the impact of schedule agreements based on a 15-minute distribution. While that limitation was not incorporated as a condition in the August 2004 Order, it largely has been maintained by air carriers through on-going consultation with FAA on proposals to move arrivals between 15 minute periods.

departing the gate within 15 minutes of scheduled time, the percentage of flights delayed for more than one hour, recent actual arrival and departure rates, and have considered whether there have been any material capacity enhancements that would provide a basis for a higher hourly cap on scheduled arrivals. Our review indicated there have been variations in delay levels, airport acceptance rates, and weather patterns since the Order took effect in November 2004 but no significant capacity enhancement measures have been realized.

As stated, the City proposed a new cap of 92 scheduled domestic (and Canadian arrivals) per hour and no limits on international arrivals of either domestic or foreign air carriers.[10] The combined arrival demand under such a scenario could be accommodated only under optimal weather conditions and then, with some delays. Such a proposal would significantly increase delays over current levels in non-optimal conditions.

We noted in the NPRM that if during the pendency of this rulemaking, the actual performance of O'Hare—as indicated in the cumulative delay statistics and modeling results—demonstrated that an increase in the cap on operations would still allow for acceptable operational performance, then the arrival cap might be raised in the final rule. The final rule, however, adopts the proposed limits of 88 scheduled arrivals per hour and no more than 50 scheduled arrivals in each half-hour period beginning at 7 a.m. The final rule also adopts the higher limit of 98 arrivals during the 8 p.m. hour but amends the half-hour limit in that hour to be the same as in the other half-hours.[11] Accordingly, in the 8 p.m. hour, each half-hour cannot exceed 50 scheduled arrivals.

The limits proposed in the NPRM mirror those reached during the August 2004 schedule discussions and incorporated in the August 19, 2004 Order, as amended. We accepted the higher limit in the 8 p.m. hour in the negotiated agreement and in recognition that the following hour had sufficient capacity to quickly absorb any potential delays. The actual flight schedules during the half-hour limits for 8 p.m. proposed in the NPRM, however, were not balanced. In reviewing the operational impact of the compression of arrivals in the first part of the 8 p.m. hour, we conclude that it is not appropriate to adopt the proposed higher, half-hour limit for this hour. While we will assign Arrival Authorizations in accordance with the carrier limits established in the Order, should any Arrival Authorizations in the 8 p.m. hour, or any other hour, be returned or withdrawn, they will be reassigned but within the half-hourly limit not to exceed 50 Arrival Authorizations.

Some periods may have minor variations from the adopted hourly or half-hourly limits based on the Arrival Authorizations initially assigned. Some periods may be slightly over the adopted limits, while others are slightly under. We do not expect any new, major operational impacts, but we expect that some of these variations will be resolved over time as we consider schedule adjustments by carriers.

We are also adopting provisions to accommodate newly requested international arrivals above the hourly limits,[12] and we will also assign Arrival Authorizations for international arrivals, as described later. We have decided not to withdraw Arrival Authorizations from domestic operations in order to accommodate new international arrivals, as the Department expects the number of new international arrivals to be minimal during the life of this rule. The FAA intends to work with operators of international flights to minimize any potential impacts during peak hours but ultimately expects to accommodate these new flights even if there may be some operational or delay impacts. Additional discussion on the adopted rules that apply to international arrivals appears in a later section.

Although overall performance of the airport has exceeded the modeled results, several hours have scheduled arrivals below the levels permitted by the Order. Some carriers are not utilizing all their authorized scheduled arrival times, resulting in periods when the airport could accommodate additional flights. This rule adopts a usage provision in addition to a blind buy/sell/lease provision, which we expect to increase the actual utilization of the Authorizations (because carriers will either use them for their own flights or sell/lease them to other carriers). Some Arrival Authorizations are available and will be assigned at the time of initial assignment under this rule. Requests for Arrival Authorizations for new international service will be accommodated first and any remaining Arrival Authorizations will then be assigned using a preferred lottery. Both of these assignment mechanisms and our rationale supporting the use of these mechanisms are fully described further in this document.

In the third extension of the Order,[13] the FAA specifically addressed the ten Arrival Authorizations previously operated by Independence Air and explained why those operations are not excess capacity. Independence Air ceased operations all operations on January 6, and because Arrival Authorizations cannot be sold, leased, or transferred except on a one-for-one basis under the August 2005 order, they have been unused since that date. We concluded that all the subject Arrival Authorizations may not be available for reallocation because when negotiating scheduled reductions in anticipation of the August 2004 order, the FAA had to allocate Arrival Authorization in some peak afternoon and evening hours at levels that exceed the peak-hour target of 88 scheduled arrivals per hour. Furthermore, foreign carriers whose operations were not affected by the Order, have adjusted their schedules from August 2004 resulting in increased scheduled arrivals during certain hours. The Arrival Authorizations assigned to Independence Air, particularly in the peak afternoon and evening hours will offset these periods of continued scheduling over the operational target. We expect that approximately four Arrival Authorizations that were operated by Independence Air will be available in the morning hours for assignment under this rule.

As proposed, the FAA will semi-annually review the operational performance metrics for O'Hare, as well as any new, procedural or other capacity enhancement measures, to determine if additional Arrival Authorizations may be assigned. The FAA intends to increase the cap on operations when doing so is supported by the operational analyses performed in these reviews and our delay reduction objectives. We believe that various provisions of this rule discussed above adequately address the City's concern about utilizing existing capacity at the airport.

This rule adopts a caveat in the provisions governing the initial assignment of Arrival Authorizations that was not proposed in the notice. The NPRM proposed that carriers conducting scheduled service to O'Hare under the August 2004 Order would receive corresponding Arrival Authorizations for that service. Recent

[10] We note that there would also be an average of four unscheduled arrivals per hour.

[11] The NPRM proposed no more than 67 Arrival Authorizations between 8 and 8:30 p.m.

[12] The hourly limit of 88 scheduled arrivals per hour includes international arrivals scheduled for the Summer 2004 scheduling season.

[13] Third extension of the Order dated March 27, 2006.

events have required that we contemplate a situation for which a carrier was operating at ORD under the Order but has since terminated all service at O'Hare prior to our concluding this rulemaking. In such a case, we conclude such carrier(s) should not be entitled to corresponding Arrival Authorizations under this rule. Arrival Authorizations are not property and in view of such, the agency has expressly limited opportunities to monetize and collateralize this authority under the rule adopted here. In the above situation, permitting a carrier to ''retain'' this authority under the rule would provide the carrier with the ability to unfairly monetize its operating authority at the expense of other carriers seeking to operate at O'Hare or increase service. We do not find it fair or in the public interest to provide a carrier that is not serving the airport with the opportunity to monetize and collateralize the authority under the rule adopted here. Consequently, we have included a provision to require that for a carrier to receive an initial assignment of Arrival Authorizations, the carrier must be conducting some level of service at the airport as of October 29, 2006.

New Entrant/Limited Incumbent Preference for New Capacity

The proposal contemplated initially assigning all of the Arrival Authorizations based on the airport's existing scheduling limits and according to the carriers' existing operations. This assignment would benefit all of the incumbent carriers, especially United and American, which would hold the vast majority of Arrival Authorizations.

The Notice proposed that any Arrival Authorizations withdrawn or returned to the FAA would be reallocated by lottery to new entrants and to carriers with few operations (''limited incumbents''). In addition, the Notice proposed that, with respect to additional capacity created by an increase in operational caps from 88 to 89 or 90 arrivals per hour, the resulting additional Arrival Authorizations also be assigned by lottery to new entrants and limited incumbents. Under both scenarios, those Arrival Authorizations remaining after lottery would be assigned to incumbent carriers and then on an interim basis until the next lottery. Under the proposal, with respect to additional capacity created by an increase in operational caps above 90 arrivals per hour, the additional Arrival Authorizations would be assigned by lottery with no preference based on carrier identity.

We invited comments on whether the preference for new entrants and limited incumbents would promote competition. Specifically, we asked whether the service benefits potentially obtainable from incumbent carriers' networks argue against use of a lottery that prefers new entrant and limited incumbent carriers.

We first address our authority to adopt such a preference and then address the policy considerations supporting the preference. Lastly, we address arguments relating to allegations of an unconstitutional taking of property or deprivation of due process.

1. *Authority to impose a preference for new entrants/limited incumbents.*

American and United challenged the FAA's authority to impose a preference and argued that the FAA cannot engage in economic regulation by favoring some carriers over others to ''promote competition.''

Any scheme to limit flights at O'Hare must allocate those operating authorities according to some criteria. We expect that any set of criteria adopted would benefit certain carriers to the detriment of others and no one formula would be universally acceptable to all affected carriers. The FAA's statutory authority to regulate the navigable airspace does not expressly direct the agency to consider any specific factor in allocating airspace rights. Absent such expression, we must look to the public interest in determining criteria for assignment of these Arrival Authorizations. In considering the public interest, we are guided by the policy goals prescribed for the Secretary [14] and the pro-competition policies followed by Congress in adopting legislation on matters such as slot exemptions and airport grant programs. *See*, *e.g.*, *Delta Air Lines* v. *CAB*, 674 F.2d 1 (D.C. Cir. 1982). The courts have approved the Secretary's reliance on the pro-competition polices in allocating slots under the HDR. *Northwest Airlines* v. *Goldschmidt*, 645 F.2d 1309, 1315 (8th Cir. 1980).

As we articulated in the August 2004 Order, Congress has set forth a policy of promoting deregulation and competition in the airline industry by means of the Airline Deregulation Act of 1978 and subsequent legislation. In AIR–21, Congress authorized the award of slot exemptions at the HDR airports to new entrants and limited incumbents—*i.e.*, those carriers that have little or no presence at the slot-controlled airports. (See 49 U.S.C. 41714(c), (h), 41716(b), 41717(c), 41718(b)(1).) Congress also included similar provisions in statutes governing airport grants and passenger facilities charges, designed to encourage airports to adopt policies that will promote competition. (See 49 U.S.C. 40117(k), 47106(f), and 47107(s).)

The Department's prior pronouncements and decisions on the efficient use of the airspace have frequently cited concerns about airport access and competition. For example, under the HDR, we established a regulatory framework that included a buy/sell provision to address the goals of access, competition and small community service. Also, under the HDR, the Department sought to alleviate the advantage that incumbent carriers gained under the initial allocation of the HDR—which ''grandfathered'' hundreds of slots for existing operations)—and to afford new entry at the slot-controlled airports. We did so by withdrawing up to 5 percent of the air carrier slots at LaGuardia, O'Hare and Washington National Airport to allocate by lottery to new entrants and limited incumbents.[15] More recently, in response to the escalating number of AIR–21 slot exemptions filed for LaGuardia Airport in December 2000, the FAA issued orders governing the allocation of those slot exemptions that took into account the need to promote competition.[16]

2. *Policy considerations concerning the new entrant/limited incumbent preference.*

This part of the proposal received the most comment. Support for the preference came from those air carriers or their representatives that could benefit from the proposal, such as Alaska Airlines, America West, Independence Air, and ACAA. Those opposed to the preference include American, Delta Air Lines (Delta), US Airways, United, LECG LLC (in coordination with United), Regional Airline Association (RAA), the City, and Members of Congress.

Alaska Airlines strongly supported our reliance on competition considerations and argued that the preference is fair, appropriate and supports a key public interest objective. America West urged the FAA to

[14] *See* 49 U.S.C. 40101(a)(4), (6), (10–13)).

[15] *See* FAA's ''Special Slot Withdrawal and Reallocation Procedures,'' 51 FR 8632 (1986).

[16] *See* High Density Airports; Notice of Extension for the Lottery Allocation and Notice of Lottery for Limited Slot Exemptions at LaGuardia Airport 66 FR 41294 (Aug. 7, 2001) (expanding the scope of new entrants eligible to participate in the lottery to those that did not participate in the Dec. 4, 2000 lottery and those that had not applied for the AIR–21 slot exemptions by Dec. 4, 2000); High Density Airports, 67 FR 65826 (Oct. 28, 2002) (adopting the new entrant preference procedure for reallocating by lottery withdrawn or returned exemption slots at LaGuardia).

establish a system by which Arrival Authorizations are withdrawn from incumbent carriers if any new entrant or limited incumbent requests one and none are available. America West further commented that new entrants and limited incumbents should have first access to all new Arrival Authorizations even if they exceed 90 per hour. ACAA supported preferential treatment for new entrants and limited incumbents and asked that Arrival Authorizations held by American and United be withdrawn and redistributed at the rate of 2 additional Arrival Authorizations per hour. Additionally, ACAA asked that 5% of those Arrival Authorizations held by American and United be withdrawn and redistributed to new entrants and limited incumbents each year the rule is in place.

The City argued, in contrast, that the FAA should not discriminate among types of carriers and noted that O'Hare is one of the most competitive markets in the nation. The City also was concerned that the proposed preference would discourage incumbent carriers from working on meaningful delay reduction (that is, capacity enhancing) technological, and/or procedural changes at O'Hare, given that any resulting new capacity would initially benefit its competitors. The City also noted that allocation by random lottery may not result in the highest and best use of a limited resource.

Members of Congress commented that the proposal treats foreign carriers, new entrants, and limited incumbents preferentially and severely disadvantages the hub carriers, who have invested heavily in O'Hare. They also commented that Chicago is a highly competitive marketplace and all but four of the major U.S. carriers are represented in this region.

American commented that it and United had both reduced operations throughout 2004 while other carriers were allowed to increase operations without any constraint. American refuted the assertion in the NPRM that it can shift flights in response to consumer demand stating that, as O'Hare is its hub airport, the timing of flights is critically important to creating the maximum number of potential connecting opportunities. American contended that it reduced its schedule to meet the agency's scheduling target under the August 2004 Order and that Arrival Authorizations in excess of 88 per hour do not realistically represent ''new'' capacity.

Delta commented that the preference for allocating capacity does not place ''maximum reliance upon competitive market forces and competition'' as stated in the NPRM. Delta argued that the proposal undermines competition by favoring some carriers over others, and that future capacity should be distributed using the same public auction procedure proposed for buy/sell transactions, with all carriers permitted to compete equally for those rights.

US Airways commented that it is uniquely disadvantaged by the preference for new entrants and limited incumbents. US Airways argues that new entrants and limited incumbents could get new capacity and large incumbent carriers could operate flexibly with their larger holdings, but it could not respond competitively because it is neither a limited incumbent nor a large carrier at O'Hare.[17] US Airways noted that the NPRM did not provide any analysis indicating new entrant and limited incumbent carriers would, in fact, offer the travelling public more benefits than the network carriers or any analysis assessing the impact of Midway Airport. US Airways would prefer that all additional Arrival Authorizations be allocated through a no-preference lottery available to all carriers. US Airways claimed the stated policy directive to rely on competitive market forces and the pro-competition policies in the Airline Deregulation Act are not served by the proposed preferred lottery because it favors certain types of competitors at the expense of others.

United also argued that adequate competition clearly exists at O'Hare and that findings presented in comments filed by LECG show Chicago to have the ''second highest penetration of low fare carriers out of 11 major hub cities and it also has the lowest weighted average fare of any of the 11 major hub cities examined.'' [18] United contended that the FAA offered contradictory arguments by acknowledging Chicago as a competitive market in the cost-benefit analysis while proposing preferential treatment for certain carriers in the name of competition. Additionally, United asked the FAA to take Midway Airport into account when considering competition.[19]

United also expressed concern that the inability to obtain new Arrival Authorizations could put it at a competitive disadvantage while demand for international service grows and that it would have to decrease its service to small and mid-size communities in order to compete internationally.

We have decided to retain the proposed lottery preference. The rule will give new entrants and limited incumbents a relatively small advantage in obtaining additional Arrival Authorizations from a pool that, at most, will be 30 Arrival Authorizations per day—out of the more than 1,200 scheduled peak hour arrivals at O'Hare. By way of contrast, American and United each operate more than 400 arrivals per day. Additionally, both carriers conduct international operations and might benefit by receiving Authorizations for those flights outside the operational cap. (See discussion on international allocation in this document.) Unlike airlines with only a few flights at O'Hare, these carriers also have the ability to maintain their market presence by substituting larger jets for regional jets on some of their flights.

New entrants and limited incumbents will receive a preference in the reassignment of available Arrival Authorizations created by any increase in the hourly limitation from 88 to 89 or 90 authorizations per hour. In addition, we are adopting a ''blind'' buy/sell mechanism for transactions involving Arrival Authorizations by shielding the identity of parties to proposed transactions. This process should give a greater opportunity for smaller carriers to purchase or lease necessary arrival privileges. In this regard, we are influenced by the views of DOJ and others criticizing the lack of a robust secondary market under the HDR and urging us to adopt procedures that will result in an efficient allocation of slots and competitive entry at constrained airports.[20] At the same time, however, by leaving the current assignment of arrival privileges essentially unchanged from our existing orders, the vast majority of operating privileges will be held by the two largest carriers at the airport.

Entry, particularly by low-fare airlines, is an essential ingredient for airline competition. Studies of airline industry competition under deregulation have concluded that low-fare entry has a substantial impact on price and service. For instance,

[17] US Airways does not indicate specifically why having 17 arrivals is unique relative to other non-hub carriers. Air Canada has 16 arrivals; Northwest has 20; Delta has 21; and Continental has 22.

[18] Hub cities included in the LECG analysis include: New York, Chicago, Denver, Philadelphia, Houston, Dallas, Charlotte, Detroit, Minneapolis, Atlanta, and Cincinnati.

[19] According to the LECG analysis, ''In 2004 Midway offered non-stop service to all but two of the 25 large hubs with non-stop service from O'Hare (Honolulu and Salt Lake City).''

[20] DOJ argued in its comments that transparency in the market, market power vested in the incumbents, and repeated use of temporary administrative allocation mechanisms (that do not create long-term property rights) all contributed to the insufficiency liquidity of the secondary market under the HDR.

Southwest initiated service into Philadelphia in May 2004, and since that time the fares in Philadelphia have shifted from being 19 percent higher to 2 percent lower than fares in comparable domestic markets (comparing the Fourth Quarter 2003 to the Fourth Quarter 2004). A policy that fails to provide any special treatment for new entry, the approach recommended by United and other larger incumbents, would curtail competition that leads to substantial fare reductions, increased service, and enables more people to travel.

The final rule also differs from our proposal in two other respects: First, we are not adopting the provision that would have required a new entrant or limited incumbent carrier to forfeit Arrival Authorizations obtained in a preferred lottery upon an agreement providing for the sale, merger, or acquisition by another person of more than 50 percent ownership or control of that carrier. The final rule provides for a 12-month limitation on the sale and lease of Arrival Authorizations obtained in a preferred lottery and we do not believe it is necessary to adopt further limitations, as doing so might interfere with normal business decisions by a carrier. Second, we are clarifying that an incumbent carrier who obtains Arrival Authorizations on an interim basis may use them for at least a year before the Authorizations would again be made available to new entrant and limited incumbent carriers in another lottery. This should provide some schedule stability without creating a material obstacle to potential new entry.

3. Takings Clause and Due Process Claims

United has claimed that the FAA would be violating the carrier's substantive due process rights by limiting its operations and giving competitors preferential access to Arrival Authorizations. United also argues that its flight schedules and operating rights at O'Hare are intangible property that the FAA confiscated without due process of law.[21] U.S. Airways also argued that the proposal could violate the takings clause of the Constitution, because ''an economically unsupported government policy is undermining the value of years of investment and business planning that was premised on the ability to compete at ORD on a national and international basis.''

We responded to a similar argument from United in the August 2004 Order. Our analysis set forth in that Order is essentially the same here. The Supreme Court instructs us to consider three factors in determining whether government action constitutes a taking requiring compensation: the action's character, its economic impact, and the extent to which the action interferes with investment-backed expectations.[22] These standards do not suggest a plausible Takings Clause claim here.

This rule, not unlike other rules or the August 2004 Order, adjusts the benefits and burdens of economic life in order to promote the common good. This rule limits flights at O'Hare in order to relieve the congestion that choked a key airport and caused delays throughout the NAS. This rule will benefit the industry and the travelling public. This rule codifies the current level of operations mandated by the August 2004 Order and does not require additional flight reductions. Since the Order has been in effect, O'Hare has experienced more than a 20 percent delay reduction from the delays experienced prior to the issuance of the Order. Furthermore, this rule will be in effect for a relatively short period so as not to unduly interfere with the marketplace more so than necessary. This type of regulation is not normally deemed a taking of property.[23] And, unlike the governmental action in *Eastern Enterprises* v. *Apfel*, 524 U.S. 498 (1998), we are not unfairly singling out an air carrier based on its conduct far in the past and unrelated to any future commitments or injury it caused. Rather, the two largest O'Hare air carriers significantly increased their flights starting in late-2003, causing over scheduling and delay conditions.

The second element of the Court's standard involves the rule's economic impact. There is no evidence that restricting O'Hare flights for a limited period of time will have an unduly harmful impact on any air carrier. To the extent there is an economic impact by virtue of this rule, it may be mitigated and moderated by the reduced operating costs resulting from prior congestion and the potential opportunities for limited growth during the life of this rule.

The third element of the Court's standard concerns whether the rule will interfere with a firm's investment expectations.[24] That is not the case here. We have repeatedly used our authority to manage the efficient use of the airspace to administer the HDR at O'Hare and three other major airports and done so over many years. More recently, we imposed additional restrictions at LaGuardia because of increased delays at that airport, and from time to time have taken other steps to cause airlines to reduce flights in order to prevent unacceptable levels of delays. Further, even though the Airline Deregulation Act of 1978 terminated the Government's regulation of air carriers' rates, routes, and services, the Department and the FAA nonetheless have extensive regulatory authority over domestic airline operations. The Department and the FAA, for example, regulate in the areas of certificates, compliance, handicapped discrimination, records on the movement of traffic, carrier management, unfair and deceptive practices, unfair methods of competition, and airline safety. The Department and the FAA's regulation of airport development and noise also affect an airline's investment expectations.

As we stated in the August 2004 Order, no airline owns the airspace at O'Hare and no airline has a license to operate a specific number of flights at the airport. The circumstances at O'Hare do not indicate that any carrier holds a cognizable ''property interest'' in maintaining its schedules at the airport. O'Hare has long been subject to slot rules, it has never had unlimited capacity, and carriers should have known that large increases in service could lead to new controls on the use of the airport's capacity. Therefore, United and U.S. Airways could not have reasonably believed they would be able to add or operate all the flights they wanted in perpetuity.

