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WHAT: Free public briefings (approximately 3 hours) to present:

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3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, September 15, 2009
9:00 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
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 97

[Docket No. 30678; Amdt. No. 3332]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 13, 2009. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 13, 2009.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800

Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or

4. 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.

*Availability—*All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit <http://www.nfdc.faa.gov> to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS-420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPs, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and

impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPs, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

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. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment 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 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on July 24, 2009.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 27 AUG 2009

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 Lansing, MI, Capital City, RNAV (GPS) RWY 10R, Orig
 Lansing, MI, Capital City, RNAV (GPS) RWY 24, Orig
 Lansing, MI, Capital City, RNAV (GPS) RWY 28L, Orig
 Lansing, MI, Capital City, VOR RWY 24, Amdt 9
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, ILS OR LOC RWY 32, Amdt 11
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, RNAV (GPS) RWY 5, Orig
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, RNAV (GPS) RWY 23, Orig
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, RNAV (GPS) RWY 32, Orig
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, VOR RWY 23, Amdt 16
 Pellston, MI, Pellston Rgnl Arpt Of Emmet County, VOR/DME RWY 5, Amdt 12
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, ILS OR LOC RWY 31, Amdt 2
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, NDB RWY 31, Amdt 2
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, RNAV (GPS) RWY 31, Orig
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, RNAV (GPS) RWY 35, Orig
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, Takeoff Minimums and Obstacle DP, Orig
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, VOR RWY 13, Amdt 1
 Fergus Falls, MN, Fergus Falls Muni-Einar Mickelson Field, VOR RWY 35, Amdt 10
 Ahsokie, NC, Tri-County, NDB RWY 1, Amdt 2, CANCELLED
 Raleigh/Durham, NC, Raleigh-Durham Intl, ILS OR LOC RWY 5L, Amdt 5
 Raleigh/Durham, NC, Raleigh-Durham Intl, ILS OR LOC RWY 5R, Amdt 27
 Raleigh/Durham, NC, Raleigh-Durham Intl, ILS OR LOC RWY 23L, Amdt 8
 Raleigh/Durham, NC, Raleigh-Durham Intl, ILS OR LOC RWY 23R, ILS RWY 23R (CAT II), ILS RWY 23R (CAT III), Amdt 11
 Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 5L, Amdt 1
 Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 5R, Amdt 1
 Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 23L, Amdt 1
 Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 23R, Amdt 1

Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 5L, Orig

Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 5R, Orig

Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 23L, Orig

Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 23R, Orig

Las Vegas, NV, McCarran Intl, VOR RWY 25L/R, Amdt 3

Dayton, OH, James M Cox Dayton Intl, ILS OR LOC RWY 6L, ILS RWY 6L (CAT II), ILS RWY 6L (CAT III), Amdt 9

Dayton, OH, James M Cox Dayton Intl, ILS OR LOC RWY 18, Amdt 10

Dayton, OH, James M Cox Dayton Intl, ILS OR LOC RWY 24L, Amdt 9

Dayton, OH, James M Cox Dayton Intl, ILS OR LOC RWY 24R, Amdt 8

Dayton, OH, James M Cox Dayton Intl, NDB RWY 6R, Amdt 9

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 6L, Amdt 1

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 6R, Amdt 1

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 18, Amdt 1

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 24L, Amdt 1

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 24R, Amdt 1

Dayton, OH, James M Cox Dayton Intl, RNAV (GPS) RWY 36, Amdt 1

Redmond, OR, Roberts Field, GPS RWY 10, Orig-A, CANCELLED

Redmond, OR, Roberts Field, RNAV (GPS) RWY 4, Orig

Redmond, OR, Roberts Field, RNAV (GPS) RWY 10, Orig

Redmond, OR, Roberts Field, RNAV (GPS) RWY 22, Orig

Redmond, OR, Roberts Field, RNAV (GPS) Y RWY 28, Amdt 1

Redmond, OR, Roberts Field, RNAV (GPS) Z RWY 28, Orig

Johnstown, PA, John Murtha Johnstown-Cambria County, ILS OR LOC RWY 33, Amdt 6

Johnstown, PA, John Murtha Johnstown-Cambria County, RNAV (GPS) RWY 5, Amdt 1

Johnstown, PA, John Murtha Johnstown-Cambria County, RNAV (GPS) RWY 15, Amdt 1

Johnstown, PA, John Murtha Johnstown-Cambria County, RNAV (GPS) RWY 23, Amdt 1

Johnstown, PA, John Murtha Johnstown-Cambria County, RNAV (GPS) RWY 33, Amdt 1

Johnstown, PA, John Murtha Johnstown-Cambria County, VOR RWY 23, Amdt 8

Johnstown, PA, John Murtha Johnstown-Cambria County, VOR/DME RWY 23, Amdt 2

Reading PA, Reading Rgnl/Carl A. Spaatz Fld, NDB RWY 36, Amdt 25

San Juan, PR, Luis Munoz Marin Intl, Takeoff Minimums and Obstacle DP, Amdt 7

Aberdeen, SD, Aberdeen Rgnl, Takeoff Minimums and Obstacle DP, Orig

Nashville, TN, Nashville Intl, ILS OR LOC RWY 2C, Amdt 1

Nashville, TN, Nashville Intl, ILS OR LOC RWY 2L, ILS RWY 2L (CAT II), ILS RWY 2L (CAT III), Amdt 9

Nashville, TN, Nashville Intl, ILS OR LOC RWY 2R, ILS RWY 2R (CAT II), ILS RWY 2R (CAT III), Amdt 7

Nashville, TN, Nashville Intl, ILS OR LOC RWY 20L, Amdt 5

Nashville, TN, Nashville Intl, ILS OR LOC RWY 20R, Amdt 10

Nashville, TN, Nashville Intl, ILS OR LOC RWY 31, Amdt 9

Nashville, TN, Nashville Intl, RNAV (GPS) RWY 13, Amdt 1

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 2C, Amdt 1

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 2L, Amdt 1

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 2R, Amdt 1

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 20L, Amdt 1

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 20R, Amdt 2

Nashville, TN, Nashville Intl, RNAV (GPS) Y RWY 31, Amdt 1

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 2C, Orig

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 2L, Orig

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 2R, Orig

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 20L, Orig

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 20R, Orig

Nashville, TN, Nashville Intl, RNAV (RNP) Z RWY 31, Orig

Jasper, TX, Jasper County-Bell Field, GPS RWY 18, Amdt 1, CANCELLED

Jasper, TX, Jasper County-Bell Field, GPS RWY 36, Orig, CANCELLED

Jasper, TX, Jasper County-Bell Field, NDB RWY 18, Amdt 10

Jasper, TX, Jasper County-Bell Field, RNAV (GPS) RWY 18, Orig

Jasper, TX, Jasper County-Bell Field, RNAV (GPS) RWY 36, Orig

Jasper, TX, Jasper County-Bell Field, Takeoff Minimums and Obstacle DP, Orig

Abingdon, VA, Virginia Highlands, LOC RWY 24, Amdt 3

Abingdon, VA, Virginia Highlands, RNAV (GPS) RWY 6, Orig

Abingdon, VA, Virginia Highlands, RNAV (GPS) RWY 24, Orig

Abingdon, VA, Virginia Highlands, VOR/DME-B, Amdt 6

Hot Springs, VA, Ingalls Fld, GPS RWY 7, Orig-A, CANCELLED

Hot Springs, VA, Ingalls Fld, ILS OR LOC RWY 25, Amdt 4

Hot Springs, VA, Ingalls Fld, RNAV (GPS) RWY 7, Orig

South Boston, VA, William M. Tuck, GPS RWY 1, Orig, CANCELLED

South Boston, VA, William M. Tuck, RNAV (GPS) RWY 1, Orig

South Boston, VA, William M. Tuck, RNAV (GPS) RWY 19, Orig

South Boston, VA, William M. Tuck, VOR-A, Amdt 8

Beckley, WV, Raleigh County Memorial, VOR RWY 19, Amdt 4

Parkersburg, WV, Mid-Ohio Valley Rgnl, ILS OR LOC RWY 3, Amdt 13

[FR Doc. E9-18660 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30679; Amdt. No. 3333]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 13, 2009. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 13, 2009.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
 2. The FAA Regional Office of the region in which the affected airport is located;
 3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or
 4. 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.
- Availability*—All SIAPs are available online free of charge. Visit nfdc.faa.gov

to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS-420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates.

This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P-NOTAMs.

The SIAPs, as modified by FDC P-NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

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. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory

Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment 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 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on July 24, 2009.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * Effective Upon Publication

FDC date	State	City	Airport	FDC No.	Subject
07/09/09	OR	AURORA	AURORA STATE	9/7851	RNAV (GPS) RWY 35, ORIG-B.
07/09/09	OR	AURORA	AURORA STATE	9/7852	RNAV (GPS) RWY 17, ORIG-A.
07/09/09	NV	TONOPAH	TONOPAH	9/7854	GPS RWY 15, ORIG-A.
07/09/09	NV	TONOPAH	TONOPAH	9/7855	VOR OR GPS-A, AMDT 3A.
07/09/09	AK	PLATINUM	PLATINUM	9/7856	RNAV (GPS) RWY 13, ORIG.
07/09/09	AK	TOGIK VILLAGE	TOGIK	9/7857	RNAV (GPS) RWY 21, ORIG.
07/09/09	WY	GREYBULL	SOUTH BIG HORN COUNTY	9/7923	TAKEOFF MINIMUMS AND OB- STACLE DP, ORIG.
07/22/09	NY	ISLIP	LONG ISLAND MACARTHUR	9/8067	RNAV (GPS) RWY 6, ORIG.
07/22/09	NE	OSHKOSH	GARDEN COUNTY	9/8108	NDB RWY 12, AMDT 1A.
07/22/09	NE	CHAPPELL	BILLY G RAY FIELD	9/8109	NDB OR GPS RWY 30, AMDT 2.
07/10/09	CO	EAGLE	EAGLE COUNTY REGIONAL	9/8133	LDA/DME RWY 25, ORIG-B.
07/11/09	MT	STEVENSVILLE	STEVENSVILLE	9/8254	RNAV (GPS) A, ORIG.
07/11/09	CA	HANFORD	HANFORD MUNI	9/8255	VOR-A, AMDT 9.
07/11/09	CA	HANFORD	HANFORD MUNI	9/8257	RNAV (GPS) RWY 32, ORIG-A.

FDC date	State	City	Airport	FDC No.	Subject
07/11/09	MT	HELENA	HELENA REGIONAL	9/8260	RNAV (RNP) Z RWY 9, ORIG.
07/11/09	AL	HAMILTON	MARION COUNTY-RANKIN FITE	9/8352	RNAV (GPS) RWY 18, ORIG.
07/13/09	CA	IMPERIAL	IMPERIAL COUNTY	9/8666	TAKEOFF MINIMUMS AND OB- STACLE DP, AMDT 2.
07/14/09	WY	NEWCASTLE	MONDELL FIELD	9/8931	TAKEOFF MINIMUMS AND OB- STACLE DP, AMDT 3.
07/14/09	OK	ALTUS	ALTUS/QUARTZ MOUNTAIN RGNL ..	9/8941	VOR A, AMDT 4C.
07/15/09	NV	RENO	RENO/TAHOE INTL	9/9101	ILS RWY 16R, AMDT 10D.
07/17/09	NY	ISLIP	LONG ISLAND MACARTHUR	9/9568	RNAV (GPS) RWY 6, ORIG.
07/17/09	CA	OROVILLE	OROVILLE MUNI	9/9700	GPS RWY 1, ORIG.
07/17/09	CA	OROVILLE	OROVILLE MUNI	9/9701	VOR OR GPS-A, AMDT 6.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0045	ILS OR LOC RWY 22, AMDT 2A.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0046	VOR/DME RWY 22, AMDT 3.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0047	VOR A, AMDT 5.
07/21/09	CA	OROVILLE	OROVILLE MUNI	9/0053	TAKEOFF MINIMUMS AND OB- STACLE DP, AMDT 2.
07/21/09	WV	MORGANTOWN	MORGANTOWN MUNI-WALTER L. BILL HART FLD.	9/0093	ILS OR LOC RWY 18, AMDT 13.
07/22/09	OR	PORTLAND	PORTLAND INTL	9/0161	ILS ROR LOC RWY 28L, AMDT 1A.
07/22/09	FL	MELBOURNE	MELBOURNE INTL	9/0262	RNAV (GPS) RWY 27L, ORIG- A.
07/22/09	WY	DOUGLAS	CONVERSE COUNTY	9/0323	RNAV (GPS) RWY 29, ORIG.
07/22/09	WY	DOUGLAS	CONVERSE COUNTY	9/0324	VOR RWY 29, AMDT 1

[FR Doc. E9-18661 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2009-N-0665]

New Animal Drugs for Use in Animal Feeds; Oxytetracycline; Neomycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pennfield Oil Co. The supplemental NADA provides for the use of fixed-combination Type A medicated articles containing oxytetracycline and neomycin sulfate to formulate two-way, fixed-combination drug Type B and Type C medicated feeds for chickens, turkeys, swine, cattle, and sheep. This approval reflects FDA's effectiveness conclusions which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

DATES: This rule is effective August 13, 2009.

FOR FURTHER INFORMATION CONTACT:

Harlan Howard, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8111, e-mail: harlan.howard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57911), as part of the Drug Efficacy Study Implementation (DESI) program, CVM announced the effective conditions of use for several drug products and use combinations that were listed in § 558.15 (21 CFR 558.15). CVM proposed to withdraw the NADAs for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness.

In response to that notice, Pennfield Oil Co., (Pennfield) 14040 Industrial Rd., Omaha, NE 68144, filed a hearing request for its approved NADA 138-939 NEO-OXY 50/50, NEO-OXY 100/100, and NEO-OXY 100/100 MR (oxytetracycline and neomycin sulfate). These products are two-way, fixed-combination Type A medicated articles used to make two-way combination drug Type C medicated feeds. Pennfield subsequently filed a supplement to NADA 138-939 to revise the labeling of these products to comply with these findings of effectiveness. The supplemental NADA provided for use of these fixed-combination Type A medicated articles to formulate two-way, fixed-combination drug Type B

and Type C medicated feeds containing oxytetracycline and neomycin sulfate, in a 1:1 ratio, for several production and therapeutic indications in chickens, turkeys, swine, cattle, and sheep. The supplemental NADA is approved as of July 2, 2009, and the regulations are amended in 21 CFR 558.455 to reflect the approval. Pennfield has since withdrawn its hearing request for NDA 138-939.

Approval of this supplemental NADA did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The DESI evaluation was concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying, as described in the *Generic Animal Drug and Patent Term Restoration Act Policy Letter Eight*, August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for this fixed combination Type A medicated article.

The agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Amend § 558.455 as follows:

- a. Revise paragraph (b);
- b. Redesignate paragraph (d) as paragraph (e);
- c. Add new paragraph (d); and
- d. Revise newly redesignated paragraph (e).

The redesignation, additions, and revisions read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(b) *Sponsors*. See Nos. 048164 and 066104 in § 510.600(c) of this chapter.

* * * * *

(d) *Special considerations*. Cattle feeds shall bear the following warning statement: "Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues."

(e) *Indications for use*—(1) *Chickens*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) 10 to 50	Chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to chickens producing eggs for human consumption; in low calcium feeds withdraw 3 days before slaughter.	048164 066104
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> ; control of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.	048164 066104
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	048164 066104
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac infection) caused by <i>E. coli</i> susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.	048164 066104

(2) *Turkeys*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 grams per ton (g/ton) of feed	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to turkeys producing eggs for human consumption.	048164 066104
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	048164 066104
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by <i>M. synoviae</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	048164 066104
(iv) To provide 25 milligrams per pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	048164 066104

(3) *Swine*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 g/ton of feed	Swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(ii) To provide 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin. 2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter. Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	048164 066104 048164 066104

(4) *Cattle and sheep*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 20 g/ton of feed	Sheep: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(ii) To provide 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously; in milk replacers or starter feed.	048164 066104
(iii) To provide 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin. 2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin.	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter. Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	048164 066104 048164 066104

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
	3. Sheep: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.	048164 066104
(iv) To provide 25 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(v) To provide 75 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	Feed continuously.	048164 066104
(vi) To provide 0.5 to 2.0 g/head/ day	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.	048164 066104

Dated: August 7, 2009.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. E9-19414 Filed 8-12-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 251

[Docket ID: MMS-2008-OMM-0006]

RIN 1010-AD41

Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf—Changing Proprietary Term of Certain Geophysical Information

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This final rule extends the proprietary term of certain reprocessed geophysical information submitted to MMS under a permit. The rule gives up to 5 years of additional protection to reprocessed vintage geophysical information that MMS retains and, without an extension, is subject to release by MMS 25 years after issuing the permit. The extension provides incentives to permittees and third parties to reprocess, market, or in other

ways use geophysical information that may not otherwise be reprocessed without the term extension. The extension does not apply to geological data or information.

DATES: *Effective Date:* This rule becomes effective on September 14, 2009.

FOR FURTHER INFORMATION CONTACT:

David Zinzer, Geophysicist, Offshore Energy and Minerals Management, Resource Evaluation Division, at (703) 787-1628.

SUPPLEMENTARY INFORMATION: This final rule implements changes put forward by our proposed rulemaking published June 18, 2007 (72 FR 33417). The comment period ended August 17, 2007. The MMS received four sets of written comments. One set of comments and recommendations was from an industry association; two sets were from third party users of geophysical data and information collected on the Outer Continental Shelf (OCS); and one set was from the public.