In any event, United's argument that the regulation is tantamount to a taking without just compensation is contrary to Takings Clause precedent. *Continental Air Lines* v. *Dole*, 784 F.2d 1245 (5th Cir. 1986). The *Continental* decision quoted Justice Holmes' statement, ''Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'' 784 F. 2d at 1252 (quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 413 (1922))

United also claimed that the regulation discriminates against incumbents in violation of United's

[21] 21 United states that the FAA Chief Counsel has characterized airline operations as 'valuable assets' [n. 62 to United's Comments]. The Chief Counsel, however, stated instead that the High Density buy-sell rule had the collateral effect of creating a valuable asset. Andrew B. Steinberg & James W. Tegtimeier, *Dealing With Airport Congestion: The Regulatory Challenger of Demand Management*, 19 Air & Space Law. 1, 16 (Winter 2005).

[22] *Connolly* v. *Pension Benefit Guaranty Corp.*, 475 U.S. 211, 224–225 (1986); *Concrete Pipe & Products* v. *Construction Laborers Pension Trust*, 508 U.S. 602 (1993).

[23] *Connolly*, 475 U.S. at 225.

[24] *Cf. Connolly*, 475 U.S. at 226–227.

Equal Protection rights. The test for determining whether an economic classification is vulnerable to an Equal Protection clause challenge is if it ''proceeds along suspect lines [or] infringes fundamental constitutional rights'' and ''if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.'' [25] An incumbent air carrier is not a ''suspect'' class within the meaning of the Constitution's Equal Protection clause. Further, an air carrier has no fundamental constitutional right to an operation at a particular airport. There is a rational basis for the preference in this regulation. The limited preference will benefit consumers because it will promote entry and new competition at O'Hare and new entry has the potential to lower airfares at O'Hare. It is consistent with the public policies established by Congress. Finally, it does not impose significant harm on the incumbent carriers since the allocation to them of their November 2004 operations enables them to continue to operate their networks. Further, United has not shown that the regulation is ''so arbitrary or irrational that it runs afoul of the Due Process Clause'' and ''fails to serve any legitimate governmental objective.'' [26] This regulation serves to meet the recognized need of addressing persistent flight delays related to over scheduling at O'Hare, and is intended as an interim measure because the FAA anticipates that the rule will yield to longer-term solutions to traffic congestion at the airport.

Limited Incumbent Carriers

The NPRM proposed to define a limited incumbent carrier as a carrier that operates eight or fewer Arrival Authorizations at O'Hare and has never sold or given up an Arrival Authorization. In the proposed rule we stated our belief that this approach represented a fair approach to carriers that are not new entrants but should be afforded some additional consideration due to their limited presence at the airport. We also noted that the proposed term is consistent with the August 2004 Order.

America West commented that a cap of eight Arrival Authorizations for limited incumbents would be inadequate to generate sustained price competition at O'Hare. Furthermore, the carrier argued that the proposal does not satisfy Congress' objective to promote competition, because Congress (in AIR–21) capped limited incumbents at 20 slot exemptions at LaGuardia, which is a smaller airport than O'Hare. America West then argued that Arrival Authorizations should be withdrawn from incumbents to fulfill requests from new entrants and limited incumbents.

Conversely, American argued that the definition of limited incumbent should be consistent with the International Air Transport Association (IATA) Worldwide Scheduling Guidelines and the European Union's slot regulation (EU 793/2004), which define a new entrant carrier as a carrier that holds fewer than five slots at an airport on the day for which they are requested.

Independence Air and Alaska Airlines requested that the definition be expanded to include a carrier that operates 10 or fewer flights. Independence Air pointed out that the modest increase of two arrivals would bring that carrier into the scope of the definition of this category. The carrier also argued that this small change supports the public interest of fostering competition by affording the carrier a preference in a lottery to counter the vast number of Arrival Authorizations held by the two dominant carriers.

We proposed eight Arrival Authorizations as the threshold for determining limited incumbent status, as that was the number set forth in the August 2004 Order. There is no bright line test for limited incumbency and the initial selection of eight Arrival Authorizations was consistent with the pro-competition goals of AIR–21. We do not view it necessary to create a more generous exception for such carriers, nor are we persuaded by the arguments of the carriers to increase this number to 10. Had we proposed 10 Arrival Authorizations in the notice, it is likely that carriers (other than Independence Air) would have sought a higher number. We note that although AIR–21 changed the definition of a ''new entrant/limited incumbent'' carrier to a carrier that holds 20 slots and slot exemptions; it was very different in its provisions for slot exemptions for new entrants at O'Hare. At O'Hare, AIR–21 slot exemptions for new entrants were limited to 30 in total, in contrast to the statutory provisions for LaGuardia and JFK, which capped new entrants at 20 slot exemptions each. Consequently, we reiterate the rationale behind our test for limited incumbency as proposed in the NPRM and in the August 2004 Order and, with minor edits for clarity, we adopt the definition of limited incumbent as proposed.

Alaska Airlines supported the proposal, as stated in the NPRM, to allocate flights initially to the carrier actually operating the flight, except where the operating carrier does not market its service independently and in its own name. Alaska stated that it has full control over the flights it operates at O'Hare and it should not be penalized because some flights also carry the American code.

Alaska's comment is consistent with how we proposed to treat code share arrangements in the NPRM. We proposed that, with limited exception, Arrival Authorizations would be allocated solely to the carrier that actually operated the flight, regardless of any code sharing agreements. We further proposed that in making our initial Arrival Authorization determinations, we do not intend to assign Arrival Authorizations to a carrier that is essentially operating its service as a contractor for another carrier and does not market its service independently and in its own name. We have been presented with no information that would suggest this distinction is invalid. Therefore, this rule adopts our proposal that where the operating carrier conducts the flight solely under the control of another carrier, the carrier controlling the inventory of the flight will receive the Arrival Authorization.

We also find it necessary to adopt some minor edits to the definition for clarity. In defining this term, we resort to using the phrase ''U.S. or Canadian air carrier that *holds or operates*, on its own behalf, 8 or fewer Arrival Authorizations * * *'' As this rule also permits leasing, it is critical to characterize a carrier's rights respective to the operating authority accurately. In addition, the rule clarifies that for an Arrival Authorization held or operated by a U.S. or Canadian carrier to count towards limited incumbent status, the relevant carrier must hold or operate that authorization on its own behalf. This will not penalize a carrier that conducts service at O'Hare primarily as a contractor for another carrier and does not market its service independently and in its own name from the ability to obtain authorizations in its own name in a lottery.

Blind Buy/Sell Market

Under the proposed rule, we provided that the purchase and sale of Arrival Authorizations would be allowed to promote maximum reliance on market forces and efficient utilization of the Arrival Authorizations. To ensure that all carriers have a chance to obtain these valuable privileges, sales of Arrival Authorizations would be permitted only through a ''blind market'' overseen by

[25] *FCC* v. *Beach Communications, Inc.*, 508 U.S. 307, 313 (1993).

[26] *Lingle* v. *Chevron U.S.A. Inc.*, S. Ct. No. 04–163, slip op. at 12 (2005).

the FAA in which the only consideration for transactions would be monetary. Thus, under the proposal, the identity of the bidder would be confidential and the transaction could not involve real property, such as gates, non-monetary assets, or other services in lieu of cash. In the NPRM, we did not propose specific regulatory text to permit the leasing of Arrival Authorizations but put out the concept for comment.

The majority of commenters did not object to use of a blind secondary market as proposed for the buying and selling of Arrival Authorizations. A majority of commenters did, however, object to the prohibition on using non-monetary assets as payment and the proposed limits on the use of Arrival Authorizations as collateral for loans.

DOJ urged the Department to move aggressively to adopt either congestion pricing or an auction to allocate scarce airport/airspace capacity at O'Hare, cautioning that anything short would lead to an inefficient allocation. DOJ also stated that while the ''blind'' aspect of the secondary market may remedy problems associated with the bidding process, this proposal does nothing to encourage the two largest carriers to sell Arrival Authorizations. According to DOJ, other carriers that also have a presence at O'Hare, generally use that access to connect their hubs with Chicago and therefore, place high value on those Arrival Authorizations and thus are unlikely to sell. Consequently, DOJ does not see that this rule would result in many sales.

American supported the concept of a market for Arrival Authorizations but opposed the proposal to regulate and govern the operation of that market, arguing for an independent, free, and competitive market similar to the HDR. U.S. Airways, United and Delta argued that under the HDR, carriers selling slots in the secondary market of necessity evaluated the total compensation package being offered before choosing the successful bid. Moreover, U.S. Airways believed that given the industry's liquidity problems and the operational needs of carriers at various airports, an airline selling or buying an Arrival Authorization ought to be able to accept or offer non-monetary consideration (*i.e.* services, ground handling) as part of the bid.

United suggested a revised approach to conducting the secondary market and alternatively proposed that the FAA serve as the clearinghouse through which sales of Arrival Authorizations are completed. In this alternative, a carrier wishing to sell (or to buy) an Arrival Authorization would notify the FAA of the relevant details and the FAA would post such notice to potentially interested air carriers. United suggested a similar process for carriers seeking to obtain Arrival Authorizations. United also commented that restricting the sale to an all-cash-basis unnecessarily limits the flexibility of buyers and sellers and could effectively freeze some buyers out of the bidding entirely. Under United's proposal, sellers would be presented with all bids that are received by FAA, but the identity of the bidders would not be disclosed. Once the seller selected the offer it deems most attractive, the identity of the bidder would be disclosed to the seller and the transaction could be completed. United similarly urged the FAA to permit leasing/subleasing because it would allow carriers to adjust their schedules based on seasonal and market fluctuations. Lastly, United submitted that the secondary market will not be robust as long as new entrants, limited incumbents, and foreign carriers get Arrival Authorizations free of charge from the government.

RAA commented that the current system of buying, selling, leasing, and sub-leasing slots at HDR airports has worked effectively and does not warrant any change for the limited duration of this proposed rule. At the very least, RAA suggested that if sales are to be blind, there is no reason to preclude non-cash considerations for Arrival Authorizations.

Independence Air contended that buyers will ''undoubtedly wish to negotiate terms, including but not limited to, the terms of any warranties, the definition of what constitutes a default under the purchase agreement, limitations of liability, customary representations as to corporate authorization, approval and agreement enforceability, and damages for any breach of the agreement and other commercially and legally important matters prudently included in any significant purchase and sale agreement.'' Independence Air suggested that the FAA is not in a position to broker the details of a commercial arrangement and should not adopt a rule that cannot be readily enforced and that can so easily be manipulated by carriers. Independence Air also did not support the proposed cash only basis for transactions.

The ACAA supported the blind market system and stated that this market mechanism is reasonable and available to all carriers. ACAA further argued that American and United should be blocked from acquiring additional Arrival Authorizations if any other carrier submits a bid in any sale so that these two carriers cannot bid higher to block entry of low-fare carriers.

The City supported the buying and selling of Arrival Authorizations, but requested that as airport operator it be given a consultative role with the airlines in the process of a significant sale or lease of Arrival Authorizations (or at least advance notice of such a sale or lease), with a portion of the funds reserved for the airport.

America West also supported the proposed secondary market but commented that the FAA, not the selling carrier, should keep the proceeds of sales on the blind secondary market. America West explained that proceeds from the sale of Arrival Authorizations could be directed to enhancing capacity at O'Hare. Alternatively, if proceeds from the sale went to the selling carrier(s), America West said there would be a perverse incentive for airlines to resist expansion of airports because such expansion would eliminate the ''paper value'' of their Arrival Authorizations.

A constant criticism of the HDR buy/sell provision was that it did not ensure a ''fair'' distribution of slots across the industry because the largest slot-holders (typically, legacy carriers) could consider the identity of would-be buyers or lessees and choose not to provide them with slots—so as to deprive potential new entrants of airport access. Smaller carriers informed us that they were not even made aware when slots were available for sale or lease. The blind aspect of the buy/sell provision established by this rule should ameliorate this problem, at least to some degree, by making it more difficult for slot holders to consider the would-be buyer/lessee's likely use of Arrival Authorizations.

We acknowledge that our proposal to restrict the use of non-monetary considerations in transactions involving Arrival Authorizations (*i.e.*, the ''cash-only'' aspect of our rule) was unpopular among the commenters. Most of the comments suggested that each air carrier should be allowed to consider the value of specific gates, baggage handling, marketing arrangements, and other potential offers in lieu of cash. (Under our proposal carriers may, of course, continue to pursue business opportunities in the ordinary course so as to exchange services or facilities at O'Hare or other airports, but they cannot use Arrival Authorizations as part of any such discussions.) Although there is merit to this position, nevertheless we continue to be concerned that the uniqueness of non-monetary assets, proposed as consideration in potential

transactions, would effectively undermine the ''blind'' nature of the secondary market. The inclusion of such non-monetary assets would make it virtually impossible to hide identities during the bid evaluation process unless the FAA chose to ascribe a monetary value to non-monetary assets, a difficult and protracted exercise that would not be useful given the short duration of this rule. Therefore, the ''cash-only'' aspect of our proposal is unchanged in the final rule.

We reject United's suggested approach for similar reasons. Under United's approach, all bids would be forwarded to the selling carrier for review and selection. Once the selling carrier selected a bid, the identity of the selected bid would be released and the affected carriers would be free to consummate the transaction. United's approach only makes sense if non-monetary assets are permitted in the bidding package. If, however, the bids are strictly limited to money, nothing is gained by receiving all the bids because the only relevant bid is the highest one.

United also suggested that the FAA establish a corresponding process that would allow a carrier seeking to purchase or lease an Arrival Authorization to advise the FAA with that information to be made public in a similar (blind) manner. We accept this suggestion and provide for such notification in this rule. As in the case for sales or leases, we will not disclose the identity of the carrier but will include information such as time and frequency desired, effective date, reserve price, or other pertinent information. This information will be posted within two business days and for a period of at least 10 days. All offers of Arrival Authorizations for sale or lease will be processed in accordance with the adopted rules.

America West recommended that the FAA retain all proceeds from the sale of Arrival Authorizations for use in capacity expansion projects at the airport. While this proposal has appeal, the FAA is currently prohibited by statute from promulgating rules that result in the agency collecting user-fees [27] and accepting revenue for the sale of Arrival Authorizations.

With respect to the City's requests, the required public posting of the available Arrival Authorizations will provide all interested parties, including the City, with notice of transactions. The City may exercise its proprietary powers as airport operator with respect to managing the efficient utilization of gates and related facilities, including directing sharing of unused gate space, overseeing subleasing requests, and otherwise negotiating gate assignments or conversions to common-use, where practicable. Requiring advance airline-airport consultations otherwise would interfere with the efficient assignment mechanism we anticipate to occur in the blind market. Given our limited options, a lottery system provides the fairest and most unbiased process for allocating new capacity while the blind buy-sell market provides potential opportunities for carriers that value the Arrival Authorizations the most.

Leasing of Arrival Authorizations

The comments supported allowing leasing of Arrival Authorizations and cited positive experiences with leasing arrangements under the HDR. Delta argued that if leasing is prohibited, incumbent carriers facing temporary market conditions or seasonal fluctuations in demand for their service at the airport would be forced to operate sub-optimal service patterns to preserve their airport access rights until conditions improved. Furthermore, Delta commented that the opportunity to lease Arrival Authorizations gives carriers the flexibility to test marginal new markets without committing the potentially significant capital investment that a purchase-only rule would impose.

RAA commented that leasing and sub-leasing should be permitted as they play a crucial role in allowing carriers to adopt seasonal changes in demand.

Independence Air echoed other carriers and urged the agency to permit leasing as it is a logical and necessary means to make an efficient market and urged the FAA to allow leasing in the final rule. However, Independence Air did not believe the FAA can effectively match lessors and lessees simply on the basis of which lessee is willing to pay the most for the Arrival Authorization. As with buying/selling Arrival Authorizations, Independence Air contended that there are many commercial and legal considerations that impact a lessor's motivation to enter into an Arrival Authorization lease agreement.

As discussed in the NPRM, leasing of arrival privileges would allow the carriers to accommodate seasonality and market fluctuations inherent in airline operations. Leasing permits access to the airport that some carriers may not otherwise have. Leasing also can result in higher efficiencies and lower costs to the carriers holding the Arrival Authorizations. Allowing leases and sub-leases of Arrival Authorizations also makes sense given the minimum usage requirement.

As specified in the adopted regulations, leasing will be permitted subject to the same conditions as the buying or selling of Arrival Authorizations. A carrier seeking to lease Arrival Authorizations must notify the FAA, and the agency will post the solicitation (including relevant information) and accept all timely-filed bids. Only the highest bid will be forwarded to the potential seller or lessor, and the only permitted consideration is monetary. If the relevant carriers agree to negotiate or contract other details of the transaction that do not violate or infringe upon the applicable regulations, they may do so without FAA involvement.

In addition, we adopt several modifications in this section.

First, carriers that have Arrival Authorizations available for sale or lease may submit a base reserve price for Arrival Authorizations to the FAA for posting on the Web site along with other relevant information. Including a base reserve price provides a floor for the bids and facilitates the process.

Second, we have deleted the requirement that a carrier must notify the FAA 30 days before the planned sale date. Upon review, we concluded that the 30 day requirement could be unduly restrictive, particularly for carriers that may want to lease an Arrival Authorization and, for scheduling reasons, may not be in a position to provide 30 days notice.

Third, as a usage requirement is also adopted in this rule, carriers may need to shorten the duration of the bidding/selection process. Therefore, we have included two modifications: (1) The FAA will post notice of available Arrival Authorizations within two business days; and (2) the bidding period will be open for 10 business days. The NPRM did not specify the timeframe for bids to be submitted. We chose 10 business days, which should allow carriers sufficient time to assimilate data and make decisions. The 10 business-day period is not excessive and is intended to expedite the transaction process.

Fourth and as discussed earlier, carriers may advise the FAA of their interest in obtaining Arrival Authorizations in the market and request that the agency post the information that a carrier is seeking Arrival Authorizations.

The FAA will post listings of Arrival Authorizations for sale or lease through the blind market at *http://*

[27] Consolidated Appropriations Act, 2005, Pub. L. 108–447, Federal Aviation Administration, Operations, Title I, Division H, 118 Stat. 2809, 3201 (2204)

www.Demand-Management-Airports.faa.gov. Users may register with the Web site to receive immediate notification of information posted on this site.

Pledging of Arrival Authorizations

United, Delta, U.S. Airways, and JP Morgan Chase & Co. (JP Morgan) all commented unfavourably on the proposal's prohibition on the pledging of Authorizations as collateral. They argued that preventing the collateralization of these ''assets'' will not reduce barriers to entry but rather contribute to the barriers. They contended that carriers may need access to this financing option in order to purchase Authorizations under the rule and that this prohibition eliminates this option for affected carriers.

We have withdrawn the prohibition on pledging Arrival Authorizations as collateral in this rule. We do not seek to eliminate options available to carriers to secure needed financing. Arrival Authorizations are an operating privilege and we recognize that the buying, selling and leasing of these privileges may be advantageous to facilitate the carriers' efficient use of these privileges.

As proposed, the final rule permits Arrival Authorizations to be assigned only to eligible air carriers and not other entities. Since collateralization arrangements are strictly a matter of contract between the affected carriers and other parties, we will not record changes to the holder/operator status to reflect any pledging of these Arrival Authorizations. Carriers are free to structure the pledging of these Authorizations, subject to other requirements of this rule.

International Arrivals

In the NPRM, we proposed the following two options for assigning Arrival Authorizations to foreign air carriers:

Administrative Option—The FAA would accommodate requests by foreign air carriers for new or additional access administratively. If an Arrival Authorization was not available within the time period requested by a foreign carrier, an Arrival Authorization would be withdrawn from a domestic carrier to accommodate that request.

Elective Option—Foreign air carriers seeking additional Arrival Authorizations above the initial assignment of Arrival Authorizations could elect: (1) To obtain Arrival Authorizations as described above under the Administrative Option; or (2) or obtain Arrival Authorizations in the same manner prescribed to U.S. and Canadian air carriers, which is through the blind market and the lottery mechanisms.

Operations by Canadian air carriers were excluded from these proposed options because Annex II of the 1995 bilateral aviation agreement between the U.S. and Canadian governments provides that Canadian air carriers be treated in the same manner as U.S. air carriers under airport access rules for domestic operations at O'Hare. Therefore, arrivals at O'Hare from Canada by U.S. and Canadian air carriers are assigned under the same procedures that apply to domestic and transborder flights.

The proposal treated foreign air carriers differently than U.S. and Canadian air carriers for several reasons. First, air service agreements between U.S. and foreign governments obligate both parties to ensure fair and equal opportunity to compete in a market. Second, foreign air carrier operations have remained relatively constant over the last several years while at the same time, domestic operations have increased significantly. Third, U.S. air carriers have the ability to make international service decisions based on their allocated base of total Arrival Authorizations if additional Arrival Authorizations were not available for assignment by the FAA. This is not an option for foreign air carriers that have a limited presence at O'Hare. For most international operations, Chicago's Midway Airport is not a practical alternative airport for serving Chicago since Midway's runways could not accommodate the wide body aircraft serving many of the international points from O'Hare.

Other elements of the NPRM applicable to Arrival Authorizations assigned to foreign air carriers, irrespective of the option, were: (1) Initial Arrival Authorizations would be assigned to foreign air carriers based on historical seasonal schedules; (2) Arrival Authorizations could not be bought, sold, or leased; (3) Arrival Authorizations would not be subject to a minimum usage requirement. However, if they are not used for more than a 15-day period, under the proposal they must be returned to the FAA.

The Department faced this issue previously under the HDR. At O'Hare, foreign and domestic carriers were initially treated equally in that slots were withdrawn to accommodate international requests from both foreign and domestic carriers if not otherwise available. We subsequently amended the HDR to limit withdrawals for international operations for the benefit of carriers with 100 or more slots at O'Hare. Congress later capped the total number of domestic slots that could be withdrawn and reallocated for international service. Concurrently, Congress also authorized the Secretary of Transportation to grant exemptions from the HDR for foreign air carriers serving O'Hare. The Secretary exercised this authority as needed and until May 2000, when the slot requirements for international flights were eliminated at O'Hare.

Several commenters supported preferences or exemptions from the established cap for international arrivals without distinguishing between operations conducted by U.S. carriers and foreign air carriers.

KLM Royal Dutch Airlines, as one of two foreign carriers to comment, did not favor any particular allocation option for foreign carriers. KLM did, however, support the August 2004 Order and suggested that the FAA follow IATA Worldwide Scheduling Guidelines, which most countries follow in allocating slots at constrained airports throughout the world. IATA expressed concern that the proposals could discriminate between U.S. and foreign air carriers.

The other foreign air carrier to comment was Air France, who strongly supported an administrative assignment for new Arrival Authorizations and acknowledged that this could be accomplished under either Option 1 or 2. Air France currently operates one daily passenger flight between O'Hare and Paris, but has offered two such flights in the past. Air France stated that initiating international service requires significant investment and that foreign carriers may hesitate to make such an investment if they are unsure they can obtain an Arrival Authorization at O'Hare under the market or lottery systems. Air France argued that it is necessary to guarantee foreign carriers access to an Arrival Authorization at O'Hare should they decide to expand service there. Air France did not oppose the proposed prohibition on buying/selling, or leasing assigned Arrival Authorizations; nor did it oppose the return of Arrival Authorizations to the FAA if not used for more than 15 consecutive days.

American and United agreed that the allocation provisions should not discriminate against foreign carriers, but argued that the proposed administrative option unduly rewards foreign carriers at the expense of U.S. carriers. Furthermore, they complained that they would be restricted from adding new international services unless they reduced domestic flights. They

submitted that foreign air carriers providing similar international services would continue to receive preferred treatment, which places U.S. carriers at a competitive disadvantage.

United also pointed out that Congress had previously prohibited the Secretary of Transportation from withdrawing slots from domestic carriers to accommodate international operations while O'Hare was limited under the HDR. (*See* 49 U.S.C. 41714(b)(2)). United disputed our reliance on international air services agreements as a rationale for the proposed Administrative Option, observing that other countries do not interpret the bilateral agreements as requiring them to make slots available for U.S. air carriers. United commented that this proposal is not in the national interest because it weakens an already unfavorable trade balance by shifting carriage of international passengers (and their revenue) from U.S. carriers to foreign corporations. United prefers exempting all international arrivals, which would not arguably violate any international air service agreement. Lastly, United noted that U.S. carriers have been denied access to foreign airports when capacity is limited.

The City also argued for exempting all international flights because international operations are a small portion of the total flights at O'Hare and that the gate, immigration and terminal facilities at Terminal 5 would provide a natural limit to these flights.

We have reviewed the number of international arrivals conducted by foreign air carriers and domestic carriers during the peak hours. Together, these arrivals account for six percent of total arrivals at O'Hare. This six percent is almost equally divided between foreign air carrier arrivals and U.S. air carriers. We note that while some foreign air carriers have periodically dropped service, other foreign air carriers have added service, such that the overall level has remained constant for several scheduling seasons. International operations by U.S. air carriers have also been relatively constant over the past several years.

We do not agree with United's assertion that our reliance on international air service agreements was erroneous and misguided. We are bound by our agreements with foreign governments to ensure that the flag carriers of each party have a fair and equal opportunity to compete in the market.[28] In particular, as the Department seeks to expand Open Skies agreements, we do not want to adopt limits that might preclude either domestic or foreign air carriers from taking advantage of new opportunities. At the same time, we are mindful that U.S. carriers are also constrained by facilities or slot constraints at some foreign airports and do not always get to operate their preferred schedules. We prefer to address those issues on a case-by-case basis rather than set up a regulatory framework that makes U.S.-constrained airports more difficult to access.

In view of the comments, we are adopting a revised approach that treats all international arrivals the same, regardless of whether operated by a foreign or domestic air carrier, a position which is also consistent with international air service agreements. An Arrival Authorization will be required for any international arrival at O'Hare and will be assigned at the requested time or in the adjacent hour if one is not otherwise available. Under the rule we may also assign a time for new or rescheduled international arrivals within an hour of the requested time if needed to address operational efficiencies and facilitate schedule de-peaking.

As this approach does not involve any withdrawal of Arrival Authorizations from domestic carriers to accommodate new international arrivals, it may result in operations exceeding the adopted hourly limits. In adopting this approach, we weighed the public interest in maintaining our international obligations under various air service agreements with our congestion and delay reduction goals of this rule. Given the relative stability in the number of international arrivals since 2002 and the limited duration of this rule, we do not expect a dramatic increase in requests for Arrival Authorizations. As this rule is an interim measure, it is expected that new airport capacity will address this issue for the longer-term. We acknowledge that this approach may have some impact on the congestion and delay reduction goals of this rule. However, we believe that the public interest supports the offset of our delay reduction goals to accommodate our international obligations. We will consider the effect of any additional international arrivals as we conduct the semi-annual operational performance and capacity review.

As a result of this new approach in addressing international arrivals, we must modify how we proposed to initially assign Arrival Authorizations for domestic use and for international use initially under this rule. In calculating the proposed cap of 88 arrivals per hour, we included all international operations scheduled for August 2004 during the O'Hare schedule reduction meeting. Foreign air carriers, except Canadian air carriers, were not affected by the FAA's Order, and subsequently have added new flights and adjusted schedule times that will be reflected in the initial assignment under this rule. International operations by U.S. carriers were included in the August 2004 Order as part of the overall carrier limits, and each carrier could choose the international market, domestic market, or transborder Canadian market to serve within those limits.[29] Consequently, we will review each U.S. air carrier's operations under the August 2004 Order and assign Arrival Authorizations as either domestic or international, as appropriate. New international arrivals by U.S. carriers after the effective date of this rule will be eligible for assignment above the operational limits. The combined total of each U.S. air carriers' (initially assigned) Arrival Authorizations (domestic and international) will not exceed the total authorized for that carrier under the Order. We will make a similar determination to assign Arrival Authorizations for foreign air carrier operations using published schedules or other information available to the FAA for the base for the Summer 2006 and Winter 2006 scheduling seasons.

Beginning with the Summer 2007 scheduling season, and for every season thereafter, we will publish a notice in the **Federal Register** announcing the submission deadline for priority consideration for the assignment of historic and new international arrivals. This is similar to the IATA process followed by most slot-constrained airports outside the U.S. In assigning Arrival Authorizations for international arrivals, we expect to follow the procedures and processes of the IATA Guidelines to the extent those Guidelines do not conflict with this rule. All carriers must request Arrival Authorizations, in accordance with the scheduling season and information published by the FAA in the **Federal Register**.

As proposed, we adopt the provision that the Secretary of Transportation may withhold the assignment of an Arrival Authorization to any foreign air carrier of a country that does not provide

[28] Access to serve the Chicago area must generally be through O'Hare due to runway or facility constraints at other Chicago area airports.

[29] Canadian carriers' scheduled arrivals were limited by the Order but do not include arrivals from points outside Canada. Therefore, no adjustments are needed under this provision.

equivalent rights of access to its airports for U.S. air carriers.

As proposed, Arrival Authorizations assigned for international use may not be bought, sold, leased or otherwise transferred. Carriers may, however, trade these Arrival Authorizations assigned for international use on a one-for-one basis. We clarify that domestic Arrival Authorizations may be traded within the carrier's base subject to FAA approval. Arrival Authorizations assigned for international arrivals must be returned if not used for a 15-day period.

Lastly, we revise the definition of the scheduling seasons to recognize the change in U.S. daylight saving time start and end dates beginning in March 2007 (Energy Policy Act of 2005, Pub. L. 109–58).

Minimum Usage Requirements

In the NPRM, we sought comment on whether a minimum usage requirement would be necessary, and if so, whether an 80 percent or 90 percent usage requirement over a bimonthly reporting period would be appropriate. As an alternative to the above usage requirement, we proposed a periodic withdrawal of the least used Arrival Authorizations for redistribution.

The majority of commenters objected to having no usage requirement. The City argued that the landing rights represent scarce and valuable assets under this rule and that it is not prudent to omit a usage requirement. Delta commented that this option presented the risk that carriers that have more Arrival Authorizations than they can profitably use will simply hoard them and waste valuable capacity.

DOJ agreed that a usage requirement could prevent Arrival Authorizations from going totally unused, but argued that a usage requirement was unlikely to prevent the hoarding of Arrival Authorizations to deprive competitors of these assets. DOJ also maintained that a usage requirement does nothing to increase the liquidity in the market and allow entry by more efficient carriers.

Most commenters responded that a usage requirement in the 80–90 percent range is appropriate. U.S. Airways, American, Delta and Independence Air supported the 80 percent requirement. The City, RAA and America West supported a 90 percent standard. United supported a usage requirement of 85 percent.

American contended that the rule should conform to international minimum usage standards and seasonality. American supported an 80 percent usage standard, which is used by IATA and the European Union (EU) slot regulations on a seasonal basis. American also argued that since the FAA conceded in the NPRM that most slots (under the HDR) were operated 90 percent of the time, it is nonsensical to use a new standard over one that is already universally known and accepted. In addition, the usage period should be consistent with the IATA designated summer (seven months) and winter (five months) scheduling seasons. American stated that domestic service patterns now follow the seasonality patterns for international operations and that failure to recognize this is not efficient or equitable. Consequently, under American's suggestion, it would be logical to lose an Arrival Authorization for a season, if a carrier is not using it for that period, rather than force the carrier to inefficiently schedule a flight just to avoid losing the Arrival Authorization.

While American's suggestion to adopt a usage period similar to the IATA bi-annual scheduling season may be of some benefit, no other carrier has indicated that a two-month reporting period was unworkable. We also believe that the adoption of leasing provisions will assist carriers that experience some seasonal fluctuations in that they may choose to lease the Arrival Authorizations for the relevant period.

We conclude that a minimum usage requirement is necessary, as these Arrival Authorizations will represent a scarce resource and our desire is to ensure the efficient utilization of these privileges for the duration of this rule. Our experience at O'Hare under the August 2004 Order is that some carriers did not utilize their authorities and this resulted in unused capacity. Moreover, adoption of a minimum usage standard complements the ability to lease Arrival Authorizations, which is adopted in this rule and previously discussed.

There is not a marked difference in projected slot utilization at a 90 percent versus an 80 percent usage requirement over a two-month reporting period. We reviewed scenarios of an Arrival Authorization held Monday through Friday over a two-month reporting cycle and found that the difference in usage from 80 to 90 percent resulted in approximately 3–4 additional operations over the reporting period. Carriers, both domestic and foreign, have a lot of experience with an 80 percent usage requirement, as provided under the HDR and internationally. As American argued, most carriers exceed the 80 percent usage standard under the HDR, and we do not see that increasing the standard will result in a more efficient utilization record that warrants deviation from the present industry standard. Consequently, this rule adopts an 80 percent minimum usage requirement over a two-month reporting period.

There was no support in the comments for the alternative of periodically withdrawing the least utilized Arrival Authorizations. Comments viewed this option as disruptive to their businesses. Also, the City pointed out that even with the one percent withdrawal, there may still be ''inefficiently'' utilized Arrival Authorizations that are not withdrawn because they are not in the bottom one percent.

In the NPRM, we proposed that those Arrival Authorizations assigned to new entrants and limited incumbents via lottery would not be subject to the usage requirement for the first 90 days after assignment. For Arrival Authorizations assigned to incumbent carriers via lottery, the usage requirement would be waived only for the first 60 days. United argued all carriers experience the same issues in starting new service, including the publishing, promotion and selling of that service and that incumbents should not be afforded less time to deal with similar issues. Furthermore, United argued that this waiver period should apply to Arrival Authorizations obtained via purchase, not just via lottery.

We agree with United that different waiver periods are not warranted and that the 90-day waiver period should apply to Arrival Authorizations received by lottery and by purchase. We have determined not to extend this waiver to Arrival Authorizations involved in a lease because carriers involved in the lease transaction can determine the transaction effective date to include this issue.

Arrival Authorizations assigned for international use are not subject to the usage requirement. Arrival Authorizations assigned for international use are allocated seasonally and must be returned to the FAA if not used for more than a two-week period. We think that this approach adequately addresses usage for these operations.

In addition, we proposed two methods for reassigning Arrival Authorizations that do not meet a usage minimum, if adopted. Under the first method, the agency would conduct a lottery consisting of two rounds. In the first round, only new entrants and limited incumbents would be permitted to participate. In the second round, any remaining Arrival Authorizations would be assigned by lottery to incumbent carriers at the airport.

Under the second method, carriers losing Arrival Authorizations for failing to meet the usage requirement would be required to sell them using the blind market process. New entrants and limited incumbents would have preference in purchasing the subject Arrival Authorizations and the proceeds of a sale would go to the air carrier that lost the Arrival Authorizations. Any unsold Arrival Authorizations would be returned to the carrier that lost them.

Both Delta and United preferred the option that would permit carriers to be compensated for the loss of the Arrival Authorization, particularly if the Arrival Authorization was purchased on the market, rather than have the Arrival Authorizations withdrawn by the FAA. Furthermore, Delta contended that the mandatory sale will ensure that the Arrival Authorizations go to the highest bidder—a lottery makes no such assurance.

We have reviewed this proposal in light of the other amendments adopted in this rule and conclude that neither option is necessary. Since this rule adopts a provision that permits leasing, carriers have an option that will result in compensation, and that can address market fluctuations, seasonality, and simple usage issues. Carriers are far more likely to lease Arrival Authorizations, rather than entertain a forced sale and loss of the them. Therefore, this rule provides that Arrival Authorizations not meeting the usage requirement will be withdrawn by the FAA for reassignment.

America West also commented that carriers may circumvent a usage requirement by using Arrival Authorizations originally allocated for large aircraft operations with small aircraft. Consequently, America West requested that the rule provide that an Arrival Authorization will be withdrawn if its use is converted from large aircraft to small aircraft.

ACAA supported a 90 percent usage requirement for air carriers with more than 50 Arrival Authorizations because large carriers have too many options to protect Arrival Authorizations if the usage requirement is lower.

We do not support America West's suggestion that Arrival Authorizations for larger aircraft should receive different treatment under our usage requirements. This rule does not divide Arrival Authorizations into separate categories based on aircraft size. Furthermore, the initial assignment and subsequent reassignment of Arrival Authorizations does not contemplate aircraft size for the particular operation. Unlike the HDR, carriers have complete discretion under this rule to operate the aircraft they see fit for the service using the Arrival Authorizations. Regulating the aircraft size to use these Arrival Authorizations is unnecessary at this airport to meet the stated objectives of this rulemaking.

Likewise, we have not adopted ACAA's suggestion that the 90 percent usage requirement apply to air carriers with more than 50 Arrival Authorizations. The purpose of the usage requirement is to ensure that these resources are being used efficiently, consistently and universally. The rule offers some opportunity to new entrants and limited incumbents to gain new or additional access to O'Hare. ACAA's proposal could undermine the efficiency goal of the universal usage requirement, and would not necessarily result in additional Authorizations being available for new entrant and limited incumbents.

The City stated that given their fluidity, scheduled cargo operations, in comparison to schedule passenger operations, merit a lower usage minimum. We disagree. As discussed above, if cargo operators find that their scheduled operation cannot use the frequencies for which they hold the Arrival Authorization, the carriers are encouraged to make the frequencies available to other carriers via leasing. We do not see a need to establish a separate usage requirement for these flights.

In the NPRM, we proposed to waive the usage requirement for a specific carrier in the event of a strike or labor dispute. Although we did not receive any comments on this provision, upon reconsideration, we have decided to withdraw this part of the proposal as the term, ''labor dispute'' was so broad that it could apply to the filing of a grievance, a stop work action or other events that may or may not result in a strike. By including the provision that permits waiver in the event of a highly unusual and unpredictable condition that exceeds 5 consecutive days, the rule provides carriers with latitude and flexibility to deal with unpredictable conditions, while maintaining the integrity and purpose of the usage requirement.

Finally, we will waive the usage requirement for all carriers through December 31, 2006, which covers the first two months reporting period under the rule. The August 2004 Order does not contain any usage requirement and some carriers are not fully utilizing their permitted number of arrivals. Carriers typically complete their schedule planning process several months in advance of actual operations and most carriers have already finalized their November /December 2006 schedules. While it is possible that some flights might be added to meet the usage rules, other carriers may decide to use the sale/lease options under the rule. We conclude that a limited waiver of the usage requirement is warranted to provide for minimal disruption of carrier schedules during the transition from the August 2004 Order and the rule adopted here. Therefore, the first report detailing usage of the Arrival Authorizations will be for the January–February 2007 period.

Sunset Date

We proposed to terminate this rule on April 6, 2008. This date was selected for several reasons: (1) The City had proposed an O'Hare Modernization Program (OMP) that would increase the airport capacity and reduce the level of delays at the airport and the first phase would come on-line by the beginning of 2008 (the proposal was subsequently approved in the FAA's Record of Decision for the OMP dated September 30, 2005); (2) improvements in the Instrument Landing System for runways 27L and 27R are expected to improve the performance of the airport in adverse weather conditions; and (3) the proposed date in 2008 would allow regulation to address the present conditions at the airport until the benefits of these capacity enhancements are realized at the airport. Alternatively, if the OMP does not move forward in a timely manner, the proposed date would allow the FAA time to develop an alternative to this rulemaking.

Some carriers questioned whether the rule would really be temporary. The City opposed the sunset date and argued that the date is too long for ''an invasive rule to constrain operations at O'Hare.'' The City preferred termination of the rule after one year of the rule's effective date and argued that the sunset provision should include a contingency on changes in operating conditions at O'Hare, *i.e.*, if operations significantly decrease, the rule would sunset.

As stated in the Notice, the agency's preferred approach to reducing delay and congestion is to enhance airport infrastructure, so that capacity meets demand. See, 49 U.S.C. 47101(a)(9). If the desired capacity does not materialize within the timeframe of this rule, we may consider other congestion management techniques to replace this rule. We are also open to revisiting this date if changes to the airline industry obviate the need for a congestion management rule at O'Hare.

We cannot support a one-year rule at this point, as there will not be any measurable increase in capacity in such

a short period. We find it appropriate to extend the termination date of this rule through October 31, 2008, to reflect the current schedule for commissioning of the first runway (Runway 9L/27R). This date coordinates the rule with end of the summer scheduling season and U.S. daylight savings time, as amended by Public Law 109–58.[30] Therefore, we adopt October 31, 2008 at 9 p.m., as the sunset date for this rule.

Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA submitted a copy of the new information collection requirements(s) in this final rule to the Office of Management and Budget (OMB) for its review. OMB is still reviewing the submission and will provide an OMB Control Number when the review is complete.

An agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Economic Assessment, Regulatory Flexibility Determination, Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (5 U.S.C. 5601, *et seq.*) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 4 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to be the basis of U.S. standards. Fourth, the Unfunded Mandate Reform Act of 1995 (Public Law 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

In conducting these analyses, FAA has determined this final rule (1) Has benefits that justify its costs; is not an economically significant regulatory action as defined by Executive Order 12866; and is ''significant'' as defined in DOT's Regulatory Policies and Procedures; (2) will not have a significant economic impact on a substantial number of small entities; (3) will not adversely affect international trade; and (4) will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector. These analyses, set forth in this document, are summarized below.

Total Costs and Benefits of this Rulemaking

FAA estimates that this final rule will result in a 32% reduction in delay at O'Hare, generating present value benefits of $475.6 million relative to November 2003 delays.

The estimated present value cost of this final rule is less than $1.0 million.

Who Is Potentially Affected by This Rulemaking

- Operators of scheduled, domestic and Canadian flights at O'Hare.
- Domestic and foreign air carriers.
- All communities, including small communities with air service to O'Hare.
- Passengers of scheduled, domestic and Canadian flights to O'Hare.
- Chicago Department of Aviation.
- FAA Air Traffic Control.

Key Assumptions

- Baseline Flight Operations—Official Airline Guide (OAG) Schedule November 20, 2003 of 1,464 daily arrival flights (OAG plus 96 unscheduled).
- Daily Flight Completion Factor: 97%/Daily Flight Cancellation Factor: 3%.
- No lost revenue due to cancelled flights—All Passengers are rebooked or rerouted to their destination.
- Delay improvements are 9.6 minutes per flight and equivalent to a 32% improvement in delay. We derive delay improvements from MITRE's Queuing Delay Model, which measures queuing delays against the OAG flight schedule.
- For this evaluation, the effective date is 10/29/06 and the sunset date is 10/31/08. We adjust annual estimates to reflect the 1.5 days per week when the limits are not in effect (all-day Saturday and until noon on Sunday).

Other Important Assumptions

- Discount Rate—7%.
- Assumes 2005 Current Year Dollars.
- Final rule will sunset October 31, 2008.
- Ground and Airborne average cost per hour—$1,935.
- Passenger Value of Time—$28.60 per hour.

Alternatives We Have Considered

- Alternative #1—This alternative would have let the August 18, 2004, order expire on April 30, 2005. Based on history, FAA expects that operators would most likely continue to expand operations, further increasing airport delays.
- Alternative #2—The FAA is continuing to explore the feasibility of a market-based solution such as an auction or congestion pricing.
- Alternative #3—The FAA implements this final rule providing an interim solution while capacity enhancement measures and market-based mechanisms are reviewed.

Benefits of This Rulemaking

The primary benefits of this rule will be the airline and passenger delay cost savings. The benefits reflect a prorating of the 5.5 days per week for which the operational limits are in effect, and the flight completion factor of 97%. The total estimated benefits, shown in table 1 are $475.6 million in present value dollars.

[30] Public Law 109–58 amends the start and end dates of U.S. daylight savings time beginning March 2007.

TABLE 1.—TOTAL PRESENT VALUE BENEFITS OF FINAL RULE

	Airline delay cost savings	Passenger delay cost savings	Total benefits
2006	$19,094,170	$21,212,339	$40,306,510
2007	111,337,400	124,436,227	235,773,627
2008	82,300,269	117,219,790	199,520,059
Total	212,731,839	262,868,357	475,600,196

The total airline delay cost savings of $212.7 million is shown in Table 2. The total passenger delay costs savings of $262.9 million is shown in Table 3.

TABLE 2.—AIRLINE DELAY COST SAVING

	Avg total delay (minutes) per day	Avg total delay (hours) per Day	Avg variable cost per hour	Prorated annual airline delay cost savings	Prorated present value of airline delay cost saving
2006	13,772	230	$1,935	$20,430,762	$19,094,170
2007	13,772	230	1,935	127,470,189	111,337,400
2008	13,772	230	1,935	100,821,369	82,300,269
Total	.....	.....	.....	248,722,320	212,731,839

TABLE 3.—PASSENGER DELAY COST SAVINGS

	Total daily arrivals	Average AC seats	Average AC load factor	Passengers per flight	Passengers per day	Avg delay arrival	Total delay minutes	Total delay hours	Annual daily hours (prorated days rule is in effect)	Pax value of time	Daily pax delay costs	Prorated annual pax passenger delay reduction	Prorated PV of pax delay reduction
2006	1,420	104.3	0.728	75	107,827	9.6	1,035,142	17,252	3,864,528	$28.60	$493,417	$22,697,203	$21,212,339
2007	1,420	104.5	0.731	76	108,479	9.6	1,041,400	17,357	4,981,365	28.60	496,401	142,467,037	124,436,227
2008	1,420	104.9	0.734	76	109,341	9.6	1,049,677	17,495	1,399,569	28.60	500,346	143,599,283	117,219,790
Total	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	308,763,523	262,868,357

Costs of This Rulemaking

The major costs of this final rule cover the blind market costs incurred by buyers and sellers of Arrivals Authorizations, the public costs of developing and managing the blind market, and other administrative and compliance costs. FAA believes that market pressures as well as provisions in this rule should mitigate the potential impact of this final rule on competition and airfares at O'Hare. The total present value costs of less than $1.0 million are shown in the last column of Table 4.