Summary of Proposed Rulemaking

The MMS proposed to extend, upon successful application to MMS, the proprietary term of geophysical information that a permittee or third party reprocessed 20 or more years after MMS issued the germane permit under which the originating data were collected. The rule proposed to give up to 5 years of additional protection to reprocessed vintage geophysical

information that MMS retains and, without an extension, is subject to release by MMS 25 years after issuing the permit. The extension provides incentives to permittees and third parties to reprocess, market, or in other ways use geophysical information that may not otherwise be reprocessed without the term extension.

Analysis of Comments and Recommendations

The MMS has decided to proceed with the final rule after carefully considering all written comments on the proposed rulemaking.

Comment: One commenter continued to comment about issues and changes put forward by our proposed rulemaking, published July 17, 2002 (67 FR 46942), and the subsequent related final rulemaking, published March 30, 2006 (71 FR 16033).

Response: Changes put forth by the June 18, 2007, proposed rulemaking are directly addressed in this final rulemaking. However, MMS has clarified, where necessary, certain points or matters that pertain to all of 30 CFR part 251.

Comment: Three comments cited the substantial costs that can be incurred in reprocessing existing geophysical information. One estimated costs of reprocessing exclusive 2-D data of \$5–10 million for a project of 5,000 sq. km (1,930 sq./mi.). The second comment

noted several geophysical service companies have and continue to invest vast amounts of capital in the acquisition, processing, and reprocessing of nonexclusive geophysical data; and that the annual aggregate of investments by companies in the Gulf of Mexico (GOM) and other OCS areas is in the hundreds-of-millions of dollars. A third comment stated the time involved (typically about 1 year) in reprocessing and the substantial costs that can be incurred in reprocessing existing geophysical information warrant a minimum of 10 years proprietary term extension.

Response: The MMS recognizes the significant investment that the geophysical service industry and oil and gas industry make in acquiring, licensing, processing, and reprocessing geophysical data and information; and that the competitive and economic value of these data and information continues during the proprietary period. However, only data and information that are selected and retained by MMS will be released to the public. Data and information not retained by MMS are not subject to release by MMS; therefore, the extension does not apply to data and information not retained by MMS. The MMS maintains that the original proprietary term and the 5-year extension in the proposed rule provide an adequate incentive for investing in reprocessing and the opportunity to recoup that investment.

Comment: One comment noted that all processed or reprocessed geophysical information is of value to a licensee (third party). Instances of licensees applying their own processing techniques should be considered the exception rather than the norm; Exploration and Production (E&P) companies license raw data (from permittees). It appears that MMS is failing to consider or fully appreciate that an operator must secure a license to geophysical information in order to apply those additional processing techniques. MMS states that these sophisticated processing techniques are only performed by E&P companies, an assertion and premise the commenter categorically rejects. The commenter also noted that reprocessing of geophysical information can and does occur numerous times over a number of years.

Response: The MMS recognizes that geophysical companies make significant investment in developing reprocessed geophysical information, apply advanced algorithms and other sophisticated techniques in reprocessing geophysical information for license or sale, and acknowledges the recurrence

of reprocessing during the proprietary period. Also for clarification, MMS reminds permit applicants that we issue separate geological and geophysical permits, or one of each, for a survey. The MMS does not issue a combined geological and geophysical permit, *i.e.*, there is no "G&G" permit per se.

Comment: One comment noted that the proposed rule requires filing for an extension of the proprietary term (after a 1-year grace period) within 30 days of completion of reprocessing. The commenter believes this required time is too short and recommends the required time to file for an extension should be extended to 90 days.

Response: The MMS agrees that 30 days may be an insufficient amount of time to file for an extension, and will allow permittees and third parties up to 90 days to file (see § 251.14(b)(2)). The sooner an application is filed, the sooner MMS may approve the extension.

Comment: Another comment requested that MMS not require a seismic company to apply for an extension. If MMS still requires submission of an application, then MMS should allow the seismic company to submit the application as early as the 15th anniversary of the originating permit. The commenter also stated that MMS' proposed rulemaking creates a new administrative and management burden on MMS of tracking these extensions and the geophysical data and information to which they apply.

Response: The MMS does not require a permittee to apply for an extension of the proprietary term; absent an extension, the reprocessed information would retain its 25-year term. However, an approved application is required for a permittee to get an extension of the term. Adding 5 years to the proprietary term for information reprocessed between 15 and 20 years after the permit date will not extend the term beyond the original 25-year term. Extending the term for information that is reprocessed 20 or more years after the permit date allows a sufficient amount of time for permittees and third parties to market, sell, trade, license, or otherwise use the reprocessed information, and allows MMS to keep the number of applications for an extension at a manageable level.

Comment: One comment questioned MMS' estimates of \$3 million to \$25 million in revenue over the first 5 years after the rule becomes effective, generated by licensing or selling geophysical information reprocessed 20 or more years after MMS issued the germane permit and for which MMS extended the proprietary term. The

commenter also questioned why most eligible vintage geophysical information would come from the Alaska OCS.

Response: These are revenue estimates only, expected to be in the ballpark but with a wide range. The MMS believes that the best market for this type of vintage, reprocessed geophysical information is in the Alaska OCS where little or no modern 3-D information exists and where OCS lease sales are currently scheduled. While reprocessed vintage 2-D and 3-D geophysical information in the GOM that MMS retains is eligible for 5-year extensions of the 25-year proprietary term, there is less demand as modern 2-D and 3-D information is available in most of the same areas.

Comment: One comment asked for clarification of a "germane permit." Another commenter used the term "underlying permit" in their comments.

Response: Both refer to the MMS permit under which the original raw data were collected by the permittee.

Comment: One commenter recommended MMS add to the rule definitions for *processed geophysical information* and *date of completion of reprocessing*. Another commenter recommended adding the definition of *reprocessing*.

Response: The definitions for *processed geophysical information* and *reprocessing* are already in the 30 CFR 251 regulations (see § 251.1). It appears that commenters were not clear on what definitions apply to this rulemaking. The definition for *processed geophysical information* is contained in the definition titled *processed geophysical or geological information*. The definition for *reprocessing* is also contained in that same definition—*reprocessing* is the additional processing other than ordinary processing used in the general course of evaluation. The MMS interprets date of completion to be the date that the reprocessed information first becomes available in a useable format for inhouse interpretation by MMS or the permittee, or first becomes available to third parties via sale, trade, license agreement, or other means. We revised the definition of *processed geophysical or geological information* to include this wording for date of completion. To further clarify that this revised regulation applies strictly to reprocessed geophysical information, we have added definitions for *geophysical information* and *geological information* to the rule. Also, to recognize its growing use as a major geophysical technique in the OCS, electromagnetic is added to the list of key geophysical techniques in the definition of *geophysical exploration*.

Comment: One commenter believes there is justification for greater than a 5-year term extension, stating that Brazil has a 10-year reset when data are reprocessed before they are made public.

Response: The confidentiality (proprietary) period for geophysical data/information collected offshore Brazil by data acquisition companies (similar to permittees in the U.S.) is 10 years, plus an additional 10 years if the information is reprocessed during the initial 10-year confidentiality period. In Brazil and other countries, "data" and "information" are treated the same with regards to a proprietary term. For the U.S. OCS, geophysical data has a 50-year proprietary term while processed geophysical information has a 25-year term.

Comment: The commenter strongly supports the proposed rule and urges MMS to adopt the proposed changes quickly. The proposed rule is necessary to amend changes to the final rule in 2006, which modifies the start dates of proprietary terms for geophysical data and information and any derivatives of these data. The commenter also supports provisions in the proposed rule that would allow multiple extensions up to a maximum of 50 years.

Response: The MMS believes that the proposed extension of up to 5 years of the proprietary term of geophysical information that a permittee or third party reprocessed 20 or more years after MMS issued the germane permit under which the originating data were collected, is fair and appropriate.

Comment: Another commenter similarly believes that the concept of an extension to the proprietary period for geophysical information is a much needed addition to the regulations as they currently exist after the changes enacted in 2006. The commenter contends that the proposed extension is too short and should be extended to 10 years. The proposed 5-year extension would significantly limit the value of projects conducted by geophysical contractors and processing firms, and as a result, degrade the value of preexisting information and lessen interest in applying new reprocessing techniques to older information sets. A third commenter believes that proposing an additional 5 years, while certainly appreciated, does not adequately address concerns that the commenter articulated to the MMS Director in the April 21, 2006 letter and in a June 2006 workshop with MMS. The commenter recommends an extension by MMS of no less than 7 years. The commenter states that this is a reasonable amount

of time to ensure that a seismic company will achieve a return on their investment of the reprocessed geophysical information and creates an incentive for the seismic companies to pursue and implement technological advances in processing that will certainly occur. In turn, this will minimize the need for acquiring more costly, new geophysical data that will be constrained by obstructions offshore and marine environmental concerns.

Response: The MMS maintains that the original proprietary term and the 5-year extension in the proposed rule provide an adequate incentive for investing in reprocessing and the opportunity to recoup that investment.

Comment: The commenter also suggests MMS state that the extension of the confidentiality period may be applied to other processed or reprocessed information derived from data collected under the same originating permit.

Response: The extension of the proprietary term will be determined separately for each approved application, including reprocessed information derived from data collected under the same originating permit.

Comment: Another commenter stated that the 25-year proprietary term was too long and objected to any extension of time. The commenter proposed a 10-year [basic] term with a 5-year extension for reprocessing geophysical data. If geophysical information is allowed to become public sooner, the effect would be to encourage exploration, allow the scientific community to access important information that could be valuable to research, and to give students training to be geophysicists a much more robust data set with which to hone their processing and interpretative skills.

Response: The MMS finds that an extension of the proprietary term, by up to 5 years, is appropriate. The MMS encourages geophysical service companies and E&P companies to make vintage and other geophysical information available, as soon as possible, to the science community, students, and to government agencies for research.

Comment: One commenter contends that most, if not all, processed or reprocessed geophysical information submitted to MMS includes data added as a convenience to the user that allows the user to work the data on seismic workstations. The additional data can be used by a third party to reverse-engineer the processing, allowing them to effectively obtain the raw underlying data, at which point they can apply their own processing techniques and

market products as their own. The ending result would be a total violation of a seismic company's intellectual property rights. It would also raise a question as to whether MMS has any rights to that processed geophysical data, and whether MMS has breached its obligation to hold the raw seismic data in confidence for 50 years.

Response: The MMS does not acquire processed or reprocessed geophysical information that can be reverse-engineered back to its raw data format. Most geophysical information retained by MMS has undergone stacking and migration, following previous processing steps such as demultiplexing, gain adjustments, deconvolution, amplitude and velocity analyses, normal move-out corrections, and filtering. Other geophysical information, which has not undergone migration, would still require identification of field geometry (source and receiver locations) and other parameters and filters used to collect data before attempting reverse engineering. As such, the geophysical information that MMS retains enjoys a 25-year term, not a 50-year term since it is not, nor can it become, raw data.

Comment: The same commenter suggested that MMS incorporate in the rule, a comprehensive list of the criteria the Regional Director would use to determine whether to approve or deny a seismic company's application for an extension of the confidentiality period. Without stated criteria, a seismic company would have added uncertainty/risk to account for in its analysis and determination of whether to make an investment in reprocessing geophysical information in the later years of an originating permit.

The commenter also stated that requiring an application process to obtain an extension of the confidentiality period wrongly "implies that the seismic company may somehow be able to obfuscate the regulatory requirements of the original permit, submit geophysical information that is not in fact recently reprocessed geophysical information, or submit geophysical information that is not reprocessed geophysical information."

Response: In according confidentiality to reprocessed geophysical information, MMS does not need and will not apply any criteria other than those specified in 30 CFR part 251, and in particular, the definitions of geophysical information and processed geophysical information as they appear in this rulemaking. An applicant who completes the MMS application for the 5-year extension of the proprietary term will furnish MMS all the information MMS will need to

approve the protection. The application will request such information as name and address, the area in which the information was collected, permit number, date, description of the processing performed, date of completion of reprocessing, and certification that the geophysical information meets the definition of processed geophysical information. The MMS believes that the information required on the application is relevant to its approval of a seismic company's application for an extension.

Additional Clarification Added To the Final Rule

We have added a new paragraph to § 251.14(b) to make it clear that geophysical information that is granted the extension is subject to same submission, inspection, and selection criteria under 30 CFR 251.12 and reimbursement criteria identified under 30 CFR 251.13. This paragraph clarifies the intent that the reprocessed geophysical information is treated in the same manner as other geophysical data and information collected under a permit and processed by permittees or third parties. We also clarified paragraph (3) of § 251.14(b) by explicitly stating under what conditions one may apply for an extension for a new reprocessing of permitted data.

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

This final rule is not a significant rule as determined by the Office of Management and Budget (OMB) and is not subject to review under E.O. 12866.

(1) This final rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

The MMS estimates that over the first 5 years after the rule becomes effective, revenue generated by licensing or selling geophysical information reprocessed 20 or more years after MMS issued the germane permit, and for which MMS extended the proprietary term, will be in a range from \$3 million to \$25 million over the period. More revenue will be generated in the first year during which there is a 1-year grace period to apply for extensions of proprietary terms of all eligible reprocessed information. In subsequent years, applications must be filed within 90 days of completion of processing.

The range of estimated values depends on the number of lease sales in areas where eligible vintage geophysical information exists, mostly in the Alaska OCS, the amount and quality of reprocessed geophysical information, and economic factors. The MMS assumes 15 extensions will be approved over the 5-year period after this final rule is effective.

(2) This final rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This final rule will not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This final rule will not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the priorities set forth in E.O. 12866.

Regulatory Flexibility Act

The Department of the Interior certifies that this final rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This final rule will extend the proprietary term for vintage reprocessed geophysical information. The only entities affected by this final rule change are about 10 geophysical companies, if still in existence, whose reprocessed geophysical information being held by MMS may be released later than under current regulations. The Small Business Administration classifies geophysical surveying and mapping service companies under the North American Industry Classification System Code 541360. The criteria for determining a small entity for this classification code is annual receipts of less than \$4.5 million. All of the 10 geophysical companies potentially affected by this final rule have annual receipts greater than \$4.5 million; therefore, this final rule will not have a significant economic effect on a substantial number of small entities.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of MMS, call 1-888-734-3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the

Small Business Administration will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act

The final rule is not a major rule under 5 U.S.C. 804(2) of the Small Business Regulatory Enforcement Fairness Act. This final rule:

a. Will not have an annual effect on the economy of \$100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The final rule will not have an effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this final rule does not have significant takings implications. The final rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule does not have federalism implications. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this final rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no substantial effects on federally recognized Indian tribes. There are no Indian or tribal lands in the OCS.

Paperwork Reduction Act (PRA)

This rule contains a new information collection requirement; therefore, a submission to OMB under the PRA is required. The OMB has approved the new requirement under OMB Control Number 1010-0179 (expiration 08/31/

2012; total 3 burden hours). Once the rulemaking becomes effective, we will consolidate the burden into the primary collection, 30 CFR 251, 1010-0048.

The title of the collection of information is “30 CFR part 251, Request for Geophysical Extension.” Respondents include approximately 10 Federal OCS permittees. Responses to this collection are required to obtain or retain a benefit. The frequency of reporting is on occasion. The MMS will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under

regulations at 30 CFR part 251. The information collection does not include questions of a sensitive nature.

The final regulation will allow permittees and third parties to apply for an up to 5-year extension of the 25-year proprietary term within 90 days after the date of completion of the reprocessing. This benefit adds 3 new burden hours to the information collection requirements already approved for 30 CFR part 251. The rulemaking imposes no new non-hour burden costs. Refer to the chart for the new requirement and burden.

30 CFR 251	Reporting and recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
251.14(b)(3)	Request extension of time period for permitted activities.	Burden included in 30 CFR Part 251 (1010-0048)		0
251.14(b)(1), (2), (3)	NEW: Apply for extension of the proprietary term for geophysical information within 90 days after reprocessing completion date; any subsequent extension requests.	1	3 Extensions	3
Total			3 responses	3

Based on a comment received during the proposed rule stage, MMS extended the time allowed for respondents to request an extension of the proprietary term from 30 days to 90 days after completion of reprocessing. This change did not affect the paperwork burden between the proposed and final rule.

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. The public may comment, at any time, on the accuracy of the information collection burden of our regulations and may submit comments to the Department of the Interior; Minerals Management Service; Attention: Regulations and Standards Branch; MS-4024; 381 Elden Street; Herndon, Virginia 20170-4817.

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. The MMS has analyzed this rule under the criteria of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and determined that it falls within the categorical exclusion for “regulations * * * that are of an administrative, financial, legal, technical, or procedural nature and whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis” in that it is a rule of a legal

nature. The MMS completed a Categorical Exclusion Review for this action and concluded that the rulemaking does not include an extraordinary circumstance, therefore, preparation of an environmental analysis or environmental impact statement will not be required.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106-554, app. C § 515, 114 Stat. 2763, 2763A-153-154).

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

List of Subjects in 30 CFR Part 251

Continental shelf, Freedom of information, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements, Research.

Dated: July 2, 2009.

Ned Farquhar,

Acting Assistant Secretary—Land and Minerals Management.