TABLE 4.—PRESENT VALUES OF TOTAL ANNUAL COSTS

	FAA E-Bid develop. costs	E-Bid system operating costs	FAA E-Bid admin. costs	Other admin. costs	Reporting costs	Total costs
2006	$147,196	$23,364	$25,037	$125,183	$29,684	$350,464
2007	0	43,672	46,797	233,987	15,734	340,189
2008	0	20,407	21,868	109,339	12,254	163,868
Total	147,196	87,444	93,702	468,509	57,672	854,522

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation''. To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

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

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this

determination, and the reasoning should be clear. The basis for such FAA determination follows.

The final rule affects all scheduled operators at O'Hare, more than just a few of which are small entities (where ''small entities'' are firms with 1,500 or fewer employees). The arrivals of all carriers currently providing service at O'Hare will be accommodated, thereby minimizing the impact on their schedules. For their given schedules, this final rule will lower their fuel burn costs substantially by reducing the number and magnitude of delays below those experienced prior to the August 2004 Order.

If Arrival Authorizations are returned or withdrawn for nonuse, new entrants and limited incumbents (many of which are likely to be small entities) receive a preference in the reassignment of those authorities. If additional (new) capacity becomes available during the duration of this final rule, new entrants, limited incumbents and incumbents have equal opportunity to receive additional Arrival Authorizations through a lottery. Carriers with a limited number of operations at O'Hare are also protected from withdrawal of Arrival Authorizations if the FAA determines it is operationally necessary to reduce the number of flights at the airport. Therefore, this rule affords limited preference to small entity operators for the assignment of available capacity and again favors these small entity operators if airport operations are reduced.

In ''grandfathering'' the air carriers' existing schedules, the final rule enables airlines to continue operating all existing air service to airports of communities with populations less than 50,000. Consequently, we do not expect this final rule to negatively impact airports in small communities.

Therefore, the FAA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. This rule excludes future growth in non-Canadian international arrivals from the hourly caps imposed. Thus, the FAA has assessed the potential effect of this final rule and determined that it will not create unnecessary obstacles to the foreign commerce of the United States.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $128.1 million in lieu of $100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandate Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312F, Regulations, standards, and exemptions (excluding those which if implemented may cause a significant impact on the human environment). It has been determined that no extraordinary circumstances exist that may cause a significant impact and therefore no further environmental review is required.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order because it is not a ''significant regulatory action'' under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 14 CFR Part 93

Air traffic control, Airports, Alaska, Navigation (air), Reporting and recordkeeping requirements.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration adds Subpart B to part 93 of Chapter II of Title 14, Code of Federal Regulations, as follows:

■ 1. The authority citation for this amendment continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44719, 46301

■ 2. Subpart B is added to read as follows:

Subpart B—Congestion and Delay Reduction at Chicago O'Hare International Airport

Sec.

93.21 Applicability.
93.22 Definitions.
93.23 Arrival Authorizations.
93.24 [Reserved]
93.25 Initial assignment of Arrival Authorizations to U.S. and Canadian air carriers for domestic and U.S./Canada transborder service.
93.26 Reversion and withdrawal of Arrival Authorizations.
93.27 Sale and lease of Arrival Authorizations.
93.28 One-for-one trade of Arrival Authorizations.
93.29 International Arrival Authorizations.
93.30 Assignment provisions for domestic and U.S./Canada transborder service.
93.31 Minimum usage requirement.
93.32 Administrative provisions.
93.33 [Reserved]

Subpart B—Congestion and Delay Reduction at Chicago O'Hare International Airport

§ 93.21 Applicability.

(a) This subpart prescribes the air traffic rules for the arrival of aircraft used for scheduled service, other than helicopters, at Chicago's O'Hare International Airport (O'Hare).

(b) This subpart also prescribes procedures for the assignment, transfer, sale, lease, and withdrawal of Arrival Authorizations issued by the FAA for

scheduled operations by U.S. and foreign air carriers at O'Hare.

(c) The provisions of this subpart apply to O'Hare during the hours of 7 a.m. through 8:59 p.m. Central Time, Monday through Friday, and 12 p.m. through 8:59 p.m. Central Time on Sunday. No person shall operate any scheduled arrival into O'Hare during such hours without first obtaining an Arrival Authorization in accordance with this subpart.

(d) Carriers that have Common Ownership shall be considered to be a single U.S. air carrier or foreign air carrier for purposes of this rule.

(e) The provisions of this subpart are applicable beginning October 29, 2006, and terminate at 9 p.m. on October 31, 2008.

§ 93.22 Definitions.

For the purposes of this subpart, the following definitions apply:

Arrival Authorization is the operational authority assigned by the FAA to a U.S. or foreign air carrier to conduct one scheduled arrival operation on a specific day of the week during a specific 30-minute period at O'Hare.

Carrier is a U.S. air carrier, Canadian air carrier or foreign air carrier with authority to conduct scheduled service at O'Hare under Parts 121, 129, 135 of the Chapter and the appropriate economic authority for scheduled service under Title 49 of the United States Code.

Common Ownership with respect to two or more carriers means having in common at least 50 percent beneficial ownership or control by the same entity or entities.

Incumbent is any U.S. or Canadian air carrier that is not a New Entrant or Limited Incumbent.

International Arrival Authorization is the operational authority assigned by the FAA to a Carrier to conduct one scheduled arrival operation at O'Hare from a foreign point or a continuation of a flight that began at a foreign point, except for arrivals at O'Hare from Canada by U.S. and Canadian air carriers.

Limited Incumbent is any U.S. or Canadian air carrier that holds or operates, on its own behalf, 8 or fewer Arrival Authorizations provided that it has not sold or otherwise transferred Arrival Authorizations, other than one-for-one transfers permitted in this subpart. Any Limited Incumbent that sells or otherwise transfers an Arrival Authorization shall thereafter be treated as an Incumbent for purposes of this rule.

New Entrant is any U.S. or Canadian air carrier that does not hold or operate, and has never held or operated any Arrival Authorization at O'Hare, on its own behalf.

Preferred Lottery is a lottery conducted by the FAA to assign Arrival Authorizations, with initial preference for New Entrants and Limited Incumbents.

Scheduled Arrival is the arrival segment of any operation regularly conducted by a carrier between O'Hare and another point regularly served by that carrier.

Summer Scheduling Season is the period of time from the first Sunday in April until the last Sunday in October. Beginning March 11, 2007, the summer scheduling season is the period of time from the second Sunday in March until the first Sunday in November.

Winter Scheduling Season is the period of time from the last Sunday in October until the first Sunday in April. Beginning March 11, 2007, the winter scheduling season is the first Sunday in November until the second Sunday in March.

§ 93.23 Arrival Authorizations.

(a) Except as otherwise established by the FAA under paragraph (d) of this section and § 93.29 of this subpart, the number of Arrival Authorizations shall be limited to:

(1) 88 per hour between the hours of 7 a.m. and 7:59 p.m. Monday through Friday and 12 p.m. and 7:59 p.m. Sunday,

(i) Not to exceed 50 during each half-hour beginning at 7 a.m. and ending at 7:59 p.m.

(ii) Not to exceed 88 within any two consecutive 30-minute periods.

(2) 98 between 8 p.m. and 8:59 p.m. Monday through Friday, and Sunday, not to exceed 50 between 8 p.m. and 8:29 p.m. and 50 between 8:30 p.m and 8:59 p.m.

(b) An Arrival Authorization is a temporary operating privilege subject to FAA control. Only Carriers may hold Arrival Authorizations. Arrival Authorizations may not be bought, sold, leased, or otherwise transferred to another Carrier, except as provided in §§ 93.27 and 93.28 of this subpart.

(c) Beginning six months from the effective date of this rule and on each six-month anniversary thereafter, the FAA shall conduct a review of existing capacity at O'Hare, to determine whether to increase the number of Arrival Authorizations. The FAA will consider the following factors:

(1) The number of delays;

(2) The length of delays;

(3) Weather conditions;

(4) On-time arrivals and departures;

(5) The number of actual arrival operations;

(6) Runway utilization and capacity plans; and

(7) Other factors relating to the efficient management of the national air space system.

(d) Notwithstanding paragraph (a), the Administrator may increase the number of Arrival Authorizations based on the review conducted in paragraph (c) of this section.

§ 93.24 [Reserved]

§ 93.25 Initial assignment of Arrival Authorizations to U.S. and Canadian air carriers for domestic and U.S./Canada transborder service.

(a) The FAA shall assign to each U.S. and Canadian air carrier, conducting scheduled service at O'Hare, as of the effective date of this rule, Arrival Authorizations for each scheduled arrival that it published for either domestic or U.S./Canada transborder service for any day during the 7-day period of November 1 through 7, 2004, as evidenced by the FAA's records, not to exceed the peak-day limits for each carrier established under the August 18, 2004, ''Order Limiting Scheduled Operations at O'Hare International Airport.'' A carrier's total assignment under this paragraph will be reduced accordingly by any international Arrival Authorizations assigned under § 93.29(a).

(b) If a U.S. or Canadian air carrier did not publish a scheduled domestic or U.S./Canada transborder arrival during the period of time referenced in paragraph (a) of this section, but was entitled to do so under the August 18, 2004, ''Order Limiting Scheduled Operations at O'Hare International Airport,'' and is conducting scheduled service at O'Hare as of the effective date of this rule, a corresponding Arrival Authorization shall be assigned for that arrival.

(c) Arrival Authorizations will be assigned to the U.S. or Canadian air carrier that actually operated the flight regardless of any codeshare or marketing arrangement unless such carrier did not market the flight under its own code and the inventory of the flight was under the control of another Carrier. If the inventory was under the control of another Carrier, the FAA shall assign the Arrival Authorization to that Carrier. Carriers may subsequently transfer Arrival Authorizations for use by other Carriers under their marketing control in accordance with § 93.2(m).

(d) Any Arrival Authorization not assigned under paragraphs (a) or (b) of this section will be assigned to carriers conducting scheduled international service under § 93.29. Any remaining

Arrival Authorizations will be assigned by preferred lottery under § 93.30.

(e) The FAA Vice President, System Operations Services, is the final decision-maker for determinations under this section.

§ 93.26 Reversion and withdrawal of Arrival Authorizations.

(a) A U.S. or Canadian air carrier's Arrival Authorizations assigned under §§ 93.25 or 93.27 revert automatically to the FAA 30 days after the Carrier has ceased all operations at O'Hare for any reason other than a strike.

(b) The FAA may withdraw or temporarily suspend Arrival Authorizations at any time as a result of reduced airport capacity or to fulfill operational needs. Whenever Arrival Authorizations must be withdrawn, they will be withdrawn in the required 30-minute Arrival Authorization time periods in accordance with the priority list established under § 93.32 of this subpart.

(c) Any Arrival Authorization that is withdrawn or temporarily suspended under paragraph (b) will, if reassigned, be reassigned to the Carrier from which it was taken, provided that the Carrier continues to conduct scheduled operations at O'Hare.

(d) The FAA shall not withdraw or temporarily suspend under paragraph (b) any Arrival Authorizations if the result would be to reduce a Carrier's total number of Arrival Authorizations below eight.

(e) Except as otherwise provided in paragraph (a) of this section, the FAA will notify the affected Carrier before withdrawing or temporarily suspending any Arrival Authorization and specify the date by which operations under the authorizations must cease. The FAA will provide at least 45 days' notice unless otherwise required by operational needs.

§ 93.27 Sale and lease of Arrival Authorizations.

(a) No U.S. or Canadian air carriers may sell or lease its Arrival Authorizations at O'Hare except in accordance with the procedures in this section and in the manner prescribed by the FAA. Carriers may not buy, sell, lease or otherwise transfer control of Arrival Authorizations assigned under § 93.29.

(b) Only monetary consideration may be provided in any transaction conducted under this section.

(c) New Entrants and Limited Incumbents may not sell, lease, or otherwise transfer control of any Arrival Authorizations assigned through a Preferred Lottery within 12 months of such assignment, except to another New Entrant or Limited Incumbent. One-for-one trades to other Carriers under § 93.28 are permitted.

(d) A U.S. or Canadian air carrier seeking to sell or lease an Arrival Authorization must provide the following information in writing to the FAA:

(1) Arrival Authorization number and time;

(2) Frequency;

(3) Planned effective date(s) of transfer;

(4) Minimum reserve price, if established by the offering carrier;

(5) Other pertinent information, if applicable; and

(6) Carrier's authorized representative.

(e) The FAA will post a notice of the available Arrival Authorization and specific information concerning the proposed sale or lease transaction on the FAA Web site at *http://www.fly.faa.gov.* The Web site will include information regarding registration to be advised of posted transactions, and other relevant information pertaining to this section. The FAA will post the notice within two business days after receipt of all required information from the U.S or Canadian air carrier offering the Arrival Authorization for sale or lease. The notice will provide ten business days for bids to be received and will specify a bid closing date and time. Only U.S. and Canadian air carriers may bid on Arrival Authorizations. Information identifying the Carrier providing the Arrival Authorization for sale or lease will not be posted or released by the FAA until after the FAA has approved the transfer.

(f) All bids must be sent to the FAA electronically, via the FAA Web site, by the closing date and time, and no extensions of time will be granted. Late bids will not be considered. All bids will be held confidential, with each bidder certifying in a form acceptable to the FAA that its bid has not been disclosed to any person not its agent.

(g) The FAA will forward the highest qualifying bid to the selling or leasing U.S. or Canadian air carrier without identifying the bidder. The selling or leasing Carrier will have up to three business days to accept or reject the bid. The selling or leasing Carrier must notify the FAA via the Web site or in writing of its acceptance no later than 5 p.m. Eastern Time on the third business day. If the selling or leasing Carrier does not notify the FAA of its acceptance within the allotted time, the transaction will terminate.

(h) Upon acceptance, the FAA will notify the U. S. or Canadian air carrier, who submitted the highest bid, and request that the buyer/lessee and the seller/lessor submit to the FAA the information (such as Arrival Authorization number, frequency and effective date(s) of transfer) required to transfer the Arrival Authorization.

(i) Each U.S. or Canadian air carrier must provide the FAA evidence of its consent and each Carrier must certify that only monetary consideration will be or has been exchanged.

(j) The FAA will approve requested transfers of Arrival Authorizations that comply with these regulations. The recipient U.S. or Canadian air carrier of the transfer may not use the Arrival Authorization until the conditions in paragraph (i) of this section have been met and the FAA has approved the transfer.

(k) The FAA will keep a record of all bids received and of each Arrival Authorization transfer, including the identity of both Carriers and the winning bid price, all of which will be made available to the public.

(l) U.S. or Canadian air carriers may request the FAA post notice that it is seeking to lease or purchase an Arrival Authorization at O'Hare. The Carrier may submit information in writing or via the FAA's Web site. This information may include the effective date, number or timing of Arrival Authorizations sought, whether a Carrier is seeking to purchase or lease, maximum price offered, or other pertinent information. The FAA may edit any submissions, or choose not to post certain information, in order to ensure the integrity of the solicitation process. Information identifying the Carrier seeking an Arrival Authorization for sale or lease will not be posted or released by the FAA. The FAA will post such requests within two business days of receipt for a period of at least 30 days. Any resulting offers to sell or lease Arrival Authorizations shall be conducted in accordance with this subsection.

(m) A U.S. or Canadian air carrier may transfer an Arrival Authorization to another U.S. or Canadian air carrier that conducts operations at O'Hare solely under the transferring Carrier's marketing control, including the entire inventory of the flight. Each Carrier must provide written evidence of its consent to the transfer. The FAA will approve requested transfers that comply with these regulations. The FAA Vice President, System Operations Services, is the final decision-maker for determinations under this subsection. The recipient Carrier of the transfer may not use the Arrival Authorization until the FAA has provided written confirmation. A record of each Arrival Authorization will be kept on file by the

FAA and made available to the public on request.

§ 93.28 One-for-one trade of Arrival Authorizations.

(a) Except as otherwise provided in this subpart, any Carrier may exchange an Arrival Authorization it has been assigned with another Carrier on a one-for-one basis for the purpose of conducting that operation in a different half-hour time period.

(b) Written evidence of each Carrier's consent to the transfer must be provided to the FAA.

(c) The FAA will approve requested transfers of Arrival Authorizations that comply with these regulations. The recipient Carrier of the transfer may not use the Arrival Authorization until written confirmation has been received from the FAA.

(d) A U.S. or Canadian air carrier assigned Arrival Authorizations under § 93.29 may trade on a one-for-one basis within its own base of Arrival Authorizations subject to FAA approval, provided that the purpose is to operate the arrival flight from a foreign point outside Canada in a different half-hour time period than assigned. The FAA must confirm the transfer prior to operation.

(e) A record of each Arrival Authorization exchange will be kept on file by the FAA and made available to the public upon request.

(f) Carriers participating in a one-for-one transfer must certify to the FAA that no other consideration will be or has been provided for the exchange.

§ 93.29 International Arrival Authorizations.

(a) Except as otherwise provided in paragraph (d) of this section, the FAA shall make an initial assignment of Arrival Authorizations to U.S. and Canadian carriers arriving from a foreign point, excluding Canada, or any other foreign carrier arriving from a foreign point or the continuation of a flight that begins at a foreign point for the winter and summer scheduling seasons as follows. This section does not apply to arrivals at O'Hare from Canada by U.S. or Canadian air carriers.

(1) *Winter Scheduling Season.* Upon request, the FAA shall assign to each Carrier that published a scheduled arrival during the Winter 2006 Scheduling Season, as evidenced by the FAA's records, a corresponding Arrival Authorization for the Winter 2007 Scheduling Season.

(2) *Summer Scheduling Season.* Upon request, the FAA shall assign to each Carrier that published a scheduled arrival for the Summer 2006 Scheduling Season, as evidenced by the FAA's records, a corresponding Arrival Authorization for the Summer 2007 Scheduling Season.

(3) Arrival Authorizations will be assigned to the Carrier that actually operated the flight regardless of any codeshare or marketing arrangement unless the flight was predominately marketed, by contract, under the control of another Carrier. If the flight was under the marketing control of another Carrier or the entire inventory was under the control of another Carrier, the FAA shall assign the Arrival Authorization to that Carrier.

(4) The FAA Vice President, System Operations Services, is the final decision-maker for determinations under this subsection.

(b) Notwithstanding the limit on Arrival Authorization in § 93.23(a), any U.S. or Canadian air carrier arriving at O'Hare from a foreign point, excluding Canada, shall be assigned an Arrival Authorization under this section for that flight.

(c) Notwithstanding the limit on Arrival Authorizations in § 93.23(a), any non-Canadian, foreign air carrier conducting scheduled service and arriving at O'Hare shall be assigned an Arrival Authorization under this section for that flight.

(d) The Department of Transportation reserves the right to withhold the assignment of an Arrival Authorization to any foreign air carrier of a country that does not provide equivalent rights of access to its airports for U.S. air carriers, as determined by the Secretary of Transportation.

(e) For each scheduling season, Carriers must request Arrival Authorizations under this section in accordance with the procedures announced by the FAA in the **Federal Register**. A Carrier may request to operate more flights from foreign points than the number for which it received Arrival Authorizations under § 93.29(a) or to operate historic arrivals in a different half-hour than initially assigned for the previous corresponding scheduling season. The Arrival Authorizations will be assigned at the time requested unless:

(1) An Arrival Authorization is available within one hour of the requested time, in which case, the unassigned Arrival Authorization will be used to satisfy the request; or

(2) Operational efficiencies support assignment within one hour of the requested period. The FAA Vice President, System Operations Services, is the final decision-maker for determinations under this subsection.

(f) Each request for Arrival Authorizations under this section shall specify the complete flight information including the carrier identifier, flight number, complete flight itinerary, frequency, scheduled arrival time, aircraft and service type, effective dates and whether the Arrival Authorization is for a new or historic flight.

(g) Arrival Authorizations assigned under this section cannot be bought, sold, leased or transferred under § 93.27 but subject to FAA approval may be traded on a one-for-one basis under § 93.28 to meet the Carrier's operational needs.

(h) Arrival Authorizations assigned under this section are not subject to minimum usage requirements of § 93.31 of this subpart but will revert to the FAA if not used for 15 consecutive days. Arrival Authorizations assigned under this section may only be used for a flight arriving from a foreign point or for non-Canadian, foreign air carriers, the continuation of a flight that begins at a foreign point.

§ 93.30 Assignment provisions for domestic and U.S./Canada transborder service.

(a) Whenever the FAA has determined that sufficient Arrival Authorizations are available, they will be assigned by lottery in accordance with this section. Only U.S. and Canadian air carriers are eligible to participate in a lottery. U.S. and Canadian air carriers must hold appropriate economic authority for scheduled service under Title 49 of the U.S.C. and FAA operating authority under parts 121, 129, or 135 of this chapter to select Arrival Authorizations in a lottery.

(b) Arrival Authorizations not assigned under § 93.25, or returned to the FAA under §§ 93.26(a) or 93.31 for reassignment shall be assigned by a Preferred Lottery.

(c) Any Arrival Authorization available as the result of an increase in the hourly limits under § 93.23(a) of this part from 88 Arrival Authorizations to 89 or 90 shall be assigned by Preferred Lottery.

(d) Any Arrival Authorizations available as the result of an increase above 90 in the hourly limits specified in § 93.23(a) of this subpart shall be assigned by lottery that is open to all U.S. and Canadian air carriers eligible to participate.

(e) The FAA will publish a notice in the **Federal Register** announcing the lottery dates and any special procedures for the lotteries.

(f) Any U.S. or Canadian air carrier seeking to participate in any lottery must notify the FAA in writing, and

such notification must be received by the FAA 15 days prior to the lottery date. The U.S. or Canadian air carrier must specify if it is requesting to participate in a lottery as a New Entrant or Limited Incumbent. The U.S. or Canadian air carrier must also disclose in its notification whether it has Common Ownership with any other Carrier and, if so, identify such Carrier.

(g) A random lottery shall be held to determine the order in which participating Carriers shall select an Arrival Authorization.

(h) In any Preferred Lottery, each New Entrant and Limited Incumbent will have the opportunity to select Arrival Authorizations, if available as provided in paragraph (i) of this section, until it holds a total of eight Arrival Authorizations. Arrival Authorizations remaining after all New Entrants and Limited Incumbents have been accommodated may be assigned to any other Carrier participating in the lottery. Arrival Authorizations remaining after all New Entrants and Limited Incumbents have been accommodated may be assigned to any U.S. or Canadian air carrier participating in the lottery for a minimum of 12 months, and then until the next lottery, when such Arrival Authorizations would again be available on a preferred basis to New Entrants and Limited Incumbents.

(i) At the lottery, each Carrier must make its selection within 5 minutes after being called or it shall lose its turn. If Arrival Authorizations still remain after each Carrier has had an opportunity to select Arrival Authorizations, the assignment sequence will be repeated in the same order. A Carrier may select one Arrival Authorization during each sequence, except that New Entrants may select two Arrival Authorizations, if available, in the first sequence of a Preferred Lottery.

(j) If there are available Arrival Authorizations for a temporary period, for example, Arrival Authorizations pending assignment in a lottery or international arrivals that are temporarily returned, the FAA may assign these Authorizations on a non-permanent, first-come, first-served basis.

§ 93.31 Minimum usage requirement.

(a) Except as provided in § 93.29 and paragraphs (b) and (c) of this section, any Arrival Authorizations not used at least 80 percent of the time over a two-month period shall be withdrawn by the FAA.

(b) Paragraph (a) of this section does not apply to Arrival Authorizations obtained under § 93.30 or bought under § 93.27 during the first 90 days after assignment.

(c) Paragraph (a) of this section does not apply to Arrival Authorizations of U.S. or Canadian air carrier forced by a strike to cease operations using those Arrival Authorizations.

(d) Every U.S. and Canadian air carrier holding Arrival Authorizations shall forward in writing to the FAA Slot Administration Office in a format specified by the FAA a list of all Arrival Authorizations held by the Carrier along with a listing of the Arrival Authorizations actually operated for each day of the 2-month reporting period within 14 days after the last day of the 2-month reporting period beginning January 1 and every 2 months thereafter. The report shall identify for each assigned Arrival Authorization the withdrawal priority number and half-hour period, the flight number, 3-letter identifier of the operating Carrier used for air traffic control communications, scheduled time of operation, origin airport, and whether a scheduled arrival was actually operated by the Carrier on a specified day. The report shall identify any Common Ownership or control of, by, or with any other carrier. A senior official of the Carrier shall sign the report.

(e) The Administrator may waive the requirements of paragraph (a) of this section in the event of a highly unusual and unpredictable condition which is beyond the control of the Carrier and which exists for a period of 5 consecutive days or more. Examples of conditions that could justify waiver under this paragraph are weather conditions that result in the restricted operation of an airport for an extended period of time or the grounding of any aircraft type.

(f) The FAA will treat as used any Arrival Authorization held by a carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Sunday in January.

§ 93.32 Administrative provisions.

(a) The FAA will assign, by random lottery, withdrawal priority numbers for the recall priority of Arrival Authorizations at O'Hare. The lowest numbered Arrival Authorization will be the last withdrawn. Newly created Arrival Authorizations will be assigned a priority withdrawal number and that number will be higher than any other Arrival Authorization withdrawal number previously assigned. Each Arrival Authorization will be assigned a designation consisting of the applicable withdrawal priority number, and the 30-minute time period for the Arrival Authorization. The designation will also indicate, as appropriate, if the Arrival Authorization is daily or for certain days of the week only; and is a summer or winter Arrival Authorization.

(b) All transactions regarding Arrival Authorizations under this subpart must be in a written or electronic format approved by the FAA.

§ 93.33 [Reserved]

Issued in Washington, DC, on August 21, 2006.

Marion C. Blakey,

Administrator.

[FR Doc. 06–7138 Filed 8–23–06; 9:00 am]

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Federal Register

Tuesday,
August 29, 2006

Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Final Frameworks for Early-Season Migratory Bird Hunting Regulations; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AU42

Migratory Bird Hunting; Final Frameworks for Early-Season Migratory Bird Hunting Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes final early-season frameworks from which the States, Puerto Rico, and the Virgin Islands may select season dates, limits, and other options for the 2006–07 migratory bird hunting seasons. Early seasons are those that generally open prior to October 1, and include seasons in Alaska, Hawaii, Puerto Rico, and the Virgin Islands. The effect of this final rule is to facilitate the selection of hunting in seasons by the States and Territories to further the annual establishment of the early-season migratory bird hunting regulations.

DATES: This rule takes effect on August 29, 2006.

ADDRESSES: States and Territories should send their season selections to: Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, ms MBSP–4107–ARLSQ, 1849 C Street, NW., Washington, DC 20240. You may inspect comments during normal business hours at the Service's office in room 4107, 4501 N. Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Brian Millsap, Chief, or Ron W. Kokel, Division of Migratory bird Management, U.S. Fish and Wildlife Service, (703) 358–1714.

SUPPLEMENTARY INFORMATION:

Regulations Schedule for 2006

On April 11, 2006, we published in the **Federal Register** (71 FR 18562) a proposal to amend 50 CFR part 20. The proposal provided a background and overview of the migratory bird hunting regulations process, and dealt with the establishment of seasons, limits, proposed regulatory alternatives for the 2006–07 duck hunting season, and other regulations for hunting migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of subpart K. Major steps in the 2006–07 regulatory cycle relating to open public meetings and **Federal Register** notifications were also identified in the April 11 proposed rule. On May 30, 2006, we published in the **Federal Register** (71 FR 30786) a second document providing supplemental proposals for early- and late-season migratory bird hunting regulations and the regulatory alternatives for the 2006–07 duck hunting season. The May 30 supplement also provided detailed information on the 2006–07 regulatory schedule and announced the Service Migratory Bird Regulations Committee (SRC) and Flyway Council meetings.

On June 21 and 22, 2006, we held open meetings with the Flyway Council Consultants at which the participants reviewed information on the current status of migratory shore and upland game birds and developed recommendations for the 2006–07 regulations for these species plus regulations for migratory game birds in Alaska, Puerto Rico, and the Virgin Islands, special September waterfowl seasons in designated States, special sea duck seasons in the Atlantic Flyway, and extended falconry seasons. In addition, we reviewed and discussed preliminary information on the status of waterfowl as it relates to the development and selection of the regulatory packages for the 2006–07 regular waterfowl seasons. On July 28, 2006, we published in the **Federal Register** (71 FR 43008) a third document specifically dealing with the proposed frameworks for early-season regulations, and on August 24, 2006, we published in the **Federal Register** (71 FR 50224) a fourth document specifically dealing with the proposed frameworks for late-season regulations.

This document is the fifth in a series of proposed, supplemental, and final rulemaking documents. It establishes final frameworks from which States may select season dates, shooting hours, and daily bag and possession limits for the 2006–07 season. These selections will be published in the **Federal Register** as amendments to §§ 20.101 through 20.107, and § 20.109 of title 50 CFR part 20.

Review of Public Comments

The preliminary proposed rulemaking, which appeared in the April 11 **Federal Register**, opened the public comment period for migratory game bird hunting regulations. We have considered all pertinent comments received. Comments are summarized below and numbered in the order used in the April 11 **Federal Register**. We have included only the numbered items pertaining to early-season issues for which we received comments. Consequently, the issues do not follow in successive numerical or alphabetical order. We received recommendations from all Flyway Councils. Some recommendations supported continuation of last year's frameworks. Due to the comprehensive nature of the Councils' annual review of the frameworks, we assume Council support for continuation of last year's frameworks for items for which we received no recommendation. Council recommendations for changes are summarized below.

1. Ducks

Categories used to discuss issues related to duck harvest management are: (A) General Harvest Strategy, (B) Regulatory Alternatives, including specification of framework dates, season length, and bag limits, (C) Zones and Split Seasons, and (D) Special Seasons/Species Management. The categories correspond to previously published issues/discussions, and only those containing substantial recommendations are discussed below.

D. Special Seasons/Species Management

vii. Youth Hunt

Council Recommendations: The Atlantic Flyway Council recommended allowing the take of tundra swans during the special youth waterfowl hunt day(s) to those individuals holding a valid permit/tag.

Service Response: Tundra swans may be taken by individuals holding a valid permit/tag at any time during the open season without any additional provisions. For youth-hunt days outside the tundra swan season, we will defer a decision on the recommendation until the management plan for the Eastern Population (EP) of tundra swans has been reviewed and input from the other Flyways has been considered. An update of the management plan is scheduled to begin this year.

4. Canada Geese

A. Special Seasons

Council Recommendations: The Atlantic Flyway Council made several recommendations dealing with early Canada goose seasons. First, the Council recommended that the Service allow the use of special regulations (electronic calls, unplugged guns, extended hunting hours) later than September 15 during existing September Canada goose hunting seasons in Atlantic Flyway States. Use of these special regulations would be limited to the geographic areas of States that were open to hunting and under existing September season ending dates as approved by the Service for the 2006 regulation cycle. This regulation would take effect as soon as the final rule on resident Canada goose management is effective. Second, the

Council recommended increasing the Atlantic Flyway's September Canada goose hunting season daily bag limit to 15 geese, with a possession limit of 30 geese, beginning with the 2006–07 hunting season. Lastly, the Council recommended allowing Maryland to modify the boundary of their Early Resident Canada Goose Western Zone.

The Central Flyway Council recommended that evaluation requirements for September Canada goose hunting seasons from September 16 to September 30 be waived for all east-tier Central Flyway States south of North Dakota. The Council also recommended that the Oklahoma experimental September Canada goose season be allowed to continue until sufficient goose tail fan samples are obtained for the September 16–30 time period to meet Service evaluation requirements and that Kansas be allowed to implement a 3-year (2006—08) experimental Canada goose season during the September 16–30 period.

Service Response: First, we support the Atlantic Flyway Council's desire to increase opportunities to harvest resident Canada geese. Although there are social considerations for increasing the daily bag and possession limits to 15 and 30, respectively, we would like States to have as much flexibility as possible to reduce resident goose populations where appropriate, and we concur with the recommended increased limits. We also concur with the Council's request to modify Maryland's boundary of their Early Resident Canada Goose Western Zone, although we understand it will not be implemented this year. We do not, however, concur with the Council's recommendation for the use of special regulations in September to harvest resident Canada geese. Pending the completion, publication, and implementation of a final rule for resident Canada goose management, we will defer a decision about extending the use of these special (liberalized) regulations beyond September 15 until after the completion of that rulemaking process.

Regarding the Central Flyway Council's recommendation to waive evaluation requirements for east-tier States south of North Dakota, we concur, given the preponderance of evidence that there are relatively few, if any, migrant Canada geese present in these States at this time of the year. Given our approval of the Council's request to waive evaluation requirements for the east-tier States south of North Dakota, the Council's recommendations regarding Oklahoma and Kansas are no longer necessary.

B. Regular Seasons

Council Recommendations: The Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended that the framework opening date for all species of geese for the regular goose seasons in the Flyway be September 16 in 2006 and future years. If this recommendation is not approved, the Committees recommended that the framework opening date for all species of geese for the regular goose seasons in Michigan and Wisconsin be September 16, 2006.

The Central Flyway Council recommended that Canada goose regulations be moved to the early-season regulations schedule in the east-tier States of the Central Flyway. Further, the Council recommended a season framework of 107 days with a daily bag limit of 3 Canada geese (or any other goose species except light geese and white-fronted geese) in all east-tier States, except in the Big Stone Power Plant area of South Dakota where the daily bag limit would be 3 until November 30 and 2 thereafter. Framework dates would be September 16 to the Sunday nearest February 15 (February 18, 2007). States could split the season twice, and the possession limit would be twice the daily bag limit.

Service Response: As we stated last year (**Federal Register** (70 FR 51522)), we concur with the objective to increase harvest pressure on resident Canada geese in the Mississippi Flyway, but do not concur with a September 16 framework opening date throughout the Flyway. A September 16 opening date Flyway-wide would require that the regular season be established during the early-season regulations process, which presents a number of administrative problems. Regarding the recommendations for a September 16 framework opening date in Wisconsin and Michigan, we concur. However, the opening dates in both States will continue to be considered exceptions to the general Flyway opening date, to be reconsidered annually.

Regarding the Central Flyway Council's recommendation that Canada goose regulations be moved to the early-season regulations schedule in the east-tier States of the Central Flyway, our approval to waive evaluation requirements for special Canada goose seasons between September 16'30 in east-tier States south of North Dakota (see 4.A. Special Seasons) resulted in the Council withdrawing this recommendation from the early-season regulatory process.

9. Sandhill Cranes

Council Recommendations: The Central and Pacific Flyway Councils recommended using the 2006 Rocky Mountain Population sandhill crane harvest allocation of 1,321 birds as proposed in the allocation formula using the 2003–2005 3-year running average.

The Pacific Flyway Council recommended initiating a limited hunt for Lower Colorado River sandhill cranes in Arizona, with the goal of the hunt being a limited harvest of 10 cranes in January. To limit harvest, Arizona would issue permit tags to hunters and require mandatory check of all harvested cranes. To limit disturbance of wintering cranes, Arizona would restrict the hunt to one 3-day period. Arizona would also coordinate with the National Wildlife Refuges where cranes occur.

Service Response: We are in general support of allowing a very limited, carefully controlled harvest of sandhill cranes from this population, and we note that the management plan allows for such harvest. However, we do not believe that this limited harvest is of immediate concern, and recommend that prior to instituting such a season, which would be the first time harvest has been permitted for this population, a more detailed harvest strategy be developed by the Flyway Council. The harvest strategy should address: (1) How the number of permits will be determined each year to ensure a sustainable harvest, (2) the allocation of these permits between the States and other political entities that may be interested in sharing this harvest (*i.e.,* Idaho, Utah, Nevada, California, Arizona, and the Colorado River Indian Tribe), and (3) appropriate population levels for season closure and reinstatement. This approach is consistent with harvest strategies already in place for other harvested populations of sandhill cranes. We believe that this harvest strategy should be developed and included as an appendix to the management plan prior to any hunting season being instituted.

11. Moorhens and Gallinules

Council Recommendations: The Atlantic Flyway Council recommended changing the framework closing date for moorhens and gallinules from January 20 to January 31 to help standardize the framework ending dates for those webless species that are found in the same areas as waterfowl.

Service Response: We concur with the recommendation to align the framework closing date with the latest framework

closing date for duck seasons, which is the last Sunday in January.

12. Rails

Council Recommendations: The Atlantic Flyway Council recommended changing the framework closing date for rails from January 20 to January 31 to help standardize the framework ending dates for those webless species that are found in the same areas as waterfowl.

Service Response: We concur with the recommendation to align the framework closing date with the latest framework closing date for duck seasons, which is the last Sunday in January.

16. Mourning Doves

Council Recommendations: The Atlantic and Mississippi Flyway Councils supported the Service's recommended guidelines for dove zones and split seasons in the Eastern Management Unit. The recommended guidelines consisted of the following:

1. A zone is a geographic area or portion of a State, with a contiguous boundary, for which independent dates may be selected for the dove season.

2. States in management units approved for zoning may select a zone/split option during an open season. It must remain in place for a 5-year period.

3. Zoning periods for dove hunting will conform to those years used for ducks, e.g., 2006–2010.

4. The zone/split configuration consists of two zones with the option for 3-way (3-segment) split seasons in one or both zones. As a grandfathered arrangement, Texas will have three zones with the option for 2-way (2 segments) split seasons in one, two, or all three zones.

5. States that do not wish to zone for dove hunting may split their seasons into no more than three segments.

The Central Flyway Council endorsed the guidelines with the exception that they recommended allowing a State to revert back to the 2005 zone and split configuration in any year.

The Atlantic and Mississippi Flyway Councils also recommended allowing States in the Eastern Management Unit (EMU) to adopt hunting seasons and daily bag limits that include an aggregate daily bag limit composed of mourning doves and white-winged doves, singly or in combination. The Councils further recommended that States be allowed to begin mourning dove seasons as early as September 1, regardless of zones.

Service Response: Regarding the zone/split guidelines for dove seasons, we concur with the Central Flyway Council's recommendation to modify the proposed guidelines by allowing a State to make a one-time change and revert back to the previous zone/split configuration.

Regarding the recommendation for an opening date of September 1 management-unit-wide, we concur with the recommendation from the Atlantic and Mississippi Flyway Councils to make September 1 the framework opening date for dove hunting in all zones in the Eastern Management Unit. While we note that the Eastern Management Unit Dove Technical Committee reviewed current information and determined that there was no biological basis for the September 20 initiation date based on latitudinal lines, our concurrence is provisional with respect to Florida. Information from nesting studies in Texas suggest that a delayed framework opening date in the southern portion of that State may be warranted. Due to its similar latitude, we request that Florida provide any information it may have that would help determine an appropriate opening date for dove seasons in that State.

17. White-Winged and White-Tipped Doves

Council Recommendations: The Atlantic and Mississippi Flyway Councils recommended allowing States in the Eastern Management Unit (EMU) to adopt hunting seasons and daily bag limits that include an aggregate daily bag limit composed of mourning doves and white-winged doves, singly or in combination.

Service Response: We concur. White-winged doves appear similar to mourning doves in the field and may occur in mixed feeding flocks. Further, data indicates that whitewing populations are increasing and becoming more widespread in some portions of the EMU. The expected incidental harvest is not expected to adversely impact these expanding whitewing populations.

18. Alaska

Council Recommendations: The Pacific Flyway Council recommended maintaining status quo in the Alaska early-season frameworks, except for the following changes: (1) An increase in the daily bag limit for white geese from 3 to 4, consistent with other Pacific Flyway States; and (2) that the brant season length be restored to 107 days.

Service Response: We support the Council's recommendation for Alaska's migratory bird seasons. The recommended increase in the daily bag limit for white geese is consistent with that for the other Pacific Flyway States. While the recommended 107-day brant season is consistent with the Pacific brant management plan, we have some concern with provisions in the management plan for changes between the harvest levels. We request that the Flyway Council review these provisions in order to reduce the potential frequency of annual changes.

NEPA Consideration

NEPA considerations are covered by the programmatic document ''Final Supplemental Environmental Impact Statement: Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FSES 88–14),'' filed with the Environmental Protection Agency on June 9, 1988. We published a Notice of Availability in the **Federal Register** on June 16, 1988 (53 FR 22582). We published our Record of Decision on August 18, 1988 (53 FR 31341). In addition, an August 1985 environmental assessment entitled ''Guidelines for Migratory Bird Hunting Regulations on Federal Indian Reservations and Ceded Lands'' is available from the address indicated under the caption **ADDRESSES**. In a notice published in the September 8, 2005, **Federal Register** (70 FR 53376), we announced our intent to develop a new Supplemental Environmental Impact Statement for the migratory bird hunting program. Public scoping meetings were held in the spring of 2006, and we announced in a March 9, 2006, **Federal Register** notice (71 FR 12216).

Endangered Species Act Consideration

Section 7 of the Endangered Species Act, as amended (16 U.S.C. 1531–1543; 87 Stat. 884), provides that, ''The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act'' (and) shall ''insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat. * * *'' Consequently, we conducted formal consultations to ensure that actions resulting from these regulations would not likely jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of their critical habitat. Findings from these consultations are included in a biological opinion, which concluded that the regulations are not likely to adversely affect any endangered or threatened species. Additionally, these findings may have caused modification

of some regulatory measures previously proposed, and the final frameworks reflect any such modifications. Our biological opinions resulting from this Section 7 consultation are public documents available for public inspection at the address indicated under **ADDRESSES**.

Executive Order 12866

The migratory bird hunting regulations are economically significant and were reviewed by the Office of Management and Budget (OMB) under Executive Order 12866. As such, a cost/benefit analysis was initially prepared in 1981. This analysis was subsequently revised annually from 1990–96, updated in 1998, and updated again in 2004. It is further discussed under the heading Regulatory Flexibility Act. Results from the 2004 analysis indicate that the expected welfare benefit of the annual migratory bird hunting frameworks is on the order of $734 to $1,064 million, with a mid-point estimate of $899 million. Copies of the cost/benefit analysis are available upon request from the address indicated under **ADDRESSES** or from our Web site at *www.migratorybirds.gov*.

Regulatory Flexibility Act

These regulations have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). We analyzed the economic impacts of the annual hunting regulations on small business entities in detail as part of the 1981 cost-benefit analysis discussed under Executive Order 12866. This analysis was revised annually from 1990–95. In 1995, the Service issued a Small Entity Flexibility Analysis (Analysis), which was subsequently updated in 1996, 1998, and 2004. The primary source of information about hunter expenditures for migratory game bird hunting is the National Hunting and Fishing Survey, which is conducted at 5-year intervals. The 2004 Analysis was based on the 2001 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $481 million and $1.2 billion at small businesses in 2004. Copies of the Analysis are available upon request from the address indicated under **ADDRESSES** or from our Web site at *http://www.migratorybirds.gov*.

Small Business Regulatory Enforcement Fairness Act

This rule is a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. For the reasons outlined above, this rule has an annual effect on the economy of $100 million or more. However, because it establishes hunting seasons, we do not plan to defer the effective date required by 5 U.S.C. 801 under the exemption contained in 5 U.S.C. 808(1).

Paperwork Reduction Act

We examined these regulations under the Paperwork Reduction Act of 1995. The various recordkeeping and reporting requirements imposed under regulations established in 50 CFR part 20, Subpart K, are utilized in the formulation of migratory game bird hunting regulations. Specifically, OMB has approved the information collection requirements of the surveys associated with the Migratory Bird Harvest Information Program and assigned clearance number 1018–0015 (expires 2/29/2008). This information is used to provide a sampling frame for voluntary national surveys to improve our harvest estimates for all migratory game birds in order to better manage these populations. OMB has also approved the information collection requirements of the Sandhill Crane Harvest Survey and assigned clearance number 1018–0023 (expires 11/30/2007). The information from this survey is used to estimate the magnitude and the geographical and temporal distribution of the harvest, and the portion it constitutes of the total population.

A Federal 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.

Unfunded Mandates Reform Act

We have determined and certify, in compliance with the requirements of the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities. Therefore, this rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Civil Justice Reform—Executive Order 12988

In promulgating this rule, we have determined that it will not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988.