■ For the reasons stated in the preamble, the Minerals Management Service (MMS) amends 30 CFR part 251 as follows:

PART 251—GEOLOGICAL AND GEOPHYSICAL (G&G) EXPLORATIONS OF THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 251 continues to read as follows:

Authority: 31 U.S.C. 9701, 43 U.S.C. 1334.

■ 2. Amend § 251.1 as set forth below:

■ A. Add definitions for *Geological information*, *Geophysical data*, and *Geophysical information* in alphabetical order;

■ B. Revise the definitions for *Geophysical exploration* and *Processed geological or geophysical information*; and

■ C. Delete the definition for *Information*.

§ 251.1 Definitions.

* * * * *

Geological information means geological or geochemical data that have been analyzed, processed, or interpreted.

* * * * *

Geophysical data means measurements that have not been processed or interpreted.

Geophysical exploration means exploration that utilizes geophysical techniques (*e.g.*, gravity, magnetic, electromagnetic, or seismic) to produce data and information on oil, gas, and sulphur resources in support of possible exploration and development activities.

The term does not include geophysical scientific research.

* * * * *

Geophysical information means geophysical data that have been processed or interpreted.

* * * * *

Processed geological or geophysical information means data collected under a permit and later processed or reprocessed. Processing involves changing the form of data so as to facilitate interpretation. Processing operations may include, but are not limited to, applying corrections for known perturbing causes, rearranging or filtering data, and combining or transforming data elements. Reprocessing is the additional processing other than ordinary

processing used in the general course of evaluation. Reprocessing operations may include varying identified parameters for the detailed study of a specific problem area. Reprocessing may occur several years after the original processing date. Reprocessing is determined to be completed on the date that the reprocessed information is first available in a useable format for in-house interpretation by MMS or the permittee, or becomes first available to third parties via sale, trade, license agreement, or other means.

* * * * *

■ 3. Amend § 251.14 as set forth below:

■ A. Revise the introductory text in paragraph (b);

■ B. Revise the table in paragraph (b)(1);

■ C. Redesignate paragraphs (b)(2) and (b)(3) as (b)(7) and (b)(8), respectively; and

■ D. Add new paragraphs (b)(2), (b)(3), (b)(4), (b)(5), and (b)(6) to read as follows:

§ 251.14 Protecting and disclosing data and information submitted to MMS under a permit.

* * * * *

(b) *Timetable for release of G&G data and information related to oil, gas, and sulphur that MMS acquires.* Except for high-resolution data and information released under 30 CFR 250.197(b)(2), MMS will release or disclose acquired data and information in accordance with paragraphs (b)(1) through (b)(7) of this section.

(1) * * *

If you or a third party submit and MMS retains * * *	The Regional Director will release them to the public * * *
(i) Geological data and information, ...	10 years after MMS issued the permit.
(ii) Geophysical data, ...	50 years after MMS issued the permit.
(iii) Geophysical information processed or reprocessed less than 20 years after MMS issued the germane permit,	25 years after MMS issued the permit.
(iv) Geophysical information processed or reprocessed 20 or more years after MMS issued the germane permit,	25 years after MMS issued the permit; or, if you or a third party applied for an extension of the proprietary term, 5 years after MMS approved the application for an extension. In any case MMS will release the information no later than 50 years after MMS issued the permit.

(2) Permittees and third parties may apply to MMS for an extension of the 25-year proprietary term for geophysical information reprocessed 20 or more years after MMS issued the germane permit. You must submit the application to MMS within 90 days after completion of the reprocessing, except during the initial 1-year grace period as provided in paragraph (b)(5) below. Filing locations are listed in § 251.5(d). Your application must include:

- (i) Name and address of the permittee or third party;
- (ii) Product name;
- (iii) Identification of the geophysical information area;
- (iv) Identification of originating permit number and date;
- (v) Description of reprocessing performed;
- (vi) Identification of the date of completion of reprocessing the geophysical information;
- (vii) Certification that the product meets the definition of processed geophysical information and that all other information in the application is accurate; and
- (viii) Signature and date.

(3) With each new reprocessing of permitted data, you may apply for an extension of up to 5 years. However, the maximum proprietary term for geophysical information is 50 years after MMS issued the permit. Once the

maximum term is reached, the MMS Regional Director will release the information to the public.

(4) Geophysical information processed or reprocessed 20 or more years after MMS issued the germane permit and granted the extension will be subject to submission, inspection, and selection criteria under 30 CFR 251.12 and reimbursement criteria identified under 30 CFR 251.13.

(5) There will be a 1-year grace period, starting September 14, 2009, to allow permittees and third parties sufficient time to meet the above requirements and to apply for all eligible extensions. During this time, MMS will not release geophysical information which was reprocessed 20 or more years after the date that MMS issued the germane permit.

(6) After September 14, 2010 MMS will resume releasing eligible reprocessed information. If an application for extension is not filed, not filed on time, or not approved by MMS, the original 25-year proprietary term applies to the release date of the reprocessed geophysical information.

* * * * *

[FR Doc. E9-19198 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-MR-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2009-0460]

RIN 1625-AA08

Special Local Regulation for Marine Events; Mattaponi River, Wakema, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations during the Mattaponi Madness Drag Boat Races, a series of power boat races to be held on the waters of the Mattaponi River, near Wakema, Virginia. These special local regulations are necessary to provide for the safety of life on navigable waters during the events. This action is intended to restrict vessel traffic during the power boat races in a segment of the Mattaponi River that flows along the border of King William County and King and Queen County near Wakema, Virginia.

DATES: This rule is effective from August 15 through August 16, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble

as being available in the docket, are part of docket USCG–2009–0460 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0460 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Dennis Sens, Project Manager, Fifth Coast Guard District Prevention Division, Portsmouth, VA, telephone (757) 398–6204, e-mail Dennis.M.Sens@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On June 25, 2009, we published a notice of proposed rulemaking (NPRM) entitled Special Local Regulation for Marine Events; Mattaponi River, Wakema, VA in the **Federal Register** (74 FR 30256). We received no comments on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The potential dangers posed by high speed power boat races in a restricted waterway and in close proximity to other vessel traffic make special local regulations necessary. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the safety of the event participants, support vessels, spectator craft and other vessels transiting the event area. However, the Coast Guard will provide advance notifications to users of the affected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers.

Background and Purpose

The Mattaponi Volunteer Rescue Squad will be sponsoring a series of power boat racing events entitled the “Mattaponi Madness Drag Boat Event.” The power boat races will be held on August 15, 2009 and, in the case of

inclement weather, the event will be rescheduled for August 16, 2009. The races will be held on the Mattaponi River immediately adjacent to the Rainbow Acres Campground, King and Queen County, Virginia. The power boat races will consist of approximately 40 vessels conducting high speed straight line runs along the river and parallel with the shoreline. A fleet of spectator vessels is expected to gather near the event site to view the competition. To provide for the safety of participants, spectators and other transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the power boat races.

Discussion of Comments and Changes

The Coast Guard did not receive comments in response to the NPRM. Accordingly, the Coast Guard is establishing temporary special local regulations on specified waters of the Mattaponi River, near Wakema, Virginia.

Regulatory Analyses

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

Regulatory Planning and Review

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

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. Although this regulation will prevent traffic from transiting a portion of the Mattaponi River during the events, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notification that will be made to the maritime community via marine information broadcast, local radio stations and area newspapers so mariners can adjust their plans accordingly. Additionally, the regulated area has been narrowly tailored to impose the least impact on general navigation yet provide the level of safety deemed necessary. Vessel traffic will be able to transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so.

Small Entities

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

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

The rule will affect the following entities, some of which may be small entities: Owners or operators of vessels intending to transit the affected section of the Mattaponi River from 9 a.m. to 7 p.m. on August 15, 2009 and August 16, 2009. This rule would not have a significant economic impact on a substantial number of small entities for the following reasons. Although the regulated area will apply to a $\frac{3}{4}$ mile segment of the Mattaponi River, traffic may be allowed to pass through the regulated area with the permission of the Coast Guard Patrol Commander. In the case where the Patrol Commander authorizes passage through the regulated area during the event, vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the race course. The Patrol Commander will allow non-participating vessels to transit the area between races. Before the enforcement period, we will issue maritime advisories so mariners can adjust their plans accordingly.

Assistance for Small Entities

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

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

The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction because it establishes special local regulations under 33 CFR Part 100. An environmental analysis checklist and a

categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233.

■ 2. Add temporary § 100.35–T05–0460 to read as follows:

§ 100.35–T05–0460, Mattaponi River, Wakema, Virginia.

(a) *Regulated area.* The following is a regulated area: All waters of the Mattaponi River, from surface to bottom and shore to shore, immediately adjacent to Rainbow Acres Campground, in King and Queen County, Virginia. This area is a section of the Mattaponi River approximately ¾-mile long, bounded to the east by a line that runs parallel along longitude 076°52′43″ W near the mouth of Mitchell Hill Creek, and bounded to the west by a line that runs parallel along longitude 076°53′41″ W just north of Wakema, Virginia. All coordinates reference Datum NAD 1983.

(b) *Definitions:* (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector Hampton Roads.

(2) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Hampton Roads with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(c) *Special local regulations.* (1) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area must: (i) Stop the vessel immediately when directed to do so by any Official Patrol.

(ii) Proceed as directed by any Official Patrol.

(d) *Enforcement period.* This section will be enforced from 9 a.m. to 7 p.m. on August 15, 2009. In the case of inclement weather, this section will be enforced from 9 a.m. to 7 p.m. on August 16, 2009.

Dated: July 29, 2009.

Wayne E. Justice,

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

[FR Doc. E9-19431 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0496]

RIN 1625-AA00

Safety Zone; Hood Canal Bridge Cable Laying Operation, Hood Canal, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the vicinity of the Hood Canal Bridge due to the ongoing Hood Canal Bridge Construction Project. The safety zone is necessary to help protect construction personnel and the maritime public from the numerous dangers associated with the Hood Canal Bridge Construction Project. All persons and vessel are prohibited from entering the zone unless authorized by the Captain of the Port, Puget Sound or her Designated Representative.

DATES: This rule is effective from 6 a.m. on June 15, 2009, until 6 a.m. on September 30, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0496 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0496 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail ENS Ashley Wanzer, Waterways Management, Sector Seattle, Coast Guard; telephone 206-217-6175, e-mail Ashley.M.Wanzer@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing a NPRM would be contrary to the public interest because immediate action is necessary to ensure the safety of the construction personnel and the maritime public from the dangers associated with the Hood Canal Bridge Construction Project.

For the same reasons, the Coast Guard also finds under 5 U.S.C. 553(d)(3) that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

The Hood Canal Bridge Construction Project is a complex construction operation involving multiple construction barges and the installation of underwater cables. Due to the numerous dangers associated with such operations, the Coast Guard is establishing a temporary safety zone for the project to help protect construction personnel and the maritime public from the numerous dangers associated with it.

Discussion of Rule

The temporary safety zone established by this rule is necessary to help protect construction personnel in the Hood Canal Bridge Construction Project and the maritime public from the numerous dangers associated with the project and will do so by prohibiting any person or vessel from entering the zones unless authorized by the Captain of the Port, Puget Sound or her Designated Representative. Persons wishing to request authorization to operate within or transit through the safety zone must contact the USCG Sector Seattle Joint Harbor Operations Center at 206-217-6001. Additional information regarding the construction work may be obtained from Kiewit-General Construction Company at 360-620-3423 or the on-scene official patrol or M/V REDWOOD CITY on VHF-FM channel 13, 14, or 16.

The safety zone encompass: (1) All waters within a 100 yard radius around

any construction barge participating in the project while the barge is in operation; and, (2) all waters between any barge participating in the project and the Hood Canal Bridge itself. The safety zone will be in effect from 6 a.m. on June 15, 2009, until 6 a.m. on September 30, 2009, unless cancelled or ended sooner by the Captain of the Port or her Designated Representative.

The Captain of the Port, Puget Sound may enlist the aid and cooperation of Federal, State, or local Law Enforcement Officers to enforce the rules contained in this section pursuant to 33 CFR 6.04-11.

Regulatory Analyses

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

Regulatory Planning and Review

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

The economic impact of this temporary rule is expected to be minimal. This expectation is based on the fact that the safety zone established by this regulation will encompass small areas and be of such a short duration that the zone should not significantly impact commercial or recreational traffic.

Small Entities

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

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

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the affected waterway during the effective period.

The safety zone will not have a significant economic impact on a

substantial number of small entities for the following reasons: This rule will be in effect for a limited duration and within a limited area. The area within the zone and the surrounding waterway is not considered a critical waterway to the boating public. The Captain of the Port Puget Sound may waive any of the requirements of this rule for any vessel or class of vessels upon finding that application of the rule is unnecessary or impractical for the purposes of port security, safety, or environmental safety. The Coast Guard will give notice to the public via a Broadcast Notice to Mariners that the regulation is in effect.

Assistance for Small Entities

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

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

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a

State, local, or Tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use

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

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, because it involves the establishment of a temporary safety zone.

An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T13–092 to read as follows:

§ 165.T13-092 Safety Zone; Hood Canal Bridge Cable Laying Operation, Hood Canal, WA

(a) *Location.* The following area is a safety zones: (1) All waters of the Hood Canal, from surface to bottom, within a 100 yard radius around any construction barge participating in the Hood Canal Bridge Construction Project while the barge is in operation; and

(2) All waters of the Hood Canal, from surface to bottom, between any barge participating in the Hood Canal Bridge Construction Project and the Hood Canal Bridge itself.

(b) *Enforcement period.* This rule will be enforced from 6 a.m. on June 15, 2009, until 6 a.m. September 30, 2009, unless cancelled or ended sooner.

(c) *Regulations.*

(1) In accordance with the general regulations in 33 CFR Part 165, Subpart C, no vessel may enter, transit, moor, or anchor within this safety zone unless authorized by the Captain of the Port or her Designated Representative.

(2) "Designated Representative" means any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on her behalf.

(3) To request authorization to operate within the safety zone, contact the USCG Sector Seattle Joint Harbor Operations Center at 206-217-6001. Additional information regarding the construction work may be obtained from Kiewit-General Construction Company at 360-620-3423, or the on-scene official patrol, or M/V REDWOOD CITY on VHF-FM channel 13, 14, or 16.

Dated: June 14, 2009.

S.E. Englebert,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. E9-19434 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 223

RIN 0596-AC80

Sale and Disposal of National Forest System Timber; Downpayment and Periodic Payments

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule revises the Forest Service's downpayment and periodic payment regulations to reflect changes in contracting procedures and authorities since these regulations were

adopted in 1991. The changes remove obsolete references and procedures; make downpayments and periodic payments optional for stewardship contracts; allow downpayment and periodic payment amounts to be recalculated when contracts receive rate redeterminations; revise procedures for releasing downpayments; and allow downpayments to be temporarily reduced for certain delays, interruptions, or extensions. This final rule protects the Government's financial security, reduces speculative bidding, and encourages purchasers to harvest timber in a timely manner. In addition, the rule provides financial relief to timber purchasers when forest product prices drastically decline or purchasers receive additional contract time and are not expected to operate.

DATES: This final rule is effective September 14, 2009.

FOR FURTHER INFORMATION CONTACT:

Lathrop Smith, Forest Management staff, at (202) 205-0858, or Richard Fitzgerald, Forest Management staff, at (202) 205-1753. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The downpayment regulation (36 CFR 223.49) and periodic payments regulation (36 CFR 223.50) were adopted on July 31, 1991, (56 FR 36099) to protect the Government's financial security, reduce speculative bidding, encourage purchasers to harvest timber in a timely manner and to comply with section 2d of the Federal Timber Contract Payment Modification Act (Pub. L. 98-478, 98 Stat 2213; 16 U.S.C. 618) (Buy-out Act).¹

The downpayment regulation requires purchasers to make a cash deposit in the timber sale account at the time of sale award equal to 10 percent of the sale's total advertised value plus 20 percent of the bid premium. This cash is held by the Forest Service and cannot be used by the purchaser until (i) on scaled sales, stumpage representing 25 percent of the total bid value has been charged and paid for, or (ii) on tree measurement sales, stumpage representing 25 percent of the total bid value is shown on the timber sale statement of account to have

been cut, removed, and paid for. (36 CFR 223.49(d).)

This final rule revises 36 CFR 223.49 by: (1) Removing obsolete definitions, references and procedures; (2) making downpayments optional for stewardship contracts; (3) adding procedures to recalculate downpayments when contracts receive rate redeterminations; (4) revising procedures for releasing downpayments; and (5) adding procedures to temporarily reduce downpayments when the Forest Service authorizes or orders certain contract delays, interruptions, or extensions.

Section 223.49(b) is revised to make downpayments optional for stewardship contracts. Stewardship contracts are awarded on a best value basis, which virtually eliminates the potential for speculative bidding because factors other than price determine best value. Further, section 323 of the Department of the Interior and Related Agencies Appropriations Act of 2003 (as contained in division F of Public Law 108-7; 16 U.S.C. 2104 Note) authorizes the Forest Service to apply the value of timber or other forest products removed under a stewardship project as an offset against the cost of service work. Doing so provides financial security to the Government and incentivizes contractors to harvest timber and perform service work in a timely manner. Stewardship contracts require contractors to make cash deposits equal in value to timber they plan to cut before performing service work. To get these cash deposits back, contractors must perform the service work. Alternatively, if a contractor performs the service work first, the Government uses the value of timber the contractor harvests to offset the service work's cost. For these reasons, most stewardship contracts do not need a downpayment.