Takings Implication Assessment

In accordance with Executive Order 12630, this rule, authorized by the Migratory Bird Treaty Act, does not have significant takings implications and does not affect any constitutionally protected property rights. This rule will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. In fact, these rules allow hunters to exercise otherwise unavailable privileges and, therefore, reduce restrictions on the use of private and public property.

Energy Effects—Executive Order 13211

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. While this rule is a significant regulatory action under Executive Order 12866, it is not expected to adversely affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

Government-to-Government Relationship with Tribes

Due to the migratory nature of certain species of birds, the Federal Government has been given responsibility over these species by the Migratory Bird Treaty Act. Thus, in accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated possible effects on Federally recognized Indian tribes and have determined that there are no effects on Indian trust resources. However, in the April 11 proposed rule we solicited proposals for special migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands for the 2006–07 migratory bird hunting season. The resulting proposals will be contained in a separate proposed rule. By virtue of these actions, we have consulted with all the Tribes affected by this rule.

Federalism Effects

Due to the migratory nature of certain species of birds, the Federal Government has been given responsibility over these species by the Migratory Bird Treaty Act. We annually prescribe frameworks from which the States make selections regarding the hunting of migratory birds, and we employ guidelines to establish special regulations on Federal Indian reservations and ceded lands. This process preserves the ability of the States and tribes to determine which

seasons meet their individual needs. Any State or tribe may be more restrictive than the Federal frameworks at any time. The frameworks are developed in a cooperative process with the States and the Flyway Councils. This process allows States to participate in the development of frameworks from which they will make selections, thereby having an influence on their own regulations. These rules do not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. Therefore, in accordance with Executive Order 13132, these regulations do not have significant federalism effects and do not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulations Promulgation

The rulemaking process for migratory game bird hunting must, by its nature, operate under severe time constraints. However, we intend that the public be given the greatest possible opportunity to comment. Thus, when the preliminary proposed rulemaking was published, we established what we believed were the longest periods possible for public comment. In doing this, we recognized that when the comment period closed, time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, States would have insufficient time to select season dates and limits; to communicate those selections to us; and to establish and publicize the necessary regulations and procedures to implement their decisions. We therefore find that ''good cause'' exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, and these frameworks will, therefore, take effect immediately upon publication. Therefore, under authority of the Migratory Bird Treaty Act (July 3, 1918), as amended (16 U.S.C. 703–711), we prescribe final frameworks setting forth the species to be hunted, the daily bag and possession limits, the shooting hours, the season lengths, the earliest opening and latest closing season dates, and hunting areas, from which State conservation agency officials will select hunting season dates and other options. Upon receipt of season selections from these officials, we will publish a final rulemaking amending 50 CFR part 20 to reflect seasons, limits, and shooting hours for the conterminous United States for the 2006–07 season.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

The rules that eventually will be promulgated for the 2006–07 hunting season are authorized under 16 U.S.C. 703–712 and 16 U.S.C. 742 a–j.

Dated: August 11, 2006.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

Final Regulations Frameworks for 2006–07 Early Hunting Seasons on Certain Migratory Game Birds

Pursuant to the Migratory Bird Treaty Act and delegated authorities, the Department of the Interior approved the following frameworks, which prescribe season lengths, bag limits, shooting hours, and outside dates within which States may select hunting seasons for certain migratory game birds between September 1, 2006, and March 10, 2007.

General

Dates: All outside dates noted below are inclusive.

Shooting and Hawking (taking by falconry) Hours: Unless otherwise specified, from one-half hour before sunrise to sunset daily.

Possession Limits: Unless otherwise specified, possession limits are twice the daily bag limit.

Flyways and Management Units

Waterfowl Flyways

Atlantic Flyway—includes Connecticut, Delaware, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, and West Virginia.

Mississippi Flyway—includes Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Tennessee, and Wisconsin.

Central Flyway—includes Colorado (east of the Continental Divide), Kansas, Montana (Counties of Blaine, Carbon, Fergus, Judith Basin, Stillwater, Sweetgrass, Wheatland, and all counties east thereof), Nebraska, New Mexico (east of the Continental Divide except the Jicarilla Apache Indian Reservation), North Dakota, Oklahoma, South Dakota, Texas, and Wyoming (east of the Continental Divide).

Pacific Flyway—includes Alaska, Arizona, California, Idaho, Nevada, Oregon, Utah, Washington, and those portions of Colorado, Montana, New Mexico, and Wyoming not included in the Central Flyway.

Management Units

Mourning Dove Management Units

Eastern Management Unit—All States east of the Mississippi River, and Louisiana.

Central Management Unit—Arkansas, Colorado, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.

Western Management Unit—Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington.

Woodcock Management Regions

Eastern Management Region—Connecticut, Delaware, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, and West Virginia.

Central Management Region—Alabama, Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Tennessee, Texas, and Wisconsin.

Other geographic descriptions are contained in a later portion of this document.

Compensatory Days in the Atlantic Flyway: In the Atlantic Flyway States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Jersey, North Carolina, Pennsylvania, and Virginia, where Sunday hunting is prohibited statewide by State law, all Sundays are closed to all take of migratory waterfowl (including mergansers and coots).

Special September Teal Season

Outside Dates: Between September 1 and September 30, an open season on all species of teal may be selected by the following States in areas delineated by State regulations:

Atlantic Flyway—Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, and Virginia.

Mississippi Flyway—Alabama, Arkansas, Illinois, Indiana, Kentucky, Louisiana, Mississippi, Missouri, Ohio, and Tennessee.

Central Flyway—Colorado (part), Kansas, Nebraska (part), New Mexico (part), Oklahoma, and Texas.

Hunting Seasons and Daily Bag Limits: Not to exceed 9 consecutive days in the Atlantic Flyway and 16 consecutive days in the Mississippi and Central Flyways. The daily bag limit is 4 teal.

Shooting Hours

Atlantic Flyway—One-half hour before sunrise to sunset except in Maryland, where the hours are from sunrise to sunset.

Mississippi and Central Flyways—One-half hour before sunrise to sunset, except in the States of Arkansas, Illinois, Indiana, Missouri, and Ohio, where the hours are from sunrise to sunset.

Special September Duck Seasons

Florida, Kentucky and Tennessee: In lieu of a special September teal season, a 5-consecutive-day season may be selected in September. The daily bag limit may not exceed 4 teal and wood ducks in the aggregate, of which no more than 2 may be wood ducks.

Iowa: Iowa may hold up to 5 days of its regular duck hunting season in September. All ducks that are legal during the regular duck season may be taken during the September segment of the season. The September season segment may commence no earlier than the Saturday nearest September 20 (September 23). The daily bag and possession limits will be the same as those in effect last year, but are subject to change during the late-season regulations process. The remainder of the regular duck season may not begin before October 10.

Special Youth Waterfowl Hunting Days

Outside Dates: States may select two consecutive days (hunting days in Atlantic Flyway States with compensatory days) per duck-hunting zone, designated as ''Youth Waterfowl Hunting Days,'' in addition to their regular duck seasons. The days must be held outside any regular duck season on a weekend, holidays, or other non-school days when youth hunters would have the maximum opportunity to participate. The days may be held up to 14 days before or after any regular duck-season frameworks or within any split of a regular duck season, or within any other open season on migratory birds.

Daily Bag Limits: The daily bag limits may include ducks, geese, mergansers, coots, moorhens, and gallinules and would be the same as those allowed in the regular season. Flyway species and area restrictions would remain in effect.

Shooting Hours: One-half hour before sunrise to sunset.

Participation Restrictions: Youth hunters must be 15 years of age or younger. In addition, an adult at least 18 years of age must accompany the youth hunter into the field. This adult may not duck hunt but may participate in other seasons that are open on the special youth day.

Scoter, Eider, and Oldsquaw Ducks (Atlantic Flyway)

Outside Dates: Between September 15 and January 31.

Hunting Seasons and Daily Bag Limits: Not to exceed 107 days, with a daily bag limit of 7, singly or in the aggregate, of the listed sea-duck species, of which no more than 4 may be scoters.

Daily Bag Limits During the Regular Duck Season: Within the special sea duck areas, during the regular duck season in the Atlantic Flyway, States may choose to allow the above sea duck limits in addition to the limits applying to other ducks during the regular duck season. In all other areas, sea ducks may be taken only during the regular open season for ducks and are part of the regular duck season daily bag (not to exceed 4 scoters) and possession limits.

Areas: In all coastal waters and all waters of rivers and streams seaward from the first upstream bridge in Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, and New York; in any waters of the Atlantic Ocean and in any tidal waters of any bay which are separated by at least 1 mile of open water from any shore, island, and emergent vegetation in New Jersey, South Carolina, and Georgia; and in any waters of the Atlantic Ocean and in any tidal waters of any bay which are separated by at least 800 yards of open water from any shore, island, and emergent vegetation in Delaware, Maryland, North Carolina, and Virginia; and provided that any such areas have been described, delineated, and designated as special sea-duck hunting areas under the hunting regulations adopted by the respective States.

Special Early Canada Goose Seasons

Atlantic Flyway

General Seasons

Canada goose seasons of up to 15 days during September 1–15 may be selected for the Eastern Unit of Maryland and Delaware. Seasons not to exceed 30 days during September 1–30 may be selected for Connecticut, the Northeast Hunt Unit of North Carolina, New Jersey, and Rhode Island. Except for experimental seasons described below, seasons may not exceed 25 days during September 1–25 in the remainder of the Flyway. Areas open to the hunting of Canada geese must be described, delineated, and designated as such in each State's hunting regulations.

Daily Bag Limits: Not to exceed 15 Canada geese.

Experimental Seasons

Experimental Canada goose seasons of up to 25 days during September 1–25 may be selected for the Montezuma Region of New York and the Lake Champlain Region of New York and Vermont. Experimental seasons of up to 30 days during September 1–30 may be selected by Florida, Georgia, New York (Long Island Zone), North Carolina (except in the Northeast Hunt Unit), and South Carolina. Areas open to the hunting of Canada geese must be described, delineated, and designated as such in each State's hunting regulations.

Daily Bag Limits: Not to exceed 15 Canada geese.

Mississippi Flyway

General Seasons

Canada goose seasons of up to 15 days during September 1–15 may be selected, except in the Upper Peninsula in Michigan, where the season may not extend beyond September 10, and in Minnesota (except in the Northwest Goose Zone), where a season of up to 22 days during September 1–22 may be selected. The daily bag limit may not exceed 5 Canada geese. Areas open to the hunting of Canada geese must be described, delineated, and designated as such in each State's hunting regulations.

A Canada goose season of up to 10 consecutive days during September 1–10 may be selected by Michigan for Huron, Saginaw, and Tuscola Counties, except that the Shiawassee National Wildlife Refuge, Shiawassee River State Game Area Refuge, and the Fish Point Wildlife Area Refuge will remain closed. The daily bag limit may not exceed 5 Canada geese.

Central Flyway

General Seasons

In Kansas, Nebraska, Oklahoma, South Dakota, and Texas, Canada goose seasons of up to 30 days during September 1–30 may be selected. In Colorado, New Mexico, North Dakota, Montana, and Wyoming, Canada goose seasons of up to 15 days during September 1–15 may be selected. The daily bag limit may not exceed 5 Canada geese. Areas open to the hunting of Canada geese must be described, delineated, and designated as such in each State's hunting regulations.

Pacific Flyway

General Seasons

California may select a 9-day season in Humboldt County during the period September 1–15. The daily bag limit is 2.

Colorado may select a 9-day season during the period of September 1–15. The daily bag limit is 3.

Oregon may select a special Canada goose season of up to 15 days during the

period September 1–15. In addition, in the NW goose management zone in Oregon, a 15-day season may be selected during the period September 1–20. Daily bag limits may not exceed 5 Canada geese.

Idaho may select a 7-day season during the period September 1–15. The daily bag limit is 2 and the possession limit is 4.

Washington may select a special Canada goose season of up to 15 days during the period September 1–15. Daily bag limits may not exceed 5 Canada geese.

Wyoming may select an 8-day season on Canada geese between September 1–15. This season is subject to the following conditions:

1. Where applicable, the season must be concurrent with the September portion of the sandhill crane season.

2. A daily bag limit of 2, with season and possession limits of 4, will apply to the special season.

Areas open to hunting of Canada geese in each State must be described, delineated, and designated as such in each State's hunting regulations.

Regular Goose Seasons

Regular goose seasons may open as early as September 16 in Wisconsin and Michigan. Season lengths, bag and possession limits, and other provisions will be established during the late-season regulations process.

Sandhill Cranes

Regular Seasons in the Central Flyway

Outside Dates: Between September 1 and February 28.

Hunting Seasons: Seasons not to exceed 37 consecutive days may be selected in designated portions of North Dakota (Area 2) and Texas (Area 2). Seasons not to exceed 58 consecutive days may be selected in designated portions of the following States: Colorado, Kansas, Montana, North Dakota, South Dakota, and Wyoming. Seasons not to exceed 93 consecutive days may be selected in designated portions of the following States: New Mexico, Oklahoma, and Texas.

Daily Bag Limits: 3 sandhill cranes, except 2 sandhill cranes in designated portions of North Dakota (Area 2) and Texas (Area 2).

Permits: Each person participating in the regular sandhill crane seasons must have a valid Federal sandhill crane hunting permit and/or, in those States where a Federal sandhill crane permit is not issued, a State-issued Harvest Information Survey Program (HIP) certification for game bird hunting in their possession while hunting.

Special Seasons in the Central and Pacific Flyways

Arizona, Colorado, Idaho, Montana, New Mexico, Utah, and Wyoming may select seasons for hunting sandhill cranes within the range of the Rocky Mountain Population (RMP) subject to the following conditions:

Outside Dates: Between September 1 and January 31.

Hunting Seasons: The season in any State or zone may not exceed 30 days.

Bag limits: Not to exceed 3 daily and 9 per season.

Permits: Participants must have a valid permit, issued by the appropriate State, in their possession while hunting.

Other provisions: Numbers of permits, open areas, season dates, protection plans for other species, and other provisions of seasons must be consistent with the management plan and approved by the Central and Pacific Flyway Councils with the following exceptions:

1. In Utah, the requirement for monitoring the racial composition of the harvest in the experimental season is waived, and 100 percent of the harvest will be assigned to the RMP quota;

2. In Arizona, monitoring the racial composition of the harvest must be conducted at 3 year intervals;

3. In Idaho, seasons are experimental, and the requirement for monitoring the racial composition of the harvest is waived; 100 percent of the harvest will be assigned to the RMP quota; and

4. In New Mexico, the season in the Estancia Valley is experimental, with a requirement to monitor the level and racial composition of the harvest; greater sandhill cranes in the harvest will be assigned to the RMP quota.

Common Moorhens and Purple Gallinules

Outside Dates: Between September 1 and the last Sunday in January (January 28) in the Atlantic, Mississippi and Central Flyways. States in the Pacific Flyway have been allowed to select their hunting seasons between the outside dates for the season on ducks; therefore, they are late-season frameworks, and no frameworks are provided in this document.

Hunting Seasons and Daily Bag Limits: Seasons may not exceed 70 days in the Atlantic, Mississippi, and Central Flyways. Seasons may be split into 2 segments. The daily bag limit is 15 common moorhens and purple gallinules, singly or in the aggregate of the two species.

Zoning: Seasons may be selected by zones established for duck hunting.

Rails

Outside Dates: States included herein may select seasons between September 1 and the last Sunday in January (January 28) on clapper, king, sora, and Virginia rails.

Hunting Seasons: The season may not exceed 70 days, and may be split into 2 segments.

Daily Bag Limits: Clapper and King Rails—In Rhode Island, Connecticut, New Jersey, Delaware, and Maryland, 10, singly or in the aggregate of the two species. In Texas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina, and Virginia, 15, singly or in the aggregate of the two species.

Sora and Virginia Rails—In the Atlantic, Mississippi, and Central Flyways and the Pacific-Flyway portions of Colorado, Montana, New Mexico, and Wyoming, 25 daily and 25 in possession, singly or in the aggregate of the two species. The season is closed in the remainder of the Pacific Flyway.

Common Snipe

Outside Dates: Between September 1 and February 28, except in Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland, and Virginia, where the season must end no later than January 31.

Hunting Seasons and Daily Bag Limits: Seasons may not exceed 107 days and may be split into two segments. The daily bag limit is 8 snipe.

Zoning: Seasons may be selected by zones established for duck hunting.

American Woodcock

Outside Dates: States in the Eastern Management Region may select hunting seasons between October 1 and January 31. States in the Central Management Region may select hunting seasons between the Saturday nearest September 22 (September 23) and January 31.

Hunting Seasons and Daily Bag Limits: Seasons may not exceed 30 days in the Eastern Region and 45 days in the Central Region. The daily bag limit is 3. Seasons may be split into two segments.

Zoning: New Jersey may select seasons in each of two zones. The season in each zone may not exceed 24 days.

Band-Tailed Pigeons

Pacific Coast States (California, Oregon, Washington, and Nevada)

Outside Dates: Between September 15 and January 1.

Hunting Seasons and Daily Bag Limits: Not more than 9 consecutive

days, with a daily bag limit of 2 band-tailed pigeons.

Zoning: California may select hunting seasons not to exceed 9 consecutive days in each of two zones. The season in the North Zone must close by October 3.

Four-Corners States (Arizona, Colorado, New Mexico, and Utah)

Outside Dates: Between September 1 and November 30.

Hunting Seasons and Daily Bag Limits: Not more than 30 consecutive days, with a daily bag limit of 5 band-tailed pigeons.

Zoning: New Mexico may select hunting seasons not to exceed 20 consecutive days in each of two zones. The season in the South Zone may not open until October 1.

Mourning Doves

Outside Dates: Between September 1 and January 15, except as otherwise provided, States may select hunting seasons and daily bag limits as follows:

Eastern Management Unit

Hunting Seasons and Daily Bag Limits: Not more than 70 days with a daily bag limit of 12 mourning and white-winged doves in the aggregate, or not more than 60 days with a bag limit of 15 mourning and white-winged doves in the aggregate.

Zoning and Split Seasons: States may select hunting seasons in each of two zones. The season within each zone may be split into not more than three periods. Regulations for bag and possession limits, season length, and shooting hours must be uniform within specific hunting zones.

Central Management Unit

Hunting Seasons and Daily Bag Limits: Not more than 70 days with a daily bag limit of 12 mourning and white-winged doves in the aggregate, or not more than 60 days with a bag limit of 15 mourning and white-winged doves in the aggregate.

Zoning and Split Seasons

States may select hunting seasons in each of two zones. The season within each zone may be split into not more than three periods.

Texas may select hunting seasons for each of three zones subject to the following conditions:

A. The hunting season may be split into not more than two periods, except in that portion of Texas in which the special white-winged dove season is allowed, where a limited mourning dove season may be held concurrently with that special season (see white-winged dove frameworks).

B. A season may be selected for the North and Central Zones between September 1 and January 25; and for the South Zone between September 20 and January 25.

C. Daily bag limits are aggregate bag limits with mourning, white-winged, and white-tipped doves (see white-winged dove frameworks for specific daily bag limit restrictions).

D. Except as noted above, regulations for bag and possession limits, season length, and shooting hours must be uniform within each hunting zone.

Western Management Unit

Hunting Seasons and Daily Bag Limits:

Idaho, Oregon, and Washington—Not more than 30 consecutive days with a daily bag limit of 10 mourning doves.

Utah—Not more than 30 consecutive days with a daily bag limit that may not exceed 10 mourning doves and white-winged doves in the aggregate.

Nevada—Not more than 30 consecutive days with a daily bag limit of 10 mourning doves, except in Clark and Nye Counties, where the daily bag limit may not exceed 10 mourning and white-winged doves in the aggregate.

Arizona and California—Not more than 60 days, which may be split between two periods, September 1–15 and November 1–January 15. In Arizona, during the first segment of the season, the daily bag limit is 10 mourning and white-winged doves in the aggregate, of which no more than 6 may be white-winged doves. During the remainder of the season, the daily bag limit is 10 mourning doves. In California, the daily bag limit is 10 mourning doves, except in Imperial, Riverside, and San Bernardino Counties, where the daily bag limit may not exceed 10 mourning and white-winged doves in the aggregate.

White-Winged and White-Tipped Doves

Hunting Seasons and Daily Bag Limits: Except as shown below, seasons must be concurrent with mourning dove seasons.

Eastern Management Unit: The daily bag limit may not exceed 12 (15 under the alternative) mourning and white-winged doves in the aggregate.

Central Management Unit: In Texas, the daily bag limit may not exceed 12 mourning, white-winged, and white-tipped doves (15 under the alternative) in the aggregate, of which no more than 2 may be white-tipped doves. In addition, Texas also may select a hunting season of not more than 4 days for the special white-winged dove area of the South Zone between September 1 and September 19. The daily bag limit may not exceed 12 white-winged, mourning, and white-tipped doves in the aggregate, of which no more than 4 may be mourning doves and 2 may be white-tipped doves.

In the remainder of the Central Management Unit, the daily bag limit may not exceed 12 (15 under the alternative) mourning and white-winged doves in the aggregate.

Western Management Unit: Arizona may select a hunting season of not more than 30 consecutive days, running concurrently with the first segment of the mourning dove season. The daily bag limit may not exceed 10 mourning and white-winged doves in the aggregate, of which no more than 6 may be white-winged doves.

In Utah, the Nevada Counties of Clark and Nye, and in the California Counties of Imperial, Riverside, and San Bernardino, the daily bag limit may not exceed 10 mourning and white-winged doves in the aggregate.

In the remainder of the Western Management Unit, the season is closed.

Alaska

Outside Dates: Between September 1 and January 26.

Hunting Seasons: Alaska may select 107 consecutive days for waterfowl, sandhill cranes, and common snipe in each of 5 zones. The season may be split without penalty in the Kodiak Zone. The seasons in each zone must be concurrent.

Closures: The hunting season is closed on emperor geese, spectacled eiders, and Steller's eiders.

Daily Bag and Possession Limits

Ducks—Except as noted, a basic daily bag limit of 7 and a possession limit of 21 ducks. Daily bag and possession limits in the North Zone are 10 and 30, and in the Gulf Coast Zone, they are 8 and 24. The basic limits may include no more than 1 canvasback daily and 3 in possession and may not include sea ducks.

In addition to the basic duck limits, Alaska may select sea duck limits of 10 daily, 20 in possession, singly or in the aggregate, including no more than 6 each of either harlequin or long-tailed ducks. Sea ducks include scoters, common and king eiders, harlequin ducks, long-tailed ducks, and common and red-breasted mergansers.