However, there can be exceptions. For example, if the value of the timber greatly exceeds the cost of services under a contract, a downpayment may be needed to provide financial security. Therefore, this final rule allows contracting officers to require downpayments on stewardship contracts when needed to ensure the Government's financial security.

This rule also revises § 223.49(c) to allow downpayments to be recalculated when contracts receive rate redeterminations. The initial downpayment amount deemed necessary to protect the Government's financial security and encourage purchasers to timely harvest timber in is based on a percentage of a contract's value at time of award. However, timber sale contracts contain procedures to redetermine stumpage rates for (1)

¹ Section 2(d) provides that "[e]ffective January 1, 1985, in any contract for the sale of timber from the National Forests, the Secretary of Agriculture shall require a cash down-payment at the time the contract is executed and periodic payments to be made over the remaining period of the contract."

environmental modification; (2) catastrophic damage; (3) Forest Service ordered suspension or delay; and (4) emergency rate redeterminations. Redetermined rates can change a contract's total value. While many contracts already provide that required deposits can be redetermined when contract rates are redetermined, the practice has not been to adjust downpayments. This final rule clarifies that downpayments should be recalculated when rates are redetermined. Allowing downpayment redeterminations maintains the government's financial security because the same percentage of downpayment to total contract value deemed necessary under § 223.49 is retained under this final rule.

In addition, this rule revises § 223.49(d) to allow downpayments to be released when they equal or exceed the value of a sale's remaining timber. Section 223.49(d)(1) was added for scaled sales and § 223.49(d)(2) was added for tree measurement sales. This change was made to prevent situations where prices on sales subject to stumpage rate adjustments decline so much that the downpayment exceeds the value of remaining timber without triggering the downpayment's release. The Forest Service never intended to hold downpayments greater than the value of remaining timber.

Finally, this rule adds § 223.49(k), which allows downpayments to be temporarily reduced when the Forest Service authorizes or orders certain contract delays, interruptions, or extensions. The Forest Service has determined that it is not necessary to require full cash downpayments when the scenarios identified in § 223.49(k) occur.

Periodic payments are "amounts specified in a contract that a purchaser must pay by the periodic payment determination date(s) unless reduced by amounts paid as stumpage for volume removed." (36 CFR 223.50(a)(4).) The initial periodic payment is equal to 35 percent of the total contract value or 50 percent of the bid premium, whichever is greater. Where an additional periodic payment is required by the contract, 75 percent of the total contract value at time of award must be paid by the second periodic payment determination date. The periodic payment(s) amount is reduced when payment would result in the purchaser's credit balance for timber charges exceeding the current contract value (36 CFR 223.50(c)). Many purchasers never receive a periodic payment bill because their stumpage payments for volume removed stay ahead of periodic payment amounts. For

purchasers that are billed, or are about to be billed, the periodic payment is an economic incentive to resume or accelerate harvesting.

This final rule revises 36 CFR 223.50 by: (1) Amending paragraph (b) to clarify that periodic payments are not required for stewardship contracts and (2) amending paragraph (f) to add procedures to recalculate periodic payment(s) amounts after contractual rate redeterminations and to remove obsolete procedures. These changes were made for the same reasons as the corresponding changes made to section 223.49.

Amendments to the Downpayment Requirements

Section 223.49 is amended as follows:

In paragraph (a)(2), the definition of *ineffective purchaser credit* is removed and paragraphs (3)–(5) are renumbered (2)–(4). Section 329 of the Department of the Interior and Related Agencies Appropriations Act, 1999 (as contained in section 101(e) of division A of Public Law 105–277; 16 U.S.C. 535a) directed, among other things, that the "purchaser credit" procedure be eliminated no later than April 1, 1999. The use of purchaser credit was discontinued in timber sales advertised after March 31, 1999, by making changes in timber sale contract provisions (File code 2450 letter to Regional Foresters dated February 19, 1999). As of March 30, 2008, only \$6,000 worth of purchaser credit was being used to cover downpayment requirements. Because no additional purchaser credit is being earned, references to ineffective purchaser credit in the downpayment regulation are obsolete and unnecessary.

In paragraph (b), the option of using effective purchaser credit is eliminated for the same reasons cited above. A sentence has also been added making downpayments optional for stewardship contracts unless needed to ensure the Government's financial security.

In paragraph (c), obsolete references to converting units of measure other than board feet to board feet have been removed. The downpayment amount is calculated as a percentage of sale value without regard to unit of measure. Paragraph (c) is further amended to include procedures to recalculate downpayments when contract rates are redetermined.

Paragraph (d) is amended to allow downpayments to be released when the estimated value of remaining timber is less than the downpayment. Paragraph (d)(1) is added for scaled sales and paragraph (d)(2) is added for tree measurement sales.

Paragraph (g) is amended to allow contracts subject to paragraph (e)'s higher downpayment requirement to have their downpayments recalculated when stumpage rates are redetermined. This change was made for the same reasons as the changes to paragraph (c). In addition, paragraphs (g)(1) and (2) are removed to eliminate obsolete references to ineffective purchaser credit and converting units of measure other than board feet to board feet. The removal of those paragraphs was made for the same reasons as the deletions made in paragraph (a)(2).

Paragraph (j) is amended to specify that the Chief of the Forest Service may preclude temporary downpayment reductions under paragraph (k)(2) and (3) to deter speculation.

Paragraph (k) is added to allow temporary downpayment reductions when a contractor is not cutting or removing timber because its scheduled operations were delayed, interrupted, or extended for 30 consecutive days or more for any of the following reasons: (1) Forest Service requested or ordered delay or interruption of operations for reasons other than breach; (2) a contract term addition pursuant to contractor shifting operations to a sale designated by the Forest Service as in urgent need of harvesting; or (3) a contract term extension authorized upon a determination of substantial overriding public interest, including a market-related contract term addition, or urgent removal contract term extension under 36 CFR 223.53.

Paragraph (l) is added to allow downpayments to be reduced to the greater of \$1,000 or two percent of the amount stated in the contract during qualifying periods of delay, interruption, or extension under paragraph (k), unless the purchaser is cutting or removing timber. Purchasers cannot cut or remove a contract's timber until the downpayment stated in the contract is restored.

Amendments to the Periodic Payment Requirements

Section 223.50 is amended as follows:

Paragraph (b)(3) is added to clarify that not all stewardship contracts require periodic payments. Paragraph (f) is amended to remove obsolete contract modification procedures and add procedures to recalculate periodic payment(s) amounts following a contract rate redetermination authorized. The obsolete procedures being removed required pre-1991 contract purchasers to make a written request by 1991 to receive market-related contract term additions.

Agency Response to Major Public Comments

On October 29, 2008, the Forest Service published a notice of proposed rule and request for comment on revisions to 36 CFR 223.49 and 223.50 in the **Federal Register** (73 FR 64288). During the comment period, which ended December 29, 2008, the Forest Service received 4 comments responsive to the rule's merits and 2 non-responsive comments. The four responsive comments were from the Federal Timber Purchasers Committee, Westek Forest, Ltd., New Hampshire Timber Owners Association, and the Wilderness Society. Following are the Forest Service's responses to those comments.

Comment 1: We believe the proposed changes to the downpayment regulation are well designed and will help timber purchasers with cash management in these difficult markets.

Response 1: This is a statement for which no response is necessary.

Comment 2: We urge you to act expeditiously to give timber purchasers as much relief as possible in order to keep them viable and preserve options for the management of the National Forests.

Response 2: This is a statement for which no response is necessary.

Comment 3: I agree with the proposed rule change. This change will give contractors better flexibility to complete stewardship contracts.

Response 3: This is a statement for which no response is necessary.

Comment 4: Nationwide, the forest products industry is undergoing extreme stress due to reduced demand for forest products, lower prices, and increased costs of production. It does the American people no good to force wood producers into bankruptcy or to deal with timber sale contracts that cannot be operated profitably under current market conditions. If these sale contracts are cancelled and the timber reoffered, it would not sell or would only bring greatly reduced prices. This process would be expensive and yield no positive results. We have reviewed the proposed rules and agree that they would have an overall positive effect on the Forest Service timber sale program and are in the best interest of the people of the United States.

Response 4: These are statements for which no response is necessary.

The remaining comments were from a single respondent prefaced by the statements that (1) significant information necessary to fully understand the proposed rule and prepare informed comments is missing

and (2) the **Federal Register** notice proposes significant changes in the amount and requirements for downpayments and periodic payments yet the basic facts and conditions that have caused the agency to pursue these rule changes are undisclosed. Unless otherwise noted, no changes were made in response to the following comments.

Comment 5: The Forest Service states a desire to lower the risk of timber contract default. This would not be proposed unless default was a significant problem. What is the rate and percentage of default in the last five or ten years and over the past 12 months? What is the projected rate of default based on current market conditions?

Response 5: The Forest Service does not track defaults so it can not calculate a percentage of defaults over a five or ten year period. Although snapshots of the timber sale accounting system can be taken to determine the number of contracts coded as defaulted on specific dates, the system can not tally the number of defaults over a period of time.

On March 31, 2009, the Forest Service had 1,972 open contracts on forms FS-2400-6 and FS-2400-6T. Twenty-three of those contracts or 1.2 percent were coded in the timber sale accounting system as defaulted. On March 31, 2008, there were 1,961 open contracts on those same forms; 24 or 1.2 percent were coded as defaulted. Sales on other contract forms were not included in these calculations because the Forest Service is not aware of any other types of open contracts subject to this final rule.

A projected default rate based on current market conditions would only be an unsubstantiated estimate subject to dispute. However, it is reasonable to predict that when purchasers are forced to cease operating due to adverse market conditions, uncompleted contracts are at an increased risk of default. An objective of the final rule is to lower default risk by adjusting downpayments to reflect drastic declines in contract values and temporarily reducing downpayments when appropriate. These changes are expected to help purchaser cash flow, which may help them continue operating and/or purchasing contracts.

Comment 6: The Forest Service recently described over 1,000 agency timber sales as eligible for market-related contract term additions (MRCTA). All would then be eligible for downpayment and periodic payment redeterminations.

Response 6: The MRCTA procedures do not include a mechanism for

redetermining contract rates. Therefore, a sale's eligibility for MRCTA does not mean it will receive a rate or periodic payment redetermination. On March 31, 2009, the Forest Service had approximately 615 sales eligible for downpayment and periodic payment redeterminations under this rule. Of those 615 sales, only 199 still had downpayments on deposit, for a total value of \$6.8 million. Without looking at the statement of account for each one of those contracts, it is not possible to assess each contract's periodic payment status.

Comment 7: How many sales would be eligible for redetermination under the three clauses (environmental modification, catastrophic damage and emergency rate determination)? What percentage of sales does this represent? How often do these cases occur?

Response 7: The commenter is asking the Forest Service to quantify where and when unpredictable events such as natural disasters may occur in the future. Any attempt to do so would be purely speculative. However, we do know that on March 31, 2009, there were 1,972 open sales and 615 or 31 percent were potentially eligible for emergency rate redeterminations. Of those 615 sales, only 199 still had downpayments on deposit in the amount of \$6.8 million.

Comment 8: The Forest Service retains authority to set larger downpayment amounts and proposes to limit redeterminations in geographic areas where speculation has or could occur. Where has the agency set larger downpayments in the past? How does the agency recognize when speculation is occurring?

Response 8: The Forest Service uses appraisal performance reports, Forest Service Manual (FSM) 2422, and Bid Monitoring Reports, FSM 2432.52, to identify speculative bidding. The agency has not increased downpayments pursuant to the authority in 36 CFR 223.49(c).

Comment 9: The agency states: "Further, the Forest Service has determined that the benefits of temporarily reducing downpayments under 223.49(k) outweigh the potential increased risks to the government's financial security." **Federal Register**, Volume 73, No. 210, page 64,290. Please provide a copy of the analysis that led to this determination.

Response 9: The Forest Service has closely monitored the drastic decline in forest product markets since late 2004. As the market decline deepened, reports in the national press, trade bulletins, (such as Random Lengths, TDC Stumpage Price Report, WWPA

Barometer and others), as well as discussions with individual purchasers and representatives from industry associations, provided information about falling prices and a growing number of mill closures. Despite the current decline's severity, the default rate on open sales has been less than 1.25 percent over the last two years. The Forest Service believes this relatively low default rate, in the face of extreme market turmoil, is the result of several successful proactive measures it has taken to avoid the widespread defaults seen in the 1980s. These measures include (1) market-related contract term additions; (2) additional contract time authorized under the November 2006, November 2007, and September 2008 findings of substantial overriding public interest; (3) emergency rate redeterminations; and (5) contract cancellations, rate redeterminations, and extensions authorized by the 2008 Farm Bill. Despite the apparent success of these measures, forest product markets have continued to worsen, leading the Forest Service to conclude that this rule is needed to further reduce the risk of defaults. After careful consideration, the Forest Service determined that the benefits of further reducing potential defaults and their associated costs outweigh any potential increased risks to the government's financial security created by this rule.

This determination was made based on extensive oral discussions among the Washington Office's Forest Management staff. The Forest Management staff considered the following factors: (a) Deteriorating market conditions; (b) procedures to temporarily reduce downpayments when the Forest Service orders a delay or interruption for environmental reasons are already part of all post-April 2004 contracts; (c) existing administrative authority to change the rule to achieve its intended effect; (d) concern that these changes are needed to prevent the loss of industry infrastructure; (e) concern that costs to the government of treating vegetation under service contracts exceeds the costs of doing so under timber sale contracts; (f) general knowledge that most defaults occur after the downpayment has been released; (g) general knowledge that cash flow is critical to sustained operations for timber purchasers, and tying up money in downpayments on sales the Forest Service is not expecting purchasers to operate until market conditions improve obligates cash that may be needed elsewhere; (h) general knowledge that purchasers' fixed costs, including payments on equipment, continue even

if a purchaser isn't operating; (i) industry requests; and (j) in the event a contract defaults while the downpayment has been temporarily reduced, the government can still apply the performance bond to damages.

Since the analysis of market conditions that led to the proposed rule, the Forest Service has learned that housing starts in April 2009 hit a record low down almost 80 percent from the peak in January 2006; greatly exceeding the 46 percent decline during the 1981 downturn and the 60 percent decline in the 1986–1991 period.² U.S. Census Bureau data shows privately-owned housing starts in April were at a seasonally adjusted annual rate of 458,000 which is 12.8 percent below the revised March estimate of 525,000 and is 54.2 percent below the revised April 2008 rate of 1,001,000.³ Adding to this dismal picture, a Western Wood Products Association (WWPA) March 24, 2009, news release predicted that the poor economy and a weak housing market are expected to reduce demand for lumber in the U.S to the lowest level in modern history.⁴ The article notes that since reaching an all-time high of 64.3 billion board feet in 2005, U.S. demand for lumber has dropped by more than 55 percent representing the steepest decline in the history of the industry. While home construction which accounts for about 45 percent of the lumber used each year is predicted to increase slightly in 2010 to a little over a half million, WWPA does not expect housing starts to exceed 1 million units until 2012.

Another measure of the drastic decline in lumber prices is the Bureau of Labor Statistics index for softwood lumber. The Forest Service monitors this index to determine when drastic declines in forest products prices sufficient to trigger granting Market-Related Contract Term Additions pursuant to 36 CFR 223.52 occur. The softwood lumber index began declining in the 3rd calendar quarter of 2004 and beginning with the 3rd quarter of 2005 began triggering Market-Related Contract Term Additions. Through the first quarter of calendar year 2009 the softwood index, after adjustments to a constant dollar basis, has lost about 49 percent of its value and has triggered

² USA Today, May 20, 2009, *Record-low housing starts in April cast pall over market*, by Julie Schmidt.

³ NEW RESIDENTIAL CONSTRUCTION IN APRIL 2009, U.S. Census Bureau News, Joint Release, U.S. Department of Housing and Urban Development, May 19, 2009; <http://www.census.gov/const/newresconst>.

⁴ Western Wood Products Association, news release, Robert Bernhardt, Jr. Information Services Director, March 24, 2009.

Market-Related Contract Term Additions an unprecedented 15 consecutive quarters. The previous greatest decline of the softwood lumber index was in the early 1980s when it lost about 36 percent of its value and would have triggered 12 consecutive quarters of Market-Related Contract Term Additions if the procedure had been in place at that time. The softwood lumber index hit its lowest point yet in March 2009, and showed a slight increase in April 2009, but it is too early to tell if the April increase marks the beginning of a recovery.

The data and predictions indicate that while the decline in demand for lumber may be at or near bottoming out, the recovery will be long and gradual. Meanwhile the agency has been routinely receiving reports of sawmills curtailing operations or permanently closing. The Forest Service accomplishes many of its vegetation management objectives through timber sale contracts, which enables the Forest Service to achieve its objectives while generating revenues. A large pool of timber sale purchasers allows the Forest Service to accomplish these objectives in a more cost-effective manner by increasing competition for National Forest System timber sales, which can result in higher contract prices. Absent a viable industry infrastructure capable of purchasing and processing Forest Service timber, the Forest Service would have to pay service contractors to perform certain vegetative management objectives currently achieved by selling timber. This would substantially reduce the Agency's ability to accomplish important management objectives such as reducing hazardous fuels in wildland urban interface areas where much of the work must be performed by mechanical means and can often be done with timber sales.

Temporarily reducing downpayments is unlikely to prevent or reduce defaults by itself. However, in conjunction with other relief measures, it is expected to provide short-term relief that will help reduce the number of defaults and loss of industry infrastructure that might occur in its absence. Specifically it will free up cash purchasers need for a variety of reasons including (1) harvesting sales that are operable in this economic climate, (2) storing increasing inventories of lumber until demand picks up, (3) making payments on equipment, and (4) maintaining bonds on existing sales.

On March 31, 2009, the Forest Service had 1,972 open contracts on forms FS-2400-6 and FS-2400-6T. Twenty-three of those contracts or 1.2 percent were coded in the timber sale accounting

system as defaulted. Only five of the default sales still had downpayments on deposit, which totaled \$101,300; less than 1 percent of the \$26.1 million total value of downpayments on deposit. One year earlier, on March 31, 2008, there were 1,961 open contracts of which 24 or 1.2 percent were coded as defaulted; 5 of the defaults still had downpayments on deposit in the amount of \$100,600.

Considering the above-referenced factors, the Forest Service determined that the benefits of temporarily reducing downpayments under 223.49(k) outweigh the potential increased risks to the government's financial security.

Comment 10: This and previous **Federal Register** notices on market-related contract term additions and substantial overriding public interest (SOPI) determinations describe the government's reasons for wanting to maintain numerous economically viable timber sale purchasers. These include having a pool of contractors in situations where the Forest Service determines that timber is in need of urgent removal. But the definition of "urgent removal" at 36 CFR 223.53 applies only to private and other non-National Forest System (NFS) lands. The context for the term here and in the market-related contract term addition/substantial overriding public interest (SOPI) **Federal Register** notices imply that the term refers to NFS lands. Please provide the regulatory cite that allows the Forest Service to shift contract operations to a NFS sale in urgent need of harvesting as described on page 64,290 of the **Federal Register** notice.

Response 10: The authority is in 36 CFR 223.112, Modification of contracts. Implementation procedures are documented in Forest Service Handbook 2409.18, section 55.21. In addition, please see the response to comment 11.

Comment 11: It is unclear how exactly the agency defines "urgent" projects in each context, the conditions under which it is applied or how the Forest Service maintains consistency in the application of this term throughout the national forest system (NFS). This lack of clarity would then affect who is potentially eligible for downpayment and periodic payment redeterminations. The term and its application here should be defined.

Response 11: The determination of whether timber in a specific sale or project is in urgent need of removal is a decision the Forest Service makes on a case-by-case basis after considering the relative conditions on the ground. Indicators of a sale in urgent need of

removal include, but are not limited to situations where:

1. Dead or dying timber is subject to rapid deterioration;
2. Failure to harvest the timber promptly could threaten public safety. For example, removing hazardous trees along public roads.
3. Failure to harvest the timber promptly could create an insect disease epidemic on National Forest system lands or other lands or resources.

The Forest Service is currently drafting an amendment to chapter 50 of the sale preparation handbook, FSH 2409.18, that will provide land managers with more specific guidance to determine when a sale contains timber in urgent need of removal.

Comment 12: The proposed rule language at 36 CFR 223.49(c)(4) and 223.49(g)(4) lists "an emergency rate redetermination" as a reason for contract downpayment redetermination. But we can find no definition of the term "emergency rate redetermination."

Response 12: Emergency rate redetermination is a procedure addressed in standard timber sale contract provisions (B/BT3.34) and standard integrated resource timber contract clauses (D/DT.3.4) for adjusting rates when the Bureau of Labor Statistics Producer Price Index stated in the contract declines by 25% or more after the contract award date.

Comment 13: If the Forest Service is referring to "urgent removal" (as defined at 36 CFR 223.53) in its use of the emergency rate redetermination clause, then it should clearly state so and disclose to the public that downpayment and periodic payment reductions would be granted to allow timber companies to pursue harvest on private and non-National Forest System (NFS) lands.

Response 13: Prior to authorizing urgent removal contract extensions pursuant to 36 CFR 223.53, a Regional Forester must make a determination that there is a substantial overriding public interest in extending National Forest System timber sale contracts for undamaged (green) timber not requiring expeditious removal in order to facilitate the rapid harvest of catastrophically damaged timber requiring expeditious removal on private and other non-National Forest System lands. Similarly Forest Service policy is to grant contract term adjustments on certain timber sale contracts for undamaged (green) timber not requiring expeditious removal in order to facilitate the rapid harvest of other National Forest System timber in urgent need of harvesting (FSH 2409.18, § 55.21).

Contract provision B/BT3.34 does not permit emergency rate redeterminations for contracts receiving contract term extensions pursuant to 36 CFR 223.53. The contract permits, however, emergency rate redeterminations to facilitate the rapid harvest of National Forest System timber and the urgent removal harvesting. This is done pursuant to provision B/BT8.21. However, the Forest Service may modify timber sale contracts in accordance with 36 CFR 223.112. In response to the severity of the current market conditions, and in the interest of preventing further erosion of the timber industry infrastructure, the Forest Service is currently modifying rates on contracts extended pursuant to 36 CFR 223.53 to allow emergency rate redetermination procedures when requested by purchasers. Contracting Officers should not modify contracts that are in breach and shall seek Washington Office advice prior to modifying contracts that are determined to be at high risk for default. For much the same reason this rule allows temporary reductions in downpayments when a timber purchaser receives additional time to harvest timber in urgent need of removal on non-NFS lands pursuant to 36 CFR 223.53.

This rule does not modify emergency rate redetermination procedures.

Comment 14: We believe the Forest Service should make concurrent changes in its National Environmental Policy Act (NEPA) procedures in order to reduce the need for downpayment and periodic payment redeterminations and ensure that important resource management goals are being met.

Response 14: Changes to NEPA procedures recommended by the commenter are not responsive to the merits of the rule.

Comment 15: Stating that the proposed rule only changes the amount of the downpayment is the wrong lens through which to view environmental impacts. While downpayments may have been required for many years, the proposed reductions to just 2% of the downpayment or \$1000.00 whichever is greater while still holding the contract is significant and unprecedented. This would expose the Federal government to significant financial risk. The agency states their belief that this will not result in an increase in speculative bidding and that the benefits will outweigh the potential increased risks to the government's financial security. No evidence for these assertions is presented.

Response 15: This comment pertains to the rule's procedures to temporarily reduce downpayments when contracts

are delayed, interrupted or extended for reasons listed in § 223.49(k). Contrary to the commenter's assertion that this is significant and unprecedented, timber sale contract forms FS-2400-6 and FS-2400-6T dated April 2004 and later already allow temporary downpayment reductions when the Forest Service orders certain delays or interruptions. This rule expands this existing process to include situations where the downpayment's economic inducement to operate is not warranted.

The agency believes these temporary reductions will not increase speculative bidding because nothing in the final rule removes the downpayment requirement at time of award. Once deposited, the downpayment can not be temporarily reduced unless one of the three conditions specified in the rule occurs. Therefore, speculative bidders must speculate that the market will rise above overbids and that at least one of the conditions allowing temporary downpayment reductions will occur. Even if that happened, the downpayment still has to be reestablished before the sale can be operated. Considering these safeguards, the Forest Service concluded the rule was unlikely to increase speculative bidding.

Nevertheless, the Forest Service will continue to monitor bidding patterns and the agency will deny temporary downpayment reductions where speculative bidding is occurring. In response to this comment, the final rule has been revised to clarify that requests for temporary downpayment reductions may be denied in market areas where the Chief determines speculative bidding is occurring.

Comment 16: For the reasons cited in our response, we believe the Forest Service has failed to follow proper procedures in proposing this rule without analysis under the National Environmental Policy Act (NEPA). We believe that changes in the Forest Service Handbook (FSH), Forest Service Manual (FSM) and agency NEPA analysis of economic effects as we detailed would fulfill agency requirements for this proposed rule under NEPA. We urge the agency to consider them in completing the required regulatory certification of environmental impact for the proposed rule.

Response 16: The changes in the FSH, FSM and agency NEPA analysis of economic effects provided by the commenter are not responsive to the merits of the rule. Furthermore, this final rule is categorically excluded under 36 CFR 220.6.

Comment 17: Because commercial sales are now most often regarded as a tool to meet management objectives and not the objective or purpose and need itself, the effect of possible contract extensions (and subsequent downpayment and periodic payment redeterminations) must be analyzed under NEPA in determining the ability of commercial sales (for each alternative that uses this tool) to meet the purpose and need. We do not think this would entail undue burden on the agency given current and suggested procedures.

Response 17: Please see the response to comment 16.

Comment 18: Commenter presented a series of comments questioning agency NEPA procedures for forest management projects and proposing changes to those procedures.

Response 18: These comments are beyond the final rule's scope and are nonresponsive to its merits.

Comment 19: National Forest System (NFS) lands supply a very small percentage of the U.S. timber supply (< 4% according to recent estimates). A seemingly small percentage of Forest Service timber sale contracts (eligible for downpayment and/or periodic payment redetermination) multiplied by a small percentage of the timber supply means a very small percentage of the U.S. timber supply would be affected by this proposed rule. As described above, the Forest Service should disclose the total number of timber sale contracts eligible for downpayment and periodic payment redeterminations in order to assess the full impact of the proposed rule and its financial (and other) effects. The notion that failure to enact this change will affect the U.S. timber industry is not credible—the amount or value of timber involved simply is not large enough to be important.

Response 19: On March 31, 2009, the Forest Service had 1,972 sales on contract forms FS-2400-6 and FS-2400-6T. The remaining value of those sales was \$249.1 million. Of those sales, 615 or 31 percent were potentially eligible for emergency rate redeterminations. Only 199 of those 615 still had downpayments on deposit, in the amount of \$6.8 million. Although the data base could not be queried to show how many sales eligible for emergency rate redeterminations are also eligible for periodic payment redeterminations, it would be less than 615.

The commenter is correct that the number of Forest Service contracts eligible for downpayment and periodic payment redeterminations is small and failure to enact the rule is unlikely to significantly affect the U.S. timber

industry. However, the rule's effect may be significant for individual purchasers on the brink of closure; with unemployment rates continuing to increase at alarming rates, preventing or reducing job losses is a national issue.

One respondent commenting on this rule wrote that the forest products industry sector of New Hampshire's economy is vibrant and is the third largest sector of manufacturing in the Granite State, employing over 9,500 people directly with an annual payroll over \$320 million. The respondent also stated that high quality timber from the White Mountain National Forest provides an important raw material source.

Further, a June 2008 report by the University of Minnesota-Deluth Labovitz School's Bureau of Business and Economic Research addressed the economic impact of declines in forestry-related industries in Minnesota, Wisconsin and Michigan. (https://lsbe.d.umn.edu/departments/bber/bber_projects.php). The report documented that, in 2006, forestry related industries in the study area employed over 58,000 workers and estimated that for every worker laid off another 2.2 jobs were lost in the economy. The collapsing timber industry in this three State region provided the impetus in the 2008 Farm Bill, Section 8401 of the Food, Conservation, and Energy Act of 2008, Public Law 110-246, 122 Stat. 1651, granting additional contract time and price relief to qualifying contracts. While the National Forest System's contribution to the national timber supply may not be significant, it is an important component and in some areas it is the primary source.

Comment 20: The terms of the proposed rule would allow companies to bid on and hold National Forest System timber sales for future harvest while receiving most of their downpayment back for a number of loosely defined reasons.

Response 20: As noted previously, this final rule requires purchasers to make downpayments at time of award and only allows temporary reductions when the conditions specified in section 223.49(k) are met. Once those conditions cease to exist, purchasers must restore their downpayments.

Comment 21: The proposed rule change has been justified in part on the basis of community stability and economic health. This is dubious at best. It is questionable whether this rule will make a difference even in local or regional markets. It has been clear for years that supplying timber to local mills is an ineffective (at best) strategy

for supporting sustainable local economic development. (Rasker, R., Gorte, J. F., and Alkire, C. 1996. *Logging National Forests to Create Jobs: An Unworkable Covenant*, Washington, DC: The Wilderness Society.) The Forest Service should analyze the socio-economic costs associated with an historic emphasis on resource extraction, which has resulted in repetitious cycles of socio-economic distress for rural communities. The extractive industries, including the timber industry, represent an ever smaller portion of the total jobs and income in rural counties. The relative importance of these industries compared to expanding industries in the professional and service sectors and those which depend on non-labor income must be acknowledged.

Response 21: The Forest Service agrees that communities with a broad economic base tend to be more stable than those dependent on a single business. But a socio-economic analysis isn't needed to demonstrate that the loss of jobs has adverse economic effects, especially in small rural communities. With rising unemployment rates, any loss of jobs, regardless of business sector or community size, has a negative effect on communities where lost jobs are located. Arguing that the Forest Service program is insignificant when looking at the industry or the country as a whole and downplaying the importance of jobs in extractive industries ignores the significance of those jobs to affected individuals and communities. To the extent that this rule reduces defaults, it is also expected to help reduce job losses.

Comment 22: What is not fully discussed or disclosed is the extent of possible financial risk and exposure accruing to the Federal government, and to taxpayers, from these proposed changes, especially during extensive market downturn as is the case today.

Response 22: Any estimate or prediction of future defaults or specific damage amounts associated with them would be highly speculative and subject to challenge. The October 29, 2008, **Federal Register** notice (73 FR 64288) discussed the financial risks of the proposed changes in relative terms. In addition, data pulled from the timber sale accounting system on March 31, 2009, showed 1,972 open contracts, of which 23 were coded as defaulted. The defaulted contracts had a remaining value of \$18.3 million and performance bonds totaling about \$2.5 million. Only five of the defaults still had downpayments on deposit when they defaulted, in the amount of \$101,300. By comparison, on March 31, 2008,

there were 1,961 open contracts of which 24 or 1.2 percent were coded as defaulted. The 24 defaulted sales had performance bonds totaling about \$4.4 million; only 5 still had downpayments on deposit in the amount of \$100,600. Had this final rule been in effect when those contracts defaulted, the potential loss to the government of reduced downpayments could have equaled the reduced downpayment amounts. However, that estimate is a worst-case scenario based on the assumption that every defaulting contractor had (1) a temporarily reduced downpayment, (2) insufficient bonding to cover default damages, and (3) an inability to pay applicable damages, including those ordered by a Federal court. Such an outcome is unlikely.

Although the Government may potentially lose some financial security under this rule, the Forest Service believes this risk is outweighed by the benefits associated with averting potential defaults. Given the above data, the factors addressed in response 9, and default costs to the Forest Service, industry, and timber-dependent communities, the agency believes the potential risks associated with this rule are justified.

Comment 23: Citing the ability of potential contractors to bid on yet more Federal (and private) sales would only seem to increase Federal exposure to risk. Continued market downturn would result in continued downpayment and periodic payment redetermination. Examining the need for timber sales in the first place and other possible methods to accomplish the purpose and need for vegetation management projects would seem a more prudent and less fiscally risky approach.

Response 23: Contracting officers are required under 36 CFR 223.101 to make an affirmative determination of a purchaser's responsibility prior to awarding a contract. When conducting a responsibility determination, consideration is given to the purchaser's financial ability to complete the contract while taking into account all of the purchaser's commercial and governmental business commitments. This process limits the government's risk.

When proposing vegetation management projects, the Forest Service considers alternatives to timber sale contracts for accomplishing the necessary work, including stewardship contracts, procurement contracts, agreements, and using its own employees.

Comment 24: The commenter presented a series of comments pertaining to questions of the effect of

the proposed rule on other costs associated with timber harvest and suggested that there is research providing compelling evidence for maintaining lands in their protected state and/or for treating vegetation with methods other than timber sales.

Response 24: These comments are beyond the scope of this rule and were deemed nonresponsive to the rule's merits.

Conclusion

This final rule revises the Forest Service's downpayment and periodic payment regulations to reflect changes in contracting procedures and authorities since these regulations were adopted in 1991. The rule will protect the Government's financial security, reduce speculative bidding, and encourage purchasers to harvest timber in a timely manner. In addition, the rule provides financial relief to timber purchasers when forest product prices drastically decline or purchasers receive additional contract time and are not expected to operate.

Regulatory Certifications

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. The Office of Management and Budget (OMB) has determined that this is not a significant regulatory action and is not subject to OMB review. This rule will not have an annual effect of \$100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local Governments. This rule will not interfere with an action taken or planned by another agency nor raise new legal or policy issues. This rule consists of technical administrative changes to regulations affecting the administration of commercial timber sales on National Forest lands. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. Accordingly, this final rule is not subject to OMB review under Executive Order 12866.

Regulatory Flexibility Act

This final rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), and it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This rule makes only technical administrative changes to existing

regulations affecting the administration of certain commercial timber sales on National Forest System land. The final rule imposes minimal additional requirements on all timber purchasers while providing economic relief from current market conditions. The information required is easily within the capability of small entities to produce.

Unfunded Mandates Reform

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995, which the President signed into law on March 22, 1995, the Department has assessed the effects of this rule on State, local, and Tribal Governments and the private sector. This final rule does not compel the expenditure of \$100 million or more by any State, local, or Tribal Government or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Environmental Impact

The agency's preliminary assessment is that this rule falls within 36 CFR 220.6, which excludes from documentation in an environmental assessment or impact statement "rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions" that do not significantly affect the quality of the human environment. This final rule establishes uniform criteria to temporarily reduce or change timber sale downpayments and periodic payments. This rule does not change the longstanding requirement that timber sale contracts include downpayments and periodic payments. Implementation of this rule will be controlled at the local level by the Timber Sale Contracting Officer. This final rule falls under 36 CFR 220.6(d)(2), which excludes from documentation in an environmental assessment or impact statement "rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions" that do not significantly affect the quality of the human environment.