Light Geese—A basic daily bag limit of 4 and a possession limit of 8.

Dark Geese—A basic daily bag limit of 4 and a possession limit of 8.

Dark-goose seasons are subject to the following exceptions:

1. In Units 5 and 6, the taking of Canada geese is permitted from

September 28 through December 16. A special, permit-only Canada goose season may be offered on Middleton Island. No more than 10 permits can be issued. A mandatory goose identification class is required. Hunters must check in and check out. The bag limit is 1 daily and 1 in possession. The season will close if incidental harvest includes 5 dusky Canada geese. A dusky Canada goose is any dark-breasted Canada goose (Munsell 10 YR color value five or less) with a bill length between 40 and 50 millimeters.

2. In Unit 9(D) and the Unimak Island portion of Unit 10, the limits for dark geese are 6 daily and 12 in possession.

3. In Units 9(E) and 18, the limit for dark geese is 4 daily, including no more than 2 Canada geese.

4. In Unit 9, season length for brant is 107 days.

Brant—A daily bag limit of 2.

Common snipe—A daily bag limit of 8.

Sandhill cranes—Bag and possession limits of 2 and 4, respectively, in the Southeast, Gulf Coast, Kodiak, and Aleutian Zones, and Unit 17 in the Northern Zone. In the remainder of the Northern Zone (outside Unit 17), bag and possession limits of 3 and 6, respectively.

Tundra Swans—Open seasons for tundra swans may be selected subject to the following conditions:

1. All seasons are by registration permit only.

2. All season framework dates are September 1–October 31.

3. In Game Management Unit (GMU) 17, no more than 200 permits may be issued during this operational season. No more than 3 tundra swans may be authorized per permit with no more than 1 permit issued per hunter per season.

4. In Game Management Unit (GMU) 18, no more than 500 permits may be issued during the operational season. Up to 3 tundra swans may be authorized per permit. No more than 1 permit may be issued per hunter per season.

5. In GMU 22, no more than 300 permits may be issued during the operational season. Each permittee may be authorized to take up to 3 tundra swan per permit. No more than 1 permit may be issued per hunter per season.

6. In GMU 23, no more than 300 permits may be issued during the operational season. No more than 3 tundra swans may be authorized per permit with no more than 1 permit issued per hunter per season.

Hawaii

Outside Dates: Between October 1 and January 31.

Hunting Seasons: Not more than 65 days (75 under the alternative) for mourning doves.

Bag Limits: Not to exceed 15 (12 under the alternative) mourning doves.

Note: Mourning doves may be taken in Hawaii in accordance with shooting hours and other regulations set by the State of Hawaii, and subject to the applicable provisions of 50 CFR part 20.

Puerto Rico

Doves and Pigeons

Outside Dates: Between September 1 and January 15.

Hunting Seasons: Not more than 60 days.

Daily Bag and Possession Limits: Not to exceed 15 Zenaida, mourning, and white-winged doves in the aggregate, of which not more than 3 may be mourning doves. Not to exceed 5 scaly-naped pigeons.

Closed Areas: There is no open season on doves or pigeons in the following areas: Municipality of Culebra, Desecheo Island, Mona Island, El Verde Closure Area, and Cidra Municipality and adjacent areas.

Ducks, Coots, Moorhens, Gallinules, and Snipe

Outside Dates: Between October 1 and January 31.

Hunting Seasons: Not more than 55 days may be selected for hunting ducks, common moorhens, and common snipe. The season may be split into two segments.

Daily Bag Limits:

Ducks—Not to exceed 6.

Common moorhens—Not to exceed 6.

Common snipe—Not to exceed 8.

Closed Seasons: The season is closed on the ruddy duck, white-cheeked pintail, West Indian whistling duck, fulvous whistling duck, and masked duck, which are protected by the Commonwealth of Puerto Rico. The season also is closed on the purple gallinule, American coot, and Caribbean coot.

Closed Areas: There is no open season on ducks, common moorhens, and common snipe in the Municipality of Culebra and on Desecheo Island.

Virgin Islands

Doves and Pigeons

Outside Dates: Between September 1 and January 15.

Hunting Seasons: Not more than 60 days for Zenaida doves.

Daily Bag and Possession Limits: Not to exceed 10 Zenaida doves.

Closed Seasons: No open season is prescribed for ground or quail doves, or pigeons in the Virgin Islands.

Closed Areas: There is no open season for migratory game birds on Ruth Cay (just south of St. Croix).

Local Names for Certain Birds: Zenaida dove, also known as mountain dove; bridled quail-dove, also known as Barbary dove or partridge; Common ground-dove, also known as stone dove, tobacco dove, rola, or tortolita; scaly-naped pigeon, also known as red-necked or scaled pigeon.

Ducks

Outside Dates: Between December 1 and January 31.

Hunting Seasons: Not more than 55 consecutive days.

Daily Bag Limits: Not to exceed 6.

Closed Seasons: The season is closed on the ruddy duck, white-cheeked pintail, West Indian whistling duck, fulvous whistling duck, and masked duck.

Special Falconry Regulations

Falconry is a permitted means of taking migratory game birds in any State meeting Federal falconry standards in 50 CFR 21.29(k). These States may select an extended season for taking migratory game birds in accordance with the following:

Extended Seasons: For all hunting methods combined, the combined length of the extended season, regular season, and any special or experimental seasons must not exceed 107 days for any species or group of species in a geographical area. Each extended season may be divided into a maximum of 3 segments.

Framework Dates: Seasons must fall between September 1 and March 10.

Daily Bag and Possession Limits: Falconry daily bag and possession limits for all permitted migratory game birds must not exceed 3 and 6 birds, respectively, singly or in the aggregate, during extended falconry seasons, any special or experimental seasons, and regular hunting seasons in all States, including those that do not select an extended falconry season.

Regular Seasons: General hunting regulations, including seasons and hunting hours, apply to falconry in each State listed in 50 CFR 21.29(k). Regular-season bag and possession limits do not apply to falconry. The falconry bag limit is not in addition to gun limits.

Area, Unit, and Zone Descriptions

Mourning and White-winged Doves

Alabama

South Zone—Baldwin, Barbour, Coffee, Covington, Dale, Escambia, Geneva, Henry, Houston, and Mobile Counties.

North Zone—Remainder of the State.

California

White-winged Dove Open Areas—Imperial, Riverside, and San Bernardino Counties.

Florida

Northwest Zone—The Counties of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Liberty, Okaloosa, Santa Rosa, Walton, Washington, Leon (except that portion north of U.S. 27 and east of State Road 155), Jefferson (south of U.S. 27, west of State Road 59 and north of U.S. 98), and Wakulla (except that portion south of U.S. 98 and east of the St. Marks River).

South Zone—Remainder of State.

Louisiana

North Zone—That portion of the State north of Interstate Highway 10 from the Texas State line to Baton Rouge, Interstate Highway 12 from Baton Rouge to Slidell and Interstate Highway 10 from Slidell to the Mississippi State line.

South Zone—The remainder of the State.

Mississippi

North Zone—That portion of the State north and west of a line extending west from the Alabama State line along U.S. Highway 84 to its junction with State Highway 35, then south along State Highway 35 to the Louisiana State line.

South Zone—The remainder of Mississippi.

Nevada

White-winged Dove Open Areas—Clark and Nye Counties.

Texas

North Zone—That portion of the State north of a line beginning at the International Bridge south of Fort Hancock; north along FM 1088 to TX 20; west along TX 20 to TX 148; north along TX 148 to I–10 at Fort Hancock; east along I–10 to I–20; northeast along I–20 to I–30 at Fort Worth; northeast along I–30 to the Texas-Arkansas State line.

South Zone—That portion of the State south and west of a line beginning at the International Bridge south of Del Rio, proceeding east on U.S. 90 to State Loop 1604 west of San Antonio; then south, east, and north along Loop 1604 to Interstate Highway 10 east of San Antonio; then east on I–10 to Orange, Texas.

Special White-winged Dove Area in the South Zone—That portion of the State south and west of a line beginning at the International Bridge south of Del Rio, proceeding east on U.S. 90 to State Loop 1604 west of San Antonio, southeast on State Loop 1604 to Interstate Highway 35, southwest on Interstate Highway 35 to TX 44; east along TX 44 to TX 16 at Freer; south along TX 16 to TX 285 at Hebbronville; east along TX 285 to FM 1017; southwest along FM 1017 to TX 186 at Linn; east along TX 186 to the Mansfield Channel at Port Mansfield; east along the Mansfield Channel to the Gulf of Mexico.

Area with additional restrictions—Cameron, Hidalgo, Starr, and Willacy Counties.

Central Zone—That portion of the State lying between the North and South Zones.

Band-tailed Pigeons

California

North Zone—Alpine, Butte, Del Norte, Glenn, Humboldt, Lassen, Mendocino, Modoc, Plumas, Shasta, Sierra, Siskiyou, Tehama, and Trinity Counties.

South Zone—The remainder of the State.

New Mexico

North Zone—North of a line following U.S. 60 from the Arizona State line east to I–25 at Socorro and then south along I–25 from Socorro to the Texas State line.

South Zone—Remainder of the State.

Washington

Western Washington—The State of Washington excluding those portions lying east of the Pacific Crest Trail and east of the Big White Salmon River in Klickitat County.

Woodcock

New Jersey

North Zone—That portion of the State north of NJ 70.

South Zone—The remainder of the State.

Special September Canada Goose Seasons

Atlantic Flyway

Connecticut

North Zone—That portion of the State north of I–95.

South Zone—Remainder of the State.

Maryland

Eastern Unit—Anne Arundel, Calvert, Caroline, Cecil, Charles, Dorchester, Harford, Kent, Queen Anne's, St. Mary's, Somerset, Talbot, Wicomico, and Worcester Counties; that portion of Prince George's, Howard, and Baltimore Counties east of Interstate 95.

Western Unit—Allegany, Carroll, Frederick, Garrett, Montgomery, and Washington Counties; that portion of Prince George's, Howard, and Baltimore Counties west of Interstate 95.

Massachusetts

Western Zone—That portion of the State west of a line extending south from the Vermont border on I–91 to MA 9, west on MA 9 to MA 10, south on MA 10 to U.S. 202, south on U.S. 202 to the Connecticut border.

Central Zone—That portion of the State east of the Berkshire Zone and west of a line extending south from the New Hampshire border on I–95 to U.S. 1, south on U.S. 1 to I–93, south on I–93 to MA 3, south on MA 3 to U.S. 6, west on U.S. 6 to MA 28, west on MA 28 to I–195, west to the Rhode Island border; except the waters, and the lands 150 yards inland from the high-water mark, of the Assonet River upstream to the MA 24 bridge, and the Taunton River upstream to the Center St.-Elm St. bridge will be in the Coastal Zone.

Coastal Zone—That portion of Massachusetts east and south of the Central Zone.

New York

Lake Champlain Zone—The U.S. portion of Lake Champlain and that area east and north of a line extending along NY 9B from the Canadian border to U.S. 9, south along U.S. 9 to NY 22 south of Keesville; south along NY 22 to the west shore of South Bay, along and around the shoreline of South Bay to NY 22 on the east shore of South Bay; southeast along NY 22 to U.S. 4, northeast along U.S. 4 to the Vermont border.

Long Island Zone—That area consisting of Nassau County, Suffolk County, that area of Westchester County southeast of I–95, and their tidal waters.

Western Zone—That area west of a line extending from Lake Ontario east along the north shore of the Salmon River to I–81, and south along I–81 to the Pennsylvania border, except for the Montezuma Zone.

Montezuma Zone—Those portions of Cayuga, Seneca, Ontario, Wayne, and Oswego Counties north of U.S. Route 20, east of NYS Route 14, south of NYS Route 104, and west of NYS Route 34.

Northeastern Zone—That area north of a line extending from Lake Ontario east along the north shore of the Salmon River to I–81, south along I–81 to NY 49, east along NY 49 to NY 365, east along NY 365 to NY 28, east along NY 28 to NY 29, east along NY 29 to I–87, north along I–87 to U.S. 9 (at Exit 20), north along U.S. 9 to NY 149, east along NY 149 to U.S. 4, north along U.S. 4 to the Vermont border, exclusive of the Lake Champlain Zone.

Southeastern Zone—The remaining portion of New York.

North Carolina

Northeast Hunt Unit—Camden, Chowan, Currituck, Dare, Hyde, Pasquotank, Perquimans, Tyrrell, and Washington Counties; that portion of Bertie County north and east of a line formed by NC 45 at the Washington County line to U.S. 17 in Midway, U.S. 17 in Midway to U.S. 13 in Windsor to the Hertford County line; and that portion of Northampton County that is north of U.S. 158 and east of NC 35.

Vermont

Lake Champlain Zone: The U.S. portion of Lake Champlain and that area north and west of the line extending from the New York border along U.S. 4 to VT 22A at Fair Haven; VT 22A to U.S. 7 at Vergennes; U.S. 7 to the Canadian border.

Interior Zone: That portion of Vermont west of the Lake Champlain Zone and eastward of a line extending from the Massachusetts border at Interstate 91; north along Interstate 91 to U.S. 2; east along U.S. 2 to VT 102; north along VT 102 to VT 253; north along VT 253 to the Canadian border.

Connecticut River Zone: The remaining portion of Vermont east of the Interior Zone.

Mississippi Flyway

Illinois

Northeast Canada Goose Zone—Cook, Du Page, Grundy, Kane, Kankakee, Kendall, Lake, McHenry, and Will Counties.

North Zone: That portion of the state outside the Northeast Canada Goose Zone and north of a line extending west from the Indiana border along Peotone-Beecher Road to Illinois Route 50, south along Illinois Route 50 to Wilmington-Peotone Road, west along Wilmington-Peotone Road to Illinois Route 53, north along Illinois Route 53 to New River Road, northwest along New River Road to Interstate Highway 55, south along I–55 to Pine Bluff—Lorenzo Road, west along Pine Bluff—Lorenzo Road to Illinois Route 47, north along Illinois Route 47 to I–80, west along I–80 to I–39, south along I–39 to Illinois Route 18, west along Illinois Route 18 to Illinois Route 29, south along Illinois Route 29 to Illinois Route 17, west along Illinois Route 17 to the Mississippi River, and due south across the Mississippi River to the Iowa border.

Central Zone: That portion of the state outside the Northeast Canada Goose Zone and south of the North Zone to a line extending west from the Indiana border along Interstate Highway 70 to Illinois Route 4, south along Illinois Route 4 to Illinois Route 161, west along Illinois Route 161 to Illinois Route 158, south and west along Illinois Route 158 to Illinois Route 159, south along Illinois Route 159 to Illinois Route 156, west along Illinois Route 156 to A Road, north and west on A Road to Levee Road, north on Levee Road to the south shore of New Fountain Creek, west along the south shore of New Fountain Creek to the Mississippi River, and due west across the Mississippi River to the Missouri border.

South Zone: The remainder of Illinois.

Iowa

North Zone: That portion of the State north of U.S. Highway 20.

South Zone: The remainder of Iowa.

Cedar Rapids/Iowa City Goose Zone. Includes portions of Linn and Johnson Counties bounded as follows: Beginning at the intersection of the west border of Linn County and Linn County Road E2W; thence south and east along County Road E2W to Highway 920; thence north along Highway 920 to County Road E16; thence east along County Road E16 to County Road W58; thence south along County Road W58 to County Road E34; thence east along County Road E34 to Highway 13; thence south along Highway 13 to Highway 30; thence east along Highway 30 to Highway 1; thence south along Highway 1 to Morse Road in Johnson County; thence east along Morse Road to Wapsi Avenue; thence south along Wapsi Avenue to Lower West Branch Road; thence west along Lower West Branch Road to Taft Avenue; thence south along Taft Avenue to County Road F62; thence west along County Road F62 to Kansas Avenue; thence north along Kansas Avenue to Black Diamond Road; thence west on Black Diamond Road to Jasper Avenue; thence north along Jasper Avenue to Rohert Road; thence west along Rohert Road to Ivy Avenue; thence north along Ivy Avenue to 340th Street; thence west along 340th Street to Half Moon Avenue; thence north along Half Moon Avenue to Highway 6; thence west along Highway 6 to Echo Avenue; thence north along Echo Avenue to 250th Street; thence east on 250th Street to Green Castle Avenue; thence north along Green Castle Avenue to County Road F12; thence west along County Road F12 to County Road W30; thence north along County Road W30 to Highway 151; thence north along the Linn-Benton County line to the point of beginning.

Des Moines Goose Zone. Includes those portions of Polk, Warren, Madison and Dallas Counties bounded as follows: Beginning at the intersection of Northwest 158th Avenue and County Road R38 in Polk County; thence south along R38 to Northwest 142nd Avenue; thence east along Northwest 142nd Avenue to Northeast 126th Avenue; thence east along Northeast 126th Avenue to Northeast 46th Street; thence south along Northeast 46th Street to Highway 931; thence east along Highway 931 to Northeast 80th Street; thence south along Northeast 80th Street to Southeast 6th Avenue; thence west along Southeast 6th Avenue to Highway 65; thence south and west along Highway 65 to Highway 69 in Warren County; thence south along Highway 69 to County Road G24; thence west along County Road G24 to Highway 28; thence southwest along Highway 28 to 43rd Avenue; thence north along 43rd Avenue to Ford Street; thence west along Ford Street to Filmore Street; thence west along Filmore Street to 10th Avenue; thence south along 10th Avenue to 155th Street in Madison County; thence west along 155th Street to Cumming Road; thence north along Cumming Road to Badger Creek Avenue; thence north along Badger Creek Avenue to County Road F90 in Dallas County; thence east along County Road F90 to County Road R22; thence north along County Road R22 to Highway 44; thence east along Highway 44 to County Road R30; thence north along County Road R30 to County Road F31; thence east along County Road F31 to Highway 17; thence north along Highway 17 to Highway 415 in Polk County; thence east along Highway 415 to Northwest 158th Avenue; thence east along Northwest 158th Avenue to the point of beginning.

Michigan

North Zone: The Upper Peninsula.

Middle Zone: That portion of the Lower Peninsula north of a line beginning at the Wisconsin border in Lake Michigan due west of the mouth of Stony Creek in Oceana County; then due east to, and easterly and southerly along the south shore of, Stony Creek to Scenic Drive, easterly and southerly along Scenic Drive to Stony Lake Road, easterly along Stony Lake and Garfield Roads to Michigan Highway 20, east along Michigan 20 to U.S. Highway 10 Business Route (BR) in the city of Midland, east along U.S. 10 BR to U.S. 10, east along U.S. 10 to Interstate Highway 75/U.S. Highway 23, north along I–75/U.S. 23 to the U.S. 23 exit at Standish, east along U.S. 23 to Shore Road in Arenac County, east along Shore Road to the tip of Point Lookout, then on a line directly east 10 miles into Saginaw Bay, and from that point on a

line directly northeast to the Canada border.

South Zone: The remainder of Michigan.

Minnesota

Twin Cities Metropolitan Canada Goose Zone—

A. All of Hennepin and Ramsey Counties.

B. In Anoka County, all of Columbus Township lying south of County State Aid Highway (CSAH) 18, Anoka County; all of the cities of Ramsey, Andover, Anoka, Coon Rapids, Spring Lake Park, Fridley, Hilltop, Columbia Heights, Blaine, Lexington, Circle Pines, Lino Lakes, and Centerville; and all of the city of Ham Lake except that portion lying north of CSAH 18 and east of U.S. Highway 65.

C. That part of Carver County lying north and east of the following described line: Beginning at the northeast corner of San Francisco Township; thence west along the north boundary of San Francisco Township to the east boundary of Dahlgren Township; thence north along the east boundary of Dahlgren Township to U.S. Highway 212; thence west along U.S. Highway 212 to State Trunk Highway (STH) 284; thence north on STH 284 to County State Aid Highway (CSAH) 10; thence north and west on CSAH 10 to CSAH 30; thence north and west on CSAH 30 to STH 25; thence east and north on STH 25 to CSAH 10; thence north on CSAH 10 to the Carver County line.

D. In Scott County, all of the cities of Shakopee, Savage, Prior Lake, and Jordan, and all of the Townships of Jackson, Louisville, St. Lawrence, Sand Creek, Spring Lake, and Credit River.

E. In Dakota County, all of the cities of Burnsville, Eagan, Mendota Heights, Mendota, Sunfish Lake, Inver Grove Heights, Apple Valley, Lakeville, Rosemount, Farmington, Hastings, Lilydale, West St. Paul, and South St. Paul, and all of the Township of Nininger.

F. That portion of Washington County lying south of the following described line: Beginning at County State Aid Highway (CSAH) 2 on the west boundary of the county; thence east on CSAH 2 to U.S. Highway 61; thence south on U.S. Highway 61 to State Trunk Highway (STH) 97; thence east on STH 97 to the intersection of STH 97 and STH 95; thence due east to the east boundary of the State.

Northwest Goose Zone—That portion of the State encompassed by a line extending east from the North Dakota border along U.S. Highway 2 to State Trunk Highway (STH) 32, north along STH 32 to STH 92, east along STH 92 to County State Aid Highway (CSAH) 2 in Polk County, north along CSAH 2 to CSAH 27 in Pennington County, north along CSAH 27 to STH 1, east along STH 1 to CSAH 28 in Pennington County, north along CSAH 28 to CSAH 54 in Marshall County, north along CSAH 54 to CSAH 9 in Roseau County, north along CSAH 9 to STH 11, west along STH 11 to STH 310, and north along STH 310 to the Manitoba border.

Southeast Goose Zone—That part of the State within the following described boundaries: beginning at the intersection of U.S. Highway 52 and the south boundary of the Twin Cities Metro Canada Goose Zone; thence along the U.S. Highway 52 to State Trunk Highway (STH) 57; thence along STH 57 to the municipal boundary of Kasson; thence along the municipal boundary of Kasson County State Aid Highway (CSAH) 13, Dodge County; thence along CSAH 13 to STH 30; thence along STH 30 to U.S. Highway 63; thence along U.S. Highway 63 to the south boundary of the State; thence along the south and east boundaries of the State to the south boundary of the Twin Cities Metro Canada Goose Zone; thence along said boundary to the point of beginning.

Five Goose Zone—That portion of the State not included in the Twin Cities Metropolitan Canada Goose Zone, the Northwest Goose Zone, or the Southeast Goose Zone.

West Zone—That portion of the State encompassed by a line beginning at the junction of State Trunk Highway (STH) 60 and the Iowa border, then north and east along STH 60 to U.S. Highway 71, north along U.S. 71 to Interstate Highway 94, then north and west along I–94 to the North Dakota border.