No Takings Implications

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630. It has been determined that the rule does not pose the risk of a taking of private property. There are no private property rights to be affected because the rule applies to commercial timber sale on National Forest lands.

Civil Justice Reform Act

This final rule has been reviewed under Executive Order 12988, Civil

Justice Reform. If this rule were adopted, (1) all State and local laws and regulations that are in conflict with this rule or which would impede its full implementation would be preempted; (2) no retroactive effect may be given to this rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Controlling Paperwork Burdens on the Public

This final rule does not contain any record-keeping or reporting requirements or other information collection requirement as defined in 5 CFR Part 1320, Controlling Paperwork Burdens on the Public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

List of Subjects in 36 CFR Part 223

Administrative practice and procedures, Exports, Forests and forest products, Government contracts, National Forests, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, Part 223 of Title 36 of the Code of Federal Regulations is amended as follows:

PART 223—SALE AND DISPOSAL OF NATIONAL FOREST SYSTEM TIMBER

■ 1. The Authority citation for Part 223 continues to read as follows:

Authority: 90 Stat. 2958, 16 U.S.C. 472a; 98 Stat. 2213; 16 U.S.C. 618, 104 Stat. 714–726, 16 U.S.C. 620–620j, unless otherwise noted.

Subpart B—Timber Sale Contracts

■ 2. Revise § 223.49 to read as follows:

§ 223.49 Downpayments.

(a) For the purposes of this section, the terms listed in this paragraph shall have the following meaning:

(1) *Total bid value* is the sum of the products obtained by multiplying the rate the purchaser bid for each species by the estimated volume listed in the contract.

(2) *Bid premium* is the amount in excess of the advertised value that a purchaser bids for timber offered.

(3) *Lump sum timber sales* are premeasured sales where the entire value of the sale is paid in one payment at time of release for cutting.

(4) *Affiliate*. Concerns or individuals are affiliates if directly or indirectly, either one controls or has the power to control the other, or a third party controls or has the power to control

both. In determining whether or not affiliation exists, the Forest Service shall consider all appropriate factors, including, but not limited to, common ownership, common management, and contractual relationships.

(b) Timber sale contracts shall include provisions that require purchasers to make a downpayment in cash at the time a timber sale contract is executed, except that a downpayment is not required for stewardship contracts unless the contracting officer determines that a downpayment is needed to ensure the government's financial security.

(c) The minimum downpayment shall be equivalent to 10 percent of the total advertised value of each sale, plus 20 percent of the bid premium, except in those geographic areas where the Chief of the Forest Service determines that it is necessary to increase the amount of the downpayment in order to deter speculation. The amount of the downpayment shall be redetermined when contract rates for timber are redetermined under the terms of the contract for environmental modification; catastrophic damage; market change; or an emergency rate redetermination. For the purpose of recalculating the minimum downpayment, total advertised value shall be replaced with total redetermined value.

(d) A purchaser cannot apply the amount deposited as a downpayment to cover other obligations due on that sale until:

(1) On scaled sales, stumpage value representing 25 percent of the total bid value of the sale has been charged and paid for, or the estimated value of unscaled timber is equal to or less than the amount of the downpayment; or

(2) On tree measurement sales, stumpage value representing 25 percent of the total bid value of the sale is shown on the timber sale statement of account to have been cut, removed, and paid for, or the estimated value of timber remaining to be cut, removed and paid for as shown on the timber sale statement of account is equal to or less than the amount of the downpayment. On lump sum sales, the downpayment amount may be applied to payment for release of the single payment unit.

(e) A purchaser or any affiliate of that purchaser awarded a Forest Service timber sale contract must meet the additional downpayment requirements of paragraph (g) of this section under the following circumstances:

(1) The purchaser or its affiliate after September 29, 1988, has failed to perform in accordance with the terms of a Forest Service or Bureau of Land

Management timber sale contract and is notified by a Contracting Officer that a contract has expired uncompleted or is terminated for cause; and

(2) The estimated value of the unscaled timber on scaled sales, or the estimated value of the timber outstanding on tree measurement sales, included in those terminated or expired contracts exceeds \$100,000; and

(3) Unpaid damages claimed by the Government remain outstanding prior to award of the new sale at issue and corrective action has not been taken to avoid future deficient performance.

(f) A subsequent final determination by the Contracting Officer or by a court of competent jurisdiction that a contract was improperly classified under the criteria in paragraph (e) of this section will result in the refund or credit of any unobligated portion of the amount of downpayment exceeding that required by paragraphs (c) and (d) of this section and the limitations of paragraph (h) of this section on application of downpayment shall no longer apply.

(g) Notwithstanding the provisions of paragraphs (c) and (d) of this section, a purchaser meeting the criteria of paragraph (e) of this section must make a minimum downpayment equal to 20 percent of the total advertised value of that sale, plus 40 percent of the total bid premium. This higher downpayment requirement applies throughout the National Forest System, except in those areas where the Chief of the Forest Service determines, before advertisement of the sale, that another downpayment rate is necessary to achieve the management objectives of the National Forest System. The amount of the downpayment shall be redetermined in accordance with this paragraph when contract rates for timber are redetermined under the terms of the contract for environmental modification; catastrophic damage; market change; or an emergency rate redetermination. For the purpose of redetermining the downpayment, total advertised value shall be replaced with total redetermined value.

(h) A purchaser subject to the additional downpayment requirements of paragraph (g) of this section cannot apply the amount deposited as a downpayment to other uses until:

(1) On scaled sales, the estimated value of the unscaled timber is equal to or less than the amount of the downpayment; or

(2) On tree measurement sales, the estimated value remaining to be cut and removed as shown on the timber sale statement of account is equal to or less than the amount of the downpayment.

(i) For the purpose of releasing funds deposited as downpayment by a purchaser subject to paragraph (f) of this section, the Forest Service shall compute the estimated value of timber as follows:

(1) On scaled sales, the estimated value of the unscaled timber is the sum of the products obtained by multiplying the current contract rate for each species by the difference between the advertised volume and the volume that has been scaled of that species.

(2) On tree measurement sales, the estimated value of the timber outstanding (*i.e.*, not shown on the timber sale statement of account as cut and removed) is the sum of the products obtained by multiplying the current contract rate for each species by the difference between the advertised volume and the volume that has been shown on the timber sale statement to have been cut and removed of the species. The current contract rate for each species is that specified in the Forest Service timber sale contract.

(j) In order to deter speculation, the Chief of the Forest Service may increase the period for retention of the downpayment and/or preclude temporary reduction of the downpayment under paragraphs (k)(2) and (k)(3) of this section for future contracts subject to such criteria as the Chief may adopt after giving the public notice and opportunity to comment.

(k) The Forest Service may temporarily reduce the downpayment when a purchaser's scheduled operations are delayed, interrupted, or extended for 30 or more consecutive days for any of the following reasons:

(1) Forest Service requests or orders purchaser to delay or interrupt operations for reasons other than breach;

(2) A contract term addition pursuant to purchaser shifting operations to a sale designated by the Forest Service as in urgent need of harvesting; or

(3) An extension of the contract term authorized upon a determination of substantial overriding public interest, including a market-related contract term addition, or an urgent removal contract term extension under 36 CFR 223.53.

(l) When purchaser is not cutting or removing timber under contract during a qualifying period of delay, interruption, or extension listed in paragraph (k) of this section, the downpayment may be reduced to \$1000 or 2 percent of the downpayment amount stated in the contract, whichever is greater. The purchaser must restore the downpayment to the full amount stated in the contract within 15 days from receipt of the bill for

collection and written notice from the contracting officer that the basis for temporarily reducing the downpayment no longer exists. Purchaser shall not cut or remove timber on a contract where the downpayment has been temporarily reduced until the downpayment amount stated in the contract is fully restored.

■ 3. Amend § 223.50 by revising paragraphs (b) introductory text and (f) and adding paragraph (b)(3) to read as follows:

§ 223.50 Periodic payments.

* * * * *

(b) Except for lump sum sales, each timber sale contract of more than one full normal operating season shall provide for periodic payments. The number of periodic payments required will be dependent upon the number of normal operating seasons within the contract, but shall not exceed two such payments during the course of the contract. Periodic payments must be made by the periodic payment determination date, except that the amount of the periodic payment shall be reduced to the extent that timber has been removed and paid for by the periodic payment determination date. Should the payment fall due on a date other than normal billing dates, the contract shall provide that the payment date will be extended to coincide with the next timber sale statement of account billing date.

* * * * *

(3) Notwithstanding this paragraph (b), periodic payments are not required for stewardship contracts unless the contracting officer determines that periodic payments are needed to ensure the Government's financial security.

* * * * *

(f) The amount of any periodic payment(s) not yet reached shall be revised when rates are redetermined under the contract. The revised periodic payment amounts shall be based on a recalculated total contract value using the same procedures described in (c) and (d) of this section. The recalculated total contract value is the current contract value following the rate redetermination plus:

(1) The total value of timber scaled prior to establishing redetermined rates in a scaled sale; or

(2) The total value of timber shown on the timber sale statement of account as having been cut, removed and paid for.

Dated: August 7, 2009.

Ann Bartuska,

Acting Deputy Undersecretary, NRE.

[FR Doc. E9-19372 Filed 8-12-09; 8:45 am]

BILLING CODE 3410-11-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R05-OAR-2007-1129; FRL-8941-9]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Consumer Products Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

SUMMARY: EPA is approving a request submitted by the Ohio Environmental Protection Agency (Ohio EPA) on October 5, 2007, to revise the Ohio State Implementation Plan (SIP) under the Clean Air Act. The State has submitted new volatile organic compounds (VOCs) control rules for approval under Chapter 3745-112 of the Ohio Administrative Code (OAC). The rules include OAC 3745-112-01 to OAC 3745-112-08 and are intended to assist the State in achieving and/or maintaining the national 8-hour ground level ozone standard through the regulation of VOCs in consumer products. Ohio followed, with some modifications, the Ozone Transport Commission's "Model Rule for Consumer Products," (Model Rule) in developing the State's submittal.

DATES: This direct final rule will be effective October 13, 2009, unless EPA receives adverse comments by September 14, 2009. If adverse comments are 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-R05-OAR-2007-1129, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *E-mail*: mooney.john@epa.gov.
3. *Fax*: (312) 692-2551.
4. *Mail*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of

business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R05-OAR-2007-1129. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Andy Chang, Environmental Engineer, at (312) 886-0258 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Criteria Pollutant Section, Air Programs

Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-0258, *chang.andy@epa.gov*.

SUPPLEMENTARY INFORMATION:

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

- I. When did the State submit the requested rule revisions to EPA, and did the State satisfy the administrative requirements of 40 CFR Part 51, Appendix V?
- II. What are the revisions that the State is requesting for incorporation into the SIP?
 - A. Definitions and Applicability for Volatile Organic Compounds Emissions From Consumer Products
 - B. Standards and Exemptions for Volatile Organic Compounds Emissions From Consumer Products
 - C. Administrative and Reporting Requirements, Variances, and Testing Methods for Volatile Organic Compounds Emissions From Consumer Products
- III. What will approval of these rules accomplish?
- IV. What action is EPA taking?
- V. Statutory and Executive Order Reviews

I. When did the State submit the requested rule revisions to EPA, and did the State satisfy the administrative requirements of 40 CFR Part 51, Appendix V?

Ohio EPA submitted the requested revisions to EPA on October 7, 2007, and demonstrated through its submittal that the State satisfied all the requirements of 40 CFR Part 51, Appendix V, "Criteria for Determining the Completeness of Plan Submissions." The administrative requirements are outlined in Section 2.1 of this appendix. Most notably, a public hearing was held on June 12, 2007, and the rules became effective State-wide on September 12, 2007.

II. What are the revisions that the State is requesting for incorporation into the SIP?

The State has requested that EPA approve new rules under Chapter 3745-112 of the OAC. These rules include 3745-112-01 (Definitions); 3745-112-02 (Applicability); 3745-112-03 (Standards); 3745-112-04 (Exemptions); 3745-112-05 (Administrative Requirements); 3745-112-06 (Reporting Requirements); 3745-112-07 (Variances); and 3745-112-08 (Test Methods). All submitted rules are intended to assist the State in achieving and/or maintaining the national 8-hour ground level ozone standard through the regulation of volatile organic

compounds in consumer products. The revisions are described in detail below.

A. Definitions and Applicability for Volatile Organic Compounds Emissions From Consumer Products

Ohio EPA submitted definitions and applicability rules, which adopt almost verbatim, the rules found in the Model Rule. There are very minor modifications, which are related to implementation and compliance dates that are updated from the Model Rule. With exceptions only applicable to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulated products, the implementation date is January 1, 2009. Unless provided in subsequent rule 3745–112–04 (Exemptions), the applicability rule applies to any person who sells, supplies, offers for sale, or manufactures consumer products on or after January 1, 2009, for use in the State of Ohio. Specifying implementation and compliance dates do not make the rules less stringent; therefore, EPA concludes that the State's definitions and applicability rules for VOC emissions from consumer products are approvable.

B. Standards and Exemptions for Volatile Organic Compounds Emissions From Consumer Products

Ohio EPA adopted the Model Rule's standards for VOC emissions in their entirety with very minor modifications; Ohio EPA has specified that any consumer product manufactured prior to January 1, 2009, may be sold, supplied, or offered for sale after January 1, 2009 (sell-through of products). The State's exemptions rules were based entirely on the Model Rule, and include those for "Innovative Products." Specifying a date pertaining to sell-through of products does not weaken the rules; therefore, EPA concludes that the State's standards and exemptions rules for VOC emissions from consumer products are approvable.

C. Administrative and Reporting Requirements, Variances, and Testing Methods for Volatile Organic Compounds Emissions From Consumer Products

The rules covering these sections were drafted in their entirety based on guidance from the Model Rule. All requirements and methodologies mirror exactly those found in the Model Rule; therefore, EPA concludes that the State's administrative and reporting requirements, variances, and testing methods for VOC emissions from consumer products are approvable.

III. What will approval of these rules accomplish?

Approval of these rules submitted by Ohio EPA will help attain and maintain the national eight-hour standard for ground-level ozone, and reduce eight-hour ozone levels. Ozone is a human respiratory system irritant, and is harmful to the environment as well. Both ozone and volatile organic compounds are components of smog, which poses a significant threat to animal, plant, and human life. By maintaining the national standard for ground-level ozone and decreasing the levels of ozone, the benefits to human and environmental health in the State of Ohio and surrounding areas is expected to be permanent.

IV. What action is EPA taking?

We are approving revisions to the Ohio SIP; the State has submitted new rules under Chapter 3745–112 of the OAC. These rules encompass OAC rule 3745–112–01 to OAC rule 3745–112–08, and are intended to assist the state of Ohio in achieving and/or maintaining the national 8-hour ground level ozone standard through the regulation of VOCs in consumer products. Ohio drafted their rules based almost entirely on the Model Rule with one exception, severability, which was already addressed in OAC rule 3745–15–09.

We are approving these rules because they will help reduce emissions of volatile organic compounds and will therefore help reduce ground-level ozone concentrations in the State of Ohio and surrounding areas. Ohio EPA's rules closely follow the Model Rule, which EPA has determined to be approvable in other SIPs. The State's submittal meets the requirements of Section 183 of the Clean Air Act, as well as requirements of 40 CFR Part 51, Appendix V.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments.

However, in the Proposed Rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the State plan if relevant adverse written comments are filed. This rule will be effective October 13, 2009 without further notice unless we receive relevant adverse written comments by September 14, 2009. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule

based on the proposed action. The EPA will not institute a second comment period, therefore, any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective October 13, 2009.

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the 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 13, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action 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: July 28, 2009.

Walter W. Kovalick Jr.,

Acting Regional Administrator, Region 5.

■ 40 CFR part 52 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 KK—Ohio

■ 2. Section 52.1870 is amended by adding paragraph (c)(147) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(147) On October 5, 2007, Ohio submitted revisions to Ohio Administrative Code Chapter 3745–112, Rules 3745–112–01 through 3745–112–08. The revisions regulate the volatile organic compounds content of consumer products.

(i) Incorporation by reference.

(A) Ohio Administrative Code Rule 3745–112–01 "Definitions.", Rule 3745–112–02 "Applicability.", Rule 3745–112–03 "Standards.", Rule 3745–112–04 "Exemptions.", Rule 3745–112–05 "Administrative requirements.", Rule 3745–112–06 "Reporting requirements.", Rule 3745–112–07 "Variances.", and Rule 3745–112–08 "Test methods.", adopted September 5, 2007, effective on September 15, 2007.

(B) September 5, 2007, "Director's Final Findings and Orders", signed by Chris Korleski, Director, Ohio Environmental Protection Agency.

[FR Doc. E9–19305 Filed 8–12–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0591; FRL–8941–4]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revised Motor Vehicle Emission Budgets for the York-Adams Counties 8-Hour Ozone Maintenance Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania. The revision amends the

8-hour ozone maintenance plan for the York-Adams Counties 8-Hour Ozone Maintenance Area (the Area). This revision amends the maintenance plan's 2009 and 2018 motor vehicle emissions budgets (MVEBs) by unequally dividing the existing approved MVEBs which covers the entire maintenance area into two sub-regional MVEBs, one set of MVEBs for each county comprising the area. The revised plan continues to demonstrate maintenance of the 8-hour national ambient air quality standard (NAAQS) for ozone. EPA is approving this SIP revision to the Pennsylvania maintenance plan for York-Adams in accordance with the requirements of the Clean Air Act (CAA).