Tennessee

Middle Tennessee Zone—Those portions of Houston, Humphreys, Montgomery, Perry, and Wayne Counties east of State Highway 13; and Bedford, Cannon, Cheatham, Coffee, Davidson, Dickson, Franklin, Giles, Hickman, Lawrence, Lewis, Lincoln, Macon, Marshall, Maury, Moore, Robertson, Rutherford, Smith, Sumner, Trousdale, Williamson, and Wilson Counties.

East Tennessee Zone—Anderson, Bledsoe, Bradley, Blount, Campbell, Carter, Claiborne, Clay, Cocke, Cumberland, DeKalb, Fentress, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hawkins, Jackson, Jefferson, Johnson, Knox, Loudon, Marion, McMinn, Meigs, Monroe, Morgan, Overton, Pickett, Polk, Putnam, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, Van Buren, Warren, Washington, and White Counties.

Wisconsin

Early-Season Subzone A—That portion of the State encompassed by a line beginning at the intersection of U.S. Highway 141 and the Michigan border near Niagara, then south along U.S. 141 to State Highway 22, west and southwest along State 22 to U.S. 45, south along U.S. 45 to State 22, west and south along State 22 to State 110, south along State 110 to U.S. 10, south along U.S. 10 to State 49, south along State 49 to State 23, west along State 23 to State 73, south along State 73 to State 60, west along State 60 to State 23, south along State 23 to State 11, east along State 11 to State 78, then south along State 78 to the Illinois border.

Early-Season Subzone B—The remainder of the State.

Central Flyway

Kansas

September Canada Goose Unit—That area of Kansas east of U.S. 183 and north of KS 96.

Nebraska

September Canada Goose Unit—That part of Nebraska bounded by a line from the Nebraska-Iowa State line west on U.S. Highway 30 to U.S. Highway 81, then south on U.S. Highway 81 to NE Highway 64, then east on NE Highway 64 to NE Highway 15, then south on NE Highway 15 to NE Highway 41, then east on NE Highway 41 to NE Highway 50, then north on NE Highway 50 to NE Highway 2, then east on NE Highway 2 to the Nebraska-Iowa State line.

South Dakota

September Canada Goose Unit A—Brown, Campbell, Edmunds, Faulk, McPherson, Spink, and Walworth Counties.

September Canada Goose Unit B—Clark, Codington, Day, Deuel, Grant, Hamlin, Marshall, and Roberts Counties.

September Canada Goose Unit C—Beadle, Brookings, Hanson, Kingsbury, Lake, Lincoln, McCook, Miner, Minnehaha, Moody, Sanborn, Turner, and Union Counties.

Pacific Flyway

Idaho

East Zone—Bonneville, Caribou, Fremont, and Teton Counties.

Oregon

Northwest Zone—Benton, Clackamas, Clatsop, Columbia, Lane, Lincoln, Linn, Marion, Polk, Multnomah, Tillamook, Washington, and Yamhill Counties.

Southwest Zone—Coos, Curry, Douglas, Jackson, Josephine, and Klamath Counties.

East Zone—Baker, Gilliam, Malheur, Morrow, Sherman, Umatilla, Union, and Wasco Counties.

Washington

Area 1—Skagit, Island, and Snohomish Counties.

Area 2A (SW Quota Zone)—Clark County, except portions south of the Washougal River; Cowlitz, and Wahkiakum Counties.

Area 2B (SW Quota Zone)—Pacific County.

Area 3—All areas west of the Pacific Crest Trail and west of the Big White Salmon River that are not included in Areas 1, 2A, and 2B.

Area 4—Adams, Benton, Chelan, Douglas, Franklin, Grant, Kittitas, Lincoln, Okanogan, Spokane, and Walla Walla Counties.

Area 5—All areas east of the Pacific Crest Trail and east of the Big White Salmon River that are not included in Area 4.

Ducks

Atlantic Flyway

New York

Lake Champlain Zone: The U.S. portion of Lake Champlain and that area east and north of a line extending along NY 9B from the Canadian border to U.S. 9, south along U.S. 9 to NY 22 south of Keesville; south along NY 22 to the west shore of South Bay, along and around the shoreline of South Bay to NY 22 on the east shore of South Bay; southeast along NY 22 to U.S. 4, northeast along U.S. 4 to the Vermont border.

Long Island Zone: That area consisting of Nassau County, Suffolk County, that area of Westchester County southeast of I–95, and their tidal waters.

Western Zone: That area west of a line extending from Lake Ontario east along the north shore of the Salmon River to I–81, and south along I–81 to the Pennsylvania border.

Northeastern Zone: That area north of a line extending from Lake Ontario east along the north shore of the Salmon River to I–81, south along I–81 to NY 49, east along NY 49 to NY 365, east along NY 365 to NY 28, east along NY 28 to NY 29, east along NY 29 to I–87, north along I–87 to U.S. 9 (at Exit 20), north along U.S. 9 to NY 149, east along NY 149 to U.S. 4, north along U.S. 4 to the Vermont border, exclusive of the Lake Champlain Zone.

Southeastern Zone: The remaining portion of New York.

Mississippi Flyway

Indiana

North Zone: That portion of the State north of a line extending east from the Illinois border along State Road 18 to U.S. Highway 31, north along U.S. 31 to U.S. 24, east along U.S. 24 to Huntington, then southeast along U.S. 224 to the Ohio border.

Ohio River Zone: That portion of the State south of a line extending east from the Illinois border along Interstate Highway 64 to New Albany, east along State Road 62 to State 56, east along State 56 to Vevay, east and north on State 156 along the Ohio River to North Landing, north along State 56 to U.S. Highway 50, then northeast along U.S. 50 to the Ohio border.

South Zone: That portion of the State between the North and Ohio River Zone boundaries.

Iowa

North Zone: That portion of the State north of a line extending east from the Nebraska border along State Highway 175 to State Highway 37, southeast along State Highway 37 to State Highway 183, northeast along State Highway 183 to State Highway 141, east along State Highway 141 to U.S. Highway 30, then east along U.S. Highway 30 to the Illinois border.

South Zone: The remainder of Iowa.

Central Flyway

Colorado

Special Teal Season Area: Lake and Chaffee Counties and that portion of the State east of Interstate Highway 25.

Kansas

High Plains Zone: That portion of the State west of U.S. 283.

Low Plains Early Zone: That area of Kansas east of U.S. 283, and generally west of a line beginning at the Junction of the Nebraska State line and KS 28; south on KS 28 to U.S. 36; east on U.S. 36 to KS 199; south on KS 199 to Republic Co. Road 563; south on Republic Co. Road 563 to KS 148; east on KS 148 to Republic Co. Road 138; south on Republic Co. Road 138 to Cloud Co. Road 765; south on Cloud Co. Road 765 to KS 9; west on KS 9 to U.S. 24; west on U.S. 24 to U.S. 281; north on U.S. 281 to U.S. 36; west on U.S. 36 to U.S. 183; south on U.S. 183 to U.S. 24; west on U.S. 24 to KS 18; southeast on KS 18 to U.S. 183; south on U.S. 183 to KS 4; east on KS 4 to I–135; south on I–135 to KS 61; southwest on KS 61 to KS 96; northwest on KS 96 to U.S. 56; west on U.S. 56 to U.S. 281; south on U.S. 281 to U.S. 54; west on U.S. 54 to U.S. 183; north on U.S. 183 to U.S. 56; and southwest on U.S. 56 to U.S. 283.

Low Plains Late Zone: The remainder of Kansas.

Nebraska

Special Teal Season Area: That portion of the State south of a line beginning at the Wyoming State line; east along U.S. 26 to Nebraska Highway L62A east to U.S. 385; south to U.S. 26; east to NE 92; east along NE 92 to NE 61; south along NE 61 to U.S. 30; east along U.S. 30 to the Iowa border.

New Mexico (Central Flyway Portion)

North Zone: That portion of the State north of I–40 and U.S. 54.

South Zone: The remainder of New Mexico.

Pacific Flyway

California

Northeastern Zone: Northeastern Zone: In that portion of California lying east and north of a line beginning at the intersection of Interstate 5 with the California–Oregon line; south along Interstate 5 to its junction with Walters Lane south of the town of Yreka; west along Walters Lane to its junction with Easy Street; south along Easy Street to the junction with Old Highway 99; south along Old Highway 99 to the point of intersection with Interstate 5 north of the town of Weed; south along Interstate 5 to its junction with Highway 89; east and south along Highway 89 to Main Street Greenville; north and east to its junction with North Valley Road; south to its junction of Diamond Mountain Road; north and east to its junction with North Arm Road; south and west to the junction of North Valley Road; south to the junction with Arlington Road (A22); west to the junction of Highway 89; south and west to the junction of Highway 70; east on Highway 70 to Highway 395; south and east on Highway 395 to the point of intersection with the California–Nevada state line; north along the California–Nevada state line to the junction of the California–Nevada–Oregon state lines west along the California–Oregon line state to the point of origin.

Colorado River Zone: Those portions of San Bernardino, Riverside, and Imperial Counties east of a line extending from the Nevada border south along U.S. 95 to Vidal Junction; south on a road known as ''Aqueduct Road'' in San Bernardino County through the town of Rice to the San Bernardino–Riverside County line; south on a road known in Riverside County as the ''Desert Center to Rice Road'' to the town of Desert Center; east 31 miles on

I–10 to the Wiley Well Road; south on this road to Wiley Well; southeast along the Army–Milpitas Road to the Blythe, Brawley, Davis Lake intersections; south on the Blythe–Brawley paved road to the Ogilby and Tumco Mine Road; south on this road to U.S. 80; east 7 miles on U.S. 80 to the Andrade-Algodones Road; south on this paved road to the Mexican border at Algodones, Mexico.

Southern Zone: That portion of southern California (but excluding the Colorado River Zone) south and east of a line extending from the Pacific Ocean east along the Santa Maria River to CA 166 near the City of Santa Maria; east on CA 166 to CA 99; south on CA 99 to the crest of the Tehachapi Mountains at Tejon Pass; east and north along the crest of the Tehachapi Mountains to CA 178 at Walker Pass; east on CA 178 to U.S. 395 at the town of Inyokern; south on U.S. 395 to CA 58; east on CA 58 to I–15; east on I–15 to CA 127; north on CA 127 to the Nevada border.

Southern San Joaquin Valley Temporary Zone: All of Kings and Tulare Counties and that portion of Kern County north of the Southern Zone.

Balance-of-the-State Zone: The remainder of California not included in the Northeastern, Southern, and Colorado River Zones, and the Southern San Joaquin Valley Temporary Zone.

Canada Geese

Michigan

MVP—Upper Peninsula Zone: The MVP—Upper Peninsula Zone consists of the entire Upper Peninsula of Michigan.

MVP—Lower Peninsula Zone: The MVP—Lower Peninsula Zone consists of the area within the Lower Peninsula of Michigan that is north and west of the point beginning at the southwest corner of Branch county, north continuing along the western border of Branch and Calhoun counties to the northwest corner of Calhoun county, then east to the southwest corner of Eaton county, then north to the southern border of Ionia county, then east to the southwest corner of Clinton county, then north along the western border of Clinton County continuing north along the county border of Gratiot and Montcalm counties to the southern border of Isabella county, then east to the southwest corner of Midland county, then north along the west Midland county border to Highway M–20, then easterly to U.S. Highway 10, then easterly to U.S. Interstate 75/U.S. Highway 23, then northerly along I–75/U.S. 23 and easterly on U.S. 23 to the centerline of the Au Gres River, then southerly along the centerline of the Au Gres River to Saginaw Bay, then on a line directly east 10 miles into Saginaw Bay, and from that point on a line directly northeast to the Canadian border.

SJBP Zone is the rest of the State, that area south and east of the boundary described above.

Sandhill Cranes

Central Flyway

Colorado

The Central Flyway portion of the State except the San Luis Valley (Alamosa, Conejos, Costilla, Hinsdale, Mineral, Rio Grande, and Saguache Counties east of the Continental Divide) and North Park (Jackson County).

Kansas

That portion of the State west of a line beginning at the Oklahoma border, north on I–35 to Wichita, north on I–135 to Salina, and north on U.S. 81 to the Nebraska border.

Montana

The Central Flyway portion of the State except for that area south and west of Interstate 90, which is closed to sandhill crane hunting.

New Mexico

Regular-Season Open Area—Chaves, Curry, De Baca, Eddy, Lea, Quay, and Roosevelt Counties.

Middle Rio Grande Valley Area—The Central Flyway portion of New Mexico in Socorro and Valencia Counties.

Estancia Valley Area—Those portions of Santa Fe, Torrance and Bernallilo Counties within an area bounded on the west by New Mexico Highway 55 beginning at Mountainair north to NM 337, north to NM 14, north to I–25; on the north by I–25 east to U.S. 285; on the east by U.S. 285 south to U.S. 60; and on the south by U.S. 60 from U.S. 285 west to NM 55 in Mountainair.

Southwest Zone—Sierra, Luna, Dona Ana Counties, and those portions of Grant and Hidalgo Counties south of I–10.

North Dakota

Area 1—That portion of the State west of U.S. 281.

Area 2—That portion of the State east of U.S. 281.

Oklahoma

That portion of the State west of I–35.

South Dakota

That portion of the State west of U.S. 281.

Texas

Zone A—That portion of Texas lying west of a line beginning at the international toll bridge at Laredo, thence northeast along U.S. Highway 81 to its junction with Interstate Highway 35 in Laredo, thence north along Interstate Highway 35 to its junction with Interstate Highway 10 in San Antonio, thence northwest along Interstate Highway 10 to its junction with U.S. Highway 83 at Junction, thence north along U.S. Highway 83 to its junction with U.S. Highway 62, 16 miles north of Childress, thence east along U.S. Highway 62 to the Texas-Oklahoma State line.

Zone B—That portion of Texas lying within boundaries beginning at the junction of U.S. Highway 81 and the Texas-Oklahoma State line, thence southeast along U.S. Highway 81 to its junction with U.S. Highway 287 in Montague County, thence southeast along U.S. Highway 287 to its junction with Interstate Highway 35W in Fort Worth, thence southwest along Interstate Highway 35 to its junction with Interstate Highway 10 in San Antonio, thence northwest along Interstate Highway 10 to its junction with U.S. Highway 83 in Junction, thence north along U.S. Highway 83 to its junction with U.S. Highway 62, 16 miles north of Childress, thence east along U.S. Highway 62 to the Texas–Oklahoma State line, thence south along the Texas–Oklahoma state line to the south bank of the Red River, thence eastward along the vegetation line on the south bank of the Red River to U.S. Highway 81.

Zone C—The remainder of the State, except for the closed areas.

Closed areas—(A) That portion of the State lying east and north of a line beginning at the junction of U.S. Highway 81 and the Texas–Oklahoma State line, thence southeast along U.S. Highway 81 to its junction with U.S. Highway 287 in Montague County, thence southeast along U.S. Highway 287 to its junction with Interstate Highway 35W in Fort Worth, thence southwest along Interstate Highway 35 to its junction with U.S. Highway 290 East in Austin, thence east along U.S. Highway 290 to its junction with Interstate Loop 610 in Harris County, thence south and east along Interstate Loop 610 to its junction with Interstate Highway 45 in Houston, thence south on Interstate Highway 45 to State Highway 342, thence to the shore of the Gulf of Mexico, and thence north and east along the shore of the Gulf of Mexico to the Texas-Louisiana State line.

(B) That portion of the State lying within the boundaries of a line beginning at the Kleberg-Nueces County line and the shore of the Gulf of Mexico, thence west along the County line to Park Road 22 in Nueces County, thence north and west along Park Road 22 to its junction with State Highway 358 in Corpus Christi, thence west and north along State Highway 358 to its junction with State Highway 286, thence north along State Highway 286 to its junction with Interstate Highway 37, thence east along Interstate Highway 37 to its junction with U.S. Highway 181, thence north and west along U.S. Highway 181 to its junction with U.S. Highway 77 in Sinton, thence north and east along U.S. Highway 77 to its junction with U.S. Highway 87 in Victoria, thence south and east along U.S. Highway 87 to its junction with State Highway 35 at Port Lavaca, thence north and east along State Highway 35 to the south end of the Lavaca Bay Causeway, thence south and east along the shore of Lavaca Bay to its junction with the Port Lavaca Ship Channel, thence south and east along the Lavaca Bay Ship Channel to the Gulf of Mexico, and thence south and west along the shore of the Gulf of Mexico to the Kleberg-Nueces County line.

Wyoming

Regular-Season Open Area—Campbell, Converse, Crook, Goshen, Laramie, Niobrara, Platte, and Weston Counties.

Riverton-Boysen Unit—Portions of Fremont County.

Park and Big Horn County Unit—Portions of Park and Big Horn Counties.

Pacific Flyway

Arizona

Special-Season Area—Game Management Units 30A, 30B, 31, and 32.

Montana

Special-Season Area—See State regulations.

Utah

Special-Season Area—Rich, Cache, and Unitah Counties and that portion of Box Elder County beginning on the Utah-Idaho State line at the Box Elder–Cache County line; west on the State line to the Pocatello Valley County Road; south on the Pocatello Valley County Road to I–15; southeast on I–15 to SR–83; south on SR–83 to Lamp Junction; west and south on the Promontory Point County Road to the tip of Promontory Point; south from Promontory Point to the Box Elder–Weber County line; east on the Box Elder–Weber County line to the Box Elder–Cache County line; north on the Box Elder–Cache County line to the Utah–Idaho State line.

Wyoming

Bear River Area—That portion of Lincoln County described in State regulations.

Salt River Area—That portion of Lincoln County described in State regulations.

Farson-Eden Area—Those portions of Sweetwater and Sublette Counties described in State regulations.

All Migratory Game Birds in Alaska

North Zone—State Game Management Units 11–13 and 17–26.

Gulf Coast Zone—State Game Management Units 5–7, 9, 14–16, and 10 (Unimak Island only).

Southeast Zone—State Game Management Units 1–4.

Pribilof and Aleutian Islands Zone—State Game Management Unit 10 (except Unimak Island).

Kodiak Zone—State Game Management Unit 8.

All Migratory Game Birds in the Virgin Islands

Ruth Cay Closure Area—The island of Ruth Cay, just south of St. Croix.

All Migratory Game Birds in Puerto Rico

Municipality of Culebra Closure Area—All of the municipality of Culebra.

Desecheo Island Closure Area—All of Desecheo Island.

Mona Island Closure Area—All of Mona Island.

El Verde Closure Area—Those areas of the municipalities of Rio Grande and Loiza delineated as follows: (1) All lands between Routes 956 on the west and 186 on the east, from Route 3 on the north to the juncture of Routes 956 and 186 (Km 13.2) in the south; (2) all lands between Routes 186 and 966 from the juncture of 186 and 966 on the north, to the Caribbean National Forest Boundary on the south; (3) all lands lying west of Route 186 for 1 kilometer from the juncture of Routes 186 and 956 south to Km 6 on Route 186; (4) all lands within Km 14 and Km 6 on the west and the Caribbean National Forest Boundary on the east; and (5) all lands within the Caribbean National Forest Boundary whether private or public.

Cidra Municipality and adjacent areas—All of Cidra Municipality and portions of Aguas Buenas, Caguas, Cayey, and Comerio Municipalities as encompassed within the following boundary: beginning on Highway 172 as it leaves the municipality of Cidra on the west edge, north to Highway 156, east on Highway 156 to Highway 1, south on Highway 1 to Highway 765, south on Highway 765 to Highway 763, south on Highway 763 to the Rio Guavate, west along Rio Guavate to Highway 1, southwest on Highway 1 to Highway 14, west on Highway 14 to Highway 729, north on Highway 729 to Cidra Municipality boundary to the point of the beginning.

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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 AUGUST 29, 2006

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Natural gas pipeline facilities; damage reporting requirements; revision; published 8-29-06

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Drawbridge operations:

Texas; published 8-18-06

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Fish and Wildlife Service

Migratory bird hunting:

Various States; early-season migratory bird hunting regulations; published 8-29-06

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Animal identification standards; comments due by 9-6-06; published 3-10-06 [FR 06-02380]

Plant-related quarantine, foreign

Shelled garden peas from Kenya; comments due by 9-5-06; published 7-6-06 [FR E6-10551]

AGRICULTURE DEPARTMENT

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Food distribution programs:

Donated foods in child nutrition programs, Nutrition Services Incentive Program, and charitable institutions; distribution, management, and use; comments due by 9-7-06; published 6-8-06 [FR 06-05143]

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COMMERCE DEPARTMENT

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Special awareness training for persons flying under visual flight rules within 100 nautical miles of Washington, DC metropolitan area; comments due by 9-5-06; published 7-5-06 [FR 06-05997]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 4646/P.L. 109–273

To designate the facility of the United States Postal Service located at 7320 Reseda Boulevard in Reseda, California, as the ''Coach John Wooden Post Office Building''. (Aug. 17, 2006; 120 Stat. 773)

H.R. 4811/P.L. 109–274

To designate the facility of the United States Postal Service located at 215 West Industrial Park Road in Harrison, Arkansas, as the ''John Paul Hammerschmidt Post Office Building''. (Aug. 17, 2006; 120 Stat. 774)

H.R. 4962/P.L. 109–275

To designate the facility of the United States Postal Service located at 100 Pitcher Street in Utica, New York, as the ''Captain George A. Wood Post Office Building''. (Aug. 17, 2006; 120 Stat. 775)

H.R. 5104/P.L. 109–276

To designate the facility of the United States Postal Service located at 1750 16th Street South in St. Petersburg, Florida, as the ''Morris W. Milton Post Office''. (Aug. 17, 2006; 120 Stat. 776)

H.R. 5107/P.L. 109–277

To designate the facility of the United States Postal Service located at 1400 West Jordan Street in Pensacola, Florida, as the ''Earl D. Hutto Post Office Building''. (Aug. 17, 2006; 120 Stat. 777)

H.R. 5169/P.L. 109–278

To designate the facility of the United States Postal Service located at 1310 Highway 64 NW. in Ramsey, Indiana, as the ''Wilfred Edward 'Cousin Willie' Sieg, Sr. Post Office''. (Aug. 17, 2006; 120 Stat. 778)

H.R. 5540/P.L. 109–279

To designate the facility of the United States Postal Service located at 217 Southeast 2nd Street in Dimmitt, Texas, as the ''Sergeant Jacob Dan Dones Post Office''. (Aug. 17, 2006; 120 Stat. 779)

H.R. 4/P.L. 109–280

Pension Protection Act of 2006 (Aug. 17, 2006; 120 Stat. 780)

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