DATES: This rule is effective on October 13, 2009 without further notice, unless EPA receives adverse written comment by September 14, 2009. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2008–0591 by one of the following methods:

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. E-mail: febbo.carol@epa.gov.

C. Mail: EPA–R03–OAR–2008–0591, Carol Febbo, Chief, Energy, Radiation and Indoor Environment Branch, Mailcode 3AP23, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2008–0591. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment.

If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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

during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Martin Kotsch, (215) 814-3335, or by e-mail at kotsch.martin@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we”, “us”, or “our” is used, we mean EPA.

Table of Contents

- I. Background
- II. Summary of Pennsylvania’s SIP Revision and EPA’s Review
- III. Final Action
- IV. Statutory and Executive Order Reviews

I. Background

On January 14, 2008 (73 FR 2163) EPA redesignated the York-Adams Counties area of Pennsylvania to attainment for the 8-hour ozone NAAQS. For the York-Adams Counties area, the redesignation included approval of an 8-hour ozone maintenance plan, which identifies on-

road MVEBs for Volatile Organic Compounds (VOCs) and Nitrous Oxides (NO_x), which are ozone precursors, which are then used for transportation planning and conformity purposes. There are two separate metropolitan planning organizations (MPOs), in this maintenance area, one in each county, with individual responsibility for doing transportation conformity for their respective county. Pennsylvania has unequally divided the existing MVEBs and created sub-regional MVEBs for each county to better accommodate the transportation planning and conformity processes within the Area.

II. Summary of Pennsylvania’s SIP Revision and EPA’s Review 2009 and 2018 Motor Vehicle Emission Budgets

On May 23, 2008, the State of Pennsylvania submitted to EPA a formal revision to its State Implementation Plan (SIP). The SIP revision proposes MVEBs that reflect the unequal division of the existing MVEBs for the maintenance area. The divided MVEBs continue to ensure maintenance of the NAAQS for ozone for the York-Adams area. The following table lists the previously approved MVEBs and the proposed reallocation of the MVEBs into sub-regional budgets for the York-Adams Counties area.

YORK-ADAMS AREA REALLOCATION OF THE MVEBs INTO SUB-REGIONAL BUDGETS CURRENT MVEBs IN THE APPROVED MAINTENANCE PLAN—BOTH COUNTIES

[Tons/day]

	2004 Base year	2009 Projection	2018 Projection
VOC	16.1	15.9	9.0
NO _x	26.4	22.8	10.0

PROPOSED MVEBs IN THE REVISED MAINTENANCE PLAN FOR BOTH COUNTIES

[Tons/day]¹

	2009 Budget	2018 Budget
Adams County		
VOC	3.84	2.34
NO _x	4.87	2.54
York County		
VOC	12.09	6.72
NO _x	17.96	7.50

¹ Due to rounding, the new reallocated budgets, if combined, are insignificantly higher than the previously approved mobile budgets for the entire area. This slight difference will still ensure maintenance of the 8-hour ozone attainment as the combined MVEBs are still lower than the attainment year budgets.

EPA is proposing to approve the 2009 and 2018 MVEBs for VOCs and NO_x emissions listed above in Table 1 as the

new MVEBs for transportation conformity planning.

III. Final Action

EPA is approving Pennsylvania’s May 23, 2008 SIP revision submittal which amends the 8-hour ozone maintenance

plans for the York-Adams area. This revision unequally divides the previously approved 2009 and 2018 MVEBs to create sub-regional MVEBs for the two counties comprising the area. EPA is approving this SIP revision to the maintenance plan for the Area because the May 23, 2008 submittal continues to demonstrate maintenance of the 8-hour ozone NAAQS with the aggregated sub-regional MVEBs. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment, since no significant adverse comments were received on the SIP revision at the State level. However, in the Proposed Rules section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on October 13, 2009 without further notice unless EPA receives adverse comment by September 14, 2009.

If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

B. Submission to Congress and the Comptroller General

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

This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the 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 13, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking.

This action to approve the York-Adams Counties revised maintenance plan 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, Volatile organic compounds.

Dated: July 28, 2009.

William C. Early,

Acting Regional Administrator, Region III.

■ 40 CFR part 52 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 XX—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (e)(1) is amended by revising the entry for the 8-Hour Ozone Maintenance Plan for the York-Adams, PA Area to read as follows:

§ 52.2020 Identification of plan.

*	*	*	*	*
(e)	*	*	*	
(1)	*	*	*	

EPA-APPROVED NON-REGULATORY OR QUASI-REGULATORY MATERIAL

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
8-Hour Ozone Maintenance Plan for the York-Adams, PA Area.	York-Adams Counties Area ...	6/14/07	1/14/08, 73 FR 2163.	
		5/23/08	8/13/09 [Insert page number where the document begins].	

* * * * *

[FR Doc. E9-18864 Filed 8-12-09; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2008-0566; FRL-8939-2]

Revisions to the California State Implementation Plan, Great Basin Unified Air Pollution Control District, Kern County Air Pollution Control District, Mohave Desert Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing the following actions: A disapproval of revisions to the Great Basin Unified Air Pollution Control District (GBUAPCD) portion of the California State Implementation Plan (SIP); a limited approval and limited disapproval of revisions to the Kern County Air

Pollution Control District (KCAPCD) SIP; and, a limited approval and limited disapproval of revisions to the Mohave Desert Air Quality Management District (MDAQMD) SIP. These revisions concern particulate matter (PM) emissions from fugitive dust sources. This action was proposed in the **Federal Register** on November 18, 2008. Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), this action directs California to correct rule deficiencies in GBUAPCD Rule 401; and, this action simultaneously approves KCAPCD Rule 402 and MDAQMD Rule 403.1 and directs California to correct the deficiencies within these rules.

DATES: *Effective Date:* This rule is effective on September 14, 2009.

ADDRESSES: EPA has established docket number EPA-R09-OAR-2008-0566 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: Jerry Wamsley, EPA Region IX, (415) 947-4111, wamsley.jerry@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to EPA.

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Statutory and Executive Order Reviews

I. Proposed Action

On November 18, 2008 (73 FR 68369), EPA proposed to disapprove GBUAPCD Rule 401. In this same action, EPA proposed a limited approval and limited disapproval of KCAPCD Rule 402 and MDAQMD Rule 403.1. Table 1 lists the rules that California submitted for incorporation within the SIP.

TABLE 1—SUBMITTED RULES

Local agency	Rule #	Rule title	Adopted	Submitted
GBUAPCD	401	Fugitive Dust	12/04/06	05/08/07
KCAPCD	402	Fugitive Dust	11/03/04	01/13/05
MDAQMD	403.1	Fugitive Dust Control	11/25/96	03/03/97

We proposed to disapprove GBUAPCD Rule 401 because some provisions do not satisfy the requirements of section 110 and part D of the Act. These provisions are discussed below.

1. The rule lacks a 20% opacity limit. GBUAPCD should either incorporate or reference such a 20% opacity limit.

2. The rule lacks a clear description of required control measures for meeting the rule’s opacity and property line PM emission limits. GBUAPCD should also

remove the “reasonable precautions” language.

3. GBUAPCD should either provide a precise wind speed exemption from the rule’s emission standards, or delete the language concerning “normal wind conditions”.

4. GBUAPCD should remove director’s discretionary language in Section D.1.

5. As specified by the PM-10 plan, GBUAPCD should define required BACM provisions beyond those already

adopted to reduce Owens dry lakebed dust emissions, and specify an enforceable implementation schedule.

We proposed a limited approval of KCAPCD Rule 402 and MDAPCD Rule 403.1 because we determined that these rules improve the SIP and are largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act.

Regarding KCAPCD Rule 402, the provisions listed below conflict with section 110 and part D of the Act and prevent full approval of the SIP revision.

1. The definitions for “open storage piles” and “prevailing wind direction” contain instances of APCO discretion that should be delimited by specific criteria for adjudicating the issues within these definitions.

2. The rule provides an overly broad exemption for agricultural operations.

3. The rule provides an overly broad exemption for actions required by Federal or State endangered species legislation, or the Surface Mining and Reclamation Act.

4. The rule provides an overly broad exemption for public parks and recreation areas such as county, State, and national parks, recreation areas, forests, and monuments.

5. The rule provides exemptions for contractors provided reasonably available control measures were implemented prior to a contract termination date and a final grading inspection. However, no records are required to demonstrate implementation of reasonably available control measures.

6. Monitoring provisions are set aside for large operations for a calendar quarter. This exemption from monitoring is not justified or explained.

7. The rule states that no visible emissions are allowed beyond the property line of an active operation; however, the rule does not specify an opacity limit and the test methods for determining compliance for unpaved roads which are exempted from the property line limit.

8. The suggested reasonably available control measures for fugitive dust listed in Table 1 are not specific and lack standards for determining compliance and allied test methods.

9. Large operations may set aside applying control measures if the APCO concurs that “special technical, *e.g.* non-economic circumstances” prevent control measure implementation. This exemption is vague and allows for inappropriate Director’s Discretion. KCAPCD should define the circumstances that may prevent control measure implementation and the criteria the APCO will use to decide these issues.

10. The rule should specify that all records demonstrating compliance should be maintained for two years and made available to the Control Officer upon request.

Regarding Rule MDAQMD Rule 403.1, the provisions listed below conflict with section 110 and part D of the Act and

prevent full approval of the SIP revision.

1. The following terms should be defined: Brackish water, paved roads used for industrial activity, Dust Control Plan, industrial fugitive dust sources, industrial fugitive dust sources, and exterior transfer lines.

2. Sections C.2.(a)(i), C.2.(b)(i), C.2.(d)(i), C.4(d)(i) state that weekly brackish water treatments or biweekly sweeping and collection are presumed to be sufficient for meeting the required Road Surface Silt Loading standard. However, compliance with the rule’s silt loading standard needs to be confirmed by observations using the appropriate test method.

3. At Section C.4.(b), there is a requirement to permanently eliminate 2,750 square feet of bulk material storage piles that were exposed during 1990; however, it is unclear how this provision can be enforced effectively given the lack of specificity within the rule concerning these storage piles.

4. Section C.5 does not provide a date certain by which the BLM and the District jointly prepare a dust control plan that reduces BLM PM–10 emissions by at least 20 percent relative to 1990 levels.

5. The exemption for agricultural operations at Section D(1)(a) should be removed.

6. In Section F.1(c), the rule should state explicitly what the freeboard requirements are instead of incorporating the California Vehicle Code by reference. Also, these requirements should be incorporated within the appropriate paragraph in Section C.

Our proposed action contains more information on the basis for this rulemaking and on our evaluation of these rules.

II. Public Comments and EPA Responses

EPA’s proposed action provided a 30-day public comment period. During this period, we received no comments on our proposed actions on these rules. This comment period closed December 18, 2008.

III. EPA Action

No comments were submitted sufficient to change our assessment of these rules as described in our proposed action. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a disapproval of GBUAPCD Rule 401; this action will not incorporate GBUAPCD Rule 401 into the SIP. Also, as authorized in sections 110(k)(3) and 301(a) of the Act, we are finalizing a limited approval and a

limited disapproval of KCAPCD Rule 402 and MDAQMD Rule 403.1; these rules will be incorporated within the SIP, including those provisions identified as deficient.

In finalizing a disapproval of GBUAPCD Rule 401, our action will not incorporate submitted GBUAPCD Rule 401 into the SIP, instead, it will retain 1977 adopted rule within the SIP. We will not impose sanctions, pursuant to section 179 of the Act, because Rule 401 is not a required CAA submittal. Note that the submitted rule has been adopted by the GBUAPCD, and EPA’s final disapproval does not prevent the local agency from enforcing it.

With KCAPCD Rule 402, we will not impose sanctions under section 179 of the Act, because Rule 402 is not a required submittal under the CAA and is not an essential Reasonably Available Control Measure (RACM) under the Indian Wells Maintenance Plan. The submitted rule has been adopted by the KCAPCD, and EPA’s final limited disapproval does not prevent the local agency from enforcing it.

Regarding Rule 403.1, we will not impose sanctions under section 179 of the Act, because Rule 403.1 is not an essential RACM given the ongoing clean data observed in the Trona subregion since 1992. The submitted rule has been adopted by the MDAQMD, and EPA’s final limited disapproval does not prevent the local agency from enforcing it.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled “Regulatory Planning and Review.”

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co., v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials

in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations 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.” Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it 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. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves a state rule implementing a Federal standard.

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

This rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use “voluntary consensus standards” (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today’s action does not require the public to perform activities conducive to the use of VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other 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). This rule will be effective *September 14, 2009*.

K. Petitions for Judicial Review

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 13, 2009*. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: May 12, 2009.

Laura Yoshii,

Acting 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) (244)(i)(C)(2), (335)(i)(E), and (350)(i)(A)(2) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *
(244) * * *
(i) * * *
(C) * * *

(2) Rule 403.1, "Fugitive Dust Control for the Searles Valley Planning Area", adopted on June 22, 1994 and amended on November 25, 1996.

* * * * *

(335) * * *
(i) * * *

(E) Kern County Air Pollution Control District

(1) Rule 402, "Fugitive Dust", adopted on November 29, 1993 and amended on November 3, 2004.

* * * * *

(350) * * *

(i) * * *

(A) * * *

(2) Rule 401, "Fugitive Dust", adopted on September 5, 1974 and amended on December 04, 2006.

* * * * *

[FR Doc. E9-19338 Filed 8-12-09; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2008-0805; FRL-8426-9]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for the combined residues of spinetoram in or on almond, hulls; nut, tree, group 14; and pistachio and establishes tolerances for date; pomegranate; pineapple; pineapple, processed residue; spice, subgroup 19B, except black pepper; and hop, dried cones. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2009. Objections and requests for hearings must be received on or before October 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0805. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP

Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Samantha Hulkower, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0683; e-mail address: hulkower.samantha@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/oppts>.

www.epa.gov/opptsfrs/home/guidelin.htm.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0805 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 13, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0805, by one of the following methods:

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

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petition for Tolerance

In the **Federal Register** of December 3, 2008 (73 FR 73648) (FRL-8391-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7450) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.635 be amended by establishing tolerances for

residues of the insecticide spinetoram, expressed as a combination of:

XDE-175-J: 1-H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-, (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR);

XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS);

ND-J: (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-9-ethyl-14-methyl-13-[[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranoside; and

NF-J: (2R,3S,6S)-6-[[[(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy]-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide in or on the raw agricultural commodities pineapple at 0.02 parts per million (ppm); pomegranate at 0.3 ppm; date at 0.1 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; hop, dried cones at 22 ppm; and pineapple, process residue at 0.08 ppm.

Additionally, the petition proposed to increase the levels of existing tolerances for nut, tree, group 14 and pistachio from 0.04 to 0.08 ppm and almond, hulls from 2.0 ppm to 9.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised tolerances to higher levels than proposed for almond, hulls; nut, tree, group 14; pistachio; pineapple; and pineapple, process residue. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of spinetoram on almond, hulls at 19 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; pomegranate at 0.30 ppm; pineapple at 0.04 ppm; pineapple, processed residue at 0.15 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; and hop, dried cones at 22 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

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

Spinetoram has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is a dermal sensitizer but not an eye or dermal irritant. In subchronic toxicity studies conducted in rats, mice and dogs, spinetoram produces multi-organ toxicity. Treatment had no adverse effects on

survival but decreases in body weight, body weight gain and/or food consumption were observed in all three species. Treatment-related findings included the presence of a mild anemia, alterations in clinical chemistry parameters, increased liver weights, presence of histiocytic aggregates of macrophages in various organs and tissues, and degeneration with regeneration of the kidney tubules. Dogs appear to be the most sensitive species. In the subchronic study with dogs, lower thymus weights, atrophy of the thymic cortex, arteritis and/or perivascular inflammation in numerous organs with necrosis of the bone marrow leading to regenerative anemia was seen. In the chronic study with dogs, there were no treatment-related effects on survival, body weight, hematology, clinical chemistry or gross pathology. Treatment-related changes were limited to arteritis and necrosis of the arterial walls of the epididymides in males and thymus, thyroid, larynx, and urinary bladder in females. It is postulated that chronic treatment exacerbated the spontaneous arteritis in genetically predisposed Beagle dogs (it is called the "Beagle Pain Syndrome"). In developmental toxicity studies, there is no evidence of increased susceptibility following *in utero* exposures in rats and rabbits. In the 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity. EPA has concluded that spinetoram is toxicologically identical to another pesticide, spinosad. Based on the structural similarity of spinetoram and spinosad and the similarity of the toxicological database for the currently available studies, spinetoram is classified as "not likely to be carcinogenic to humans" based on lack of evidence for carcinogenicity of spinosad in mice and rats. No indication of neurotoxicity was observed in the acute neurotoxicity screening battery in rats, or in the subchronic and chronic toxicity studies conducted on spinetoram. All the mutagenicity studies conducted on spinetoram were negative. The no-observed-adverse-effect-level (NOAEL) derived from the chronic dog study is well characterized, and together with the traditional uncertainty/safety factors will provide adequate protection for effects observed in laboratory animals. Specific information on the studies received and the nature of the adverse effects caused by spinetoram as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at [http://](http://www.regulations.gov)

www.regulations.gov in document Human Health Risk Assessment for Application of spinosad to date and pomegranate and spinetoram to pineapple, date, pomegranate, hopes, and spices (crop subgroup 19B, except black pepper) on page 4 and attachment 3 pages 49–54 in docket ID number EPA–HQ–OPP–2008–0805.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion is based on the following: Spinetoram and spinosad are large molecules with nearly identical structures; and the

toxicological profiles for each are similar (generalized systemic toxicity) with similar doses and endpoints chosen for human-health risk assessment.

Spinosad and spinetoram should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent. Although, as stated above, the doses and endpoints for spinosad and spinetoram are similar, they are not identical due to variations in dosing levels used in the spinetoram and spinosad toxicological studies. EPA compared the spinosad and spinetoram doses and endpoints for each exposure scenario and selected the lower of the two doses for use in human risk assessment.

A summary of the toxicological endpoints for spinetoram/spinosad used for human risk assessment can be found at <http://www.regulations.gov> in the document Human Health Risk Assessment for Application of spinosad to date and pomegranate and spinetoram to pineapple, date, pomegranate, hopes, and spices (crop subgroup 19B, except black pepper) on page 8 in docket ID number EPA–HQ–OPP–2008–0805.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinetoram/spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinetoram/spinosad tolerances in 40 CFR 180.635. EPA assessed dietary exposures from spinetoram/spinosad in food as follows:

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

No such effects were identified in the toxicological studies for spinetoram/spinosad; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Spinosad is registered for application to all of the same crops as spinetoram, with similar pre-harvest and retreatment intervals, and application rates greater than or equal to spinetoram. Further, both products control the same pest species. For this reason, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. Rather, EPA aggregated exposure by either assuming that all commodities contain spinosad residues (because side-

by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues) or summing the percentage of a crop that would be treated with spinosad and the percentage that would be treated with spinetoram.

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, the chronic analysis assumed 100% crop treated for all food crop commodities; average field-trial residues for apple, Brassica leafy vegetables, citrus, fruiting vegetables, herbs, banana, and strawberry; tolerance-level residues for the remaining food crop commodities; DEEM™ (ver. 7.81) default processing factors for all commodities excluding orange juice, field corn (meal, starch, flour, and oil), grape juice, and wheat (flour and germ) where the spinosad processing factors were assumed. Residues in livestock were refined through the incorporation of a refined dietary burden (average feed-crop residues and percent crop treated estimates) and through the incorporation of average residues from the feeding and dermal magnitude of the residue studies.

iii. *Cancer.* Spinetoram is considered to be “not likely to be a carcinogen to humans” based on its similarity to another spinosin pesticide, spinosad. Preliminary results of a carcinogenicity study in mice indicate that spinetoram is not carcinogenic to mice at doses up to 37.5 milligram/kilogram/day (mg/kg/day). Consequently, a quantitative cancer exposure and risk assessment is not appropriate for spinetoram.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The EPA assumed 100% crop treated for all food crop commodities; however, in calculating beef and dairy cattle dietary burdens, the Agency used combined spinosad and spinetoram projected percent crop treated (PPCT) information as follows:

- 39% sweet corn forage.
- 50% leaves of root and tuber vegetables.
- 5% sorghum grain.
- 5% soybean seed meal.

EPA estimates an upper bound of PPCT for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA calls this the market leader PPCT estimate. In this specific case, the new use to be estimated is the combined use of spinosad together with that of spinetoram since most new use of spinetoram will likely replace previous use of spinosad. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment. The average market leader PCT may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCT may be based on a cross-section of state PCTs. Comparisons are only made among pesticides of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide), or, for refined estimates, among pesticides targeting the same pests. The market leader PCTs used to determine the average may consist of PCTs for the same pesticide or for different pesticides for any year since the same or different

pesticides may dominate for each year. Typically, EPA uses USDA/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the combined use of spinetoram and spinosad on each of these several crops. Of greatest relevance here is that both spinosad and spinetoram control a relatively narrow range of pests compared to the market leaders. Based on this analysis, EPA believes that it is unlikely that actual combined PCTs for spinetoram and spinosad will exceed the corresponding estimated PPCTs during the next 5 years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which spinetoram may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spinetoram/spinosad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinetoram/spinosad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spinetoram for acute exposures are estimated to be 14.419 parts per billion (ppb) for surface water and 0.072 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 6.171 ppb for surface water and 0.072 ppb for ground water. EDWCs for spinosad for acute exposures are estimated to be 34.5 ppb for surface water and 1.1 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 10.5 ppb for surface water and 1.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 10.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

The Agency has concluded that spinosad and spinetoram are toxicologically equivalent; therefore, residential exposure to both spinosad and spinetoram was evaluated. Spinosad is currently registered for homeowner application to turf grass and ornamentals. Spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass. No dermal endpoints for either spinetoram or spinosad were identified. Therefore, only short-term incidental oral exposures to toddlers were evaluated for the registered turf and ornamental application scenarios for spinosad and spinetoram and short-term inhalation exposure to handler/applicators for the registered home garden, turf, and ornamental application scenarios.

There is potential for residential handler and post-application exposures

to both spinosad and spinetoram. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used for the same uses in combination with each other and thus combining spinosad and spinetoram residential exposures would overstate exposure. Short-term residential inhalation risks were estimated for adult residential handlers, as well as short-term post-application incidental oral risks for toddlers, based on applications to home lawns, home gardens and ornamentals.

EPA notes that for spinosad the registered fruit fly bait application scenario permits application to non-crop vegetation and this use may result in residential exposures. Based on the application rates (fruit fly bait - 0.0003 lb ai/acre; turf/ornamental - 0.41 lbs ai/acre), EPA concludes that residential exposure resulting from the fruit fly application will be insignificant when compared to the exposure resulting from homeowner uses on the turf/ornamentals. Therefore, quantitative analysis of the residential exposure resulting from the fruit fly bait application was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found spinetoram/spinosad to share a common mechanism of toxicity with any other substances, and spinetoram/spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinetoram/spinosad does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines

based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat and rabbit fetuses to *in-utero* exposure to spinosad or spinetoram. In the spinosad and spinetoram rat and rabbit developmental toxicity studies, no developmental toxicity was observed at dose levels that did not induce maternal toxicity. In the spinosad 2-generation reproduction studies, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre-natal and/or post-natal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spinetoram is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Harmonized Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA.

There was some evidence of adverse effects on the organs of the immune system at the LOAEL in three short-term studies with spinosad or spinetoram. In these studies, anemia was observed in multiple species (rats, mice and dogs) with the presence of histiocytic aggregates of macrophages in various organs and tissues (lymph nodes, spleen, thymus, and bone marrow). Aggregation of macrophages was indicative of immune stimulation in response to insults of the chemical exposure and was considered secondary effects of the toxic effect to the hematopoietic system. Therefore, these effects are not considered to be indicative of frank immunotoxicity. In the chronic study with dogs, arteritis and necrosis of the arterial walls of the

thymus was seen in one female dog at the HDT. This finding is attributed to the exacerbation of the spontaneous arteritis present in genetically predisposed Beagle dogs ("Beagle Pain Syndrome"), not immunotoxicity. Further, a clear NOAEL was attained in each of these studies, and the observed histopathologies were generally observed in the presence of other organ toxicity. In addition, spinosad and spinetoram do not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic.

Based on the above considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a POD less than the NOAEL of 2.49 mg/kg/day already set for spinosad and spinetoram. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that spinetoram/spinosad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spinetoram/spinosad results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments utilized 100 PCT and tolerance-level residues, and DEEM™ default processing factors for all registered and proposed commodities and refined livestock estimates. These refinements are based on reliable data. The EPA used PPCT information when calculating livestock dietary burdens for sweet corn forage, leaves of root and tuber vegetables, sorghum grain, and soybean seed meal. EPA believes that the PPCT estimates used are conservative estimates. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to spinetoram/spinosad in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spinetoram/spinosad.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by

comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, spinetoram/spinosad is not expected to pose an acute risk.

2. *Chronic risk.* Since there are no registered/proposed uses which result in chronic residential exposures, the chronic aggregate exposure assessment consists of exposure from food and water. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spinetoram/spinosad from food and water will utilize 95% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Spinetoram/spinosad is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to spinetoram/spinosad.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of ≥ 160 . Short-term aggregate risk does not exceed the LOC for EPA (MOE of <100).

4. *Intermediate-term risk.* Spinetoram/spinosad is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to spinetoram/spinosad

through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* The Agency considers spinetoram to be "Not Likely to be Carcinogenic to Humans." See Unit III.C.iii. for more detailed information.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spinetoram/spinosad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

FDA Multiresidue Methods (MRMs): XDE-175-J, XDE-175-L, ND-J, NF-J, ND-L, and NF-L were screened through the Food and Drug Administration Pesticide Analytical Methods Volume I (PAM I) MRMs. None of the test substances were found to be fluorescent using procedures outlined in Protocol A. All test substances were subjected to Protocol C, modules DG1, DG5, DG13, DG17, and DG18. Test substances were determined to be non-chromatographable by the chosen gas chromatography modules described in Protocol C. Due to the poor sensitivity of the test substances to detection by methods described in Protocol C, no further analyses were performed by Protocols D, E, or F. Since the test substances are not acids, phenols, or substituted ureas, analyses were not performed using Protocols B or G. The test substances were not detectable through FDA PAM I Protocols A and C; therefore, these methods are unsuitable for enforcement. The MRM results were forwarded to the FDA.

Adequate enforcement methodology. Plants: Method GRM 05.03 (HPLC/MS/MS). Livestock: Method GRM 05.15 HPLC/mass spectrometry (MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican MRLs for residues of spinetoram on the requested crops.

C. Revisions to Petitioned-For Tolerances

The tolerance expression for spinetoram includes residues of XDE-

175-J, XDE-175-L, ND-J, and NF-J. EPA is establishing tolerances for the following commodities at levels higher than proposed: nut, tree, group 14 and pistachio raised to 0.10 ppm; almond, hulls raised to 19 ppm; pineapple to 0.04 ppm; and pineapple, processed residue 0.15 ppm. These changes are based on the residue field trial data and the North American Free Trade Agreement (NAFTA) MRL Spreadsheet.

V. Conclusion

Therefore, tolerances are established for combined residues of spinetoram, expressed as a combination of:

XDE-175-J: 1-H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-, (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR);

XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS);

ND-J: (2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-9-ethyl-14-methyl-13-[[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranoside; and

NF-J: (2R,3S,6S)-6-[[[(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide

in or on the following commodities is increased to almond, hulls at 19 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; pomegranate at 0.30 ppm; pineapple 0.04 ppm; pineapple, processed residue at 0.15 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; and hop, dried cones at 22 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the

Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 31, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.635 is amended by revising the entries in the table in paragraph (a) for almond, hulls; nut, tree, group 14; and pistachio and alphabetically adding entries for date; hop, dried cones; pineapple; pineapple, processed residue; pomegranate; and spice, subgroup 19b, except black pepper, to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Almond, hulls	19
* * * * *	*
Date	0.10
* * * * *	*
Hop, dried cones	22

Commodity	Parts per million
* * * *	*
Nut, tree, group 14	0.10
* * * *	*
Pineapple	0.04
Pineapple, processed residue	0.15
Pistachio	0.10
Pomegranate	0.30
* * * *	*
Spice, subgroup 19B, except black pepper	1.7
* * * *	*

[FR Doc. E9-19195 Filed 8-12-09; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF TRANSPORTATION**National Highway Traffic Safety Administration****49 CFR Part 571**

[Docket No. NHTSA-2009-0145]

RIN 2127-AK04

Federal Motor Vehicle Safety Standards; Controls, Telltales and Indicators

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

ACTION: Final rule.

SUMMARY: In an August 2005 final rule, we updated our standard regulating motor vehicle controls, telltales and indicators. The standard specifies requirements for the location, identification, and illumination of these items. In May 2006, we published a response to four petitions for reconsideration, including one asking us to reconsider a requirement for color contrast between identifiers and their backgrounds. We denied this petition for reconsideration.

In response to another petition for reconsideration from the Alliance of Automobile Manufacturers (the Alliance) of the color contrast requirement, specifically for the horn control identifier, in this final rule, we amend the standard to provide that an identifier is not required if the horn control is placed in the middle of the steering wheel. If the horn control is placed elsewhere in the motor vehicle, the control would be required to be identified by the specified horn symbol in a color that stands out clearly against the background.

DATES: *Effective Date:* The effective date for this final rule is February 9, 2010. The compliance date for vehicles under

10,000 pounds GVWR for S5.4.3 continues to be September 1, 2011.

Compliance date for the extension of the standard's control, indicator, and telltale requirements to vehicles at 10,000 pounds GVWR or greater over continues to be September 1, 2013.

Optional early compliance is permitted as of the date today's final rule is published.

Petitions for reconsideration: Petitions for reconsideration of today's final rule must be received not later than September 28, 2009.

ADDRESSES: Petitions for reconsideration of the final rule must refer to the docket number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For non-legal issues you may call Ms. Gayle Dalrymple, Office of Crash Avoidance Standards at (202) 366-5559. Her FAX number is (202) 366-7002. For legal issues, you may call Ms. Dorothy Nakama, Office of the Chief Counsel at (202) 366-2992. Her FAX number is (202) 366-3820. You may send mail to both of these officials at National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:**I. Background**

NHTSA issued Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays*, in 1967 (32 FR 2408) as one of the initial FMVSSs. The standard applies to passenger cars, multipurpose passenger vehicles (MPVs), trucks, and buses. The purpose of FMVSS No. 101 is to assure the accessibility and visibility of motor vehicle controls and displays under daylight and nighttime conditions, in order to reduce the safety hazards caused by the diversion of the driver's attention from the driving task, and by mistakes in selecting controls.

At present, FMVSS No. 101 specifies requirements for the location (S5.1), identification (S5.2), and illumination (S5.3) of various controls and displays. It specifies that those controls and displays must be accessible and visible to a driver properly seated wearing his or her safety belt. Table 1, "Controls, Telltales and Indicators with Illumination or Color Requirements," and Table 2, "Identifiers for Controls, Telltales and Indicators with No Color or Illumination Requirements," indicate which controls and displays are subject to the identification requirements, and how they are to be identified, colored,

and illuminated. For the horn control, Table 2 specifies the horn symbol in Column 2, and the word "Horn" in Column 3.

II. 2005 and 2006 Final Rules

In a final rule published in the **Federal Register** (70 FR 48295) on August 17, 2005, NHTSA amended FMVSS No. 101 by extending the standard's telltale and indicator requirements to vehicles of Gross Vehicle Weight Rating (GVWR) 4,536 kilograms (10,000 pounds) and over, updating the standard's requirements for multi-function controls and multi-task displays to make the requirements appropriate for advanced systems, and reorganizing the standard to make it easier to read. Table 1 and Table 2 continue to include only those symbols and words previously specified in the controls and displays standard or in another applicable FMVSS.

The final rule specified an effective date of February 13, 2006 for requirements applicable to passenger cars, multipurpose passenger vehicles, trucks and buses under 4,536 kg GVWR (10,000 pounds).¹

NHTSA received petitions for reconsideration of the August 17, 2005 final rule, including one from the Alliance. In the August 17, 2005 final rule, the requirement that the identifier for each telltale must be in a color that stands out clearly against the background was extended to identifiers for controls and indicators (see S5.4.3). The Alliance asked for reconsideration of this requirement, stating that not all identifiers are in a color that stands out clearly against the background. The Alliance further stated that it is not needed, citing as an example the horn identifier.

Most vehicle models use the horn symbol as the identifier, which is molded into the air bag cover, without a color "that stands out clearly against the background" filled in. The Alliance commented that: "The symbol is the same color as the background, but it can still be recognized because the embossment stands out against the background." The Alliance petitioned for the regulatory text at S5.4.3 to be changed to: "The identification required by Table 1 or Table 2 for a telltale, control or indicator shall contrast with the background."

In the May 15, 2006 final rule, response to petitions for reconsideration (71 FR 27964), we noted that over the years, the agency had received numerous complaints regarding the

¹ The effective date was subsequently extended to September 1, 2006 (71 FR 3786, January 24, 2006).

inability to locate the horn control. NHTSA's Office of Defects Investigation's ARTEMIS database has recorded 120 complaints in the past ten years from consumers reporting trouble locating the horn control. Of these 120 complaints, consumers reported 12 crashes, 9 near misses, and an allegation of a fatality. In the response, NHTSA explained that filling in the horn symbol with a color that "that stands out clearly against the background" would make the horn control more visible and would help drivers to find the control more readily. For these reasons, we denied this part of the Alliance's petition.

To minimize costs on industry resulting from this requirement, NHTSA delayed the compliance date to meet S5.4.3 for five years, to September 1, 2011 to "allow manufacturers to implement the necessary changes on most products during the planned product changes in normal product development cycles."

III. Petition for Reconsideration of the Color Contrast Requirement

In a submission dated June 29, 2006, the Alliance petitioned for a reconsideration of the color contrast requirement for the horn symbol. This was the only issue raised in the petition. Again, the Alliance petitioned for the regulatory text at S5.4.3 to be changed to: "The identification required by Table 1 or Table 2 for a telltale, control or indicator shall contrast with the background." In support of its petition, the Alliance stated that:

- NHTSA denied the Alliance's previous petition based on a previously undisclosed analysis of complaints;
- "[I]t is unclear and cannot be evaluated whether the complaints referred to by NHTSA were related to actual horn symbol identification,"
- The complaint information should be submitted to the DOT Docket;
- "[S]ignificant cost and investment will still be required across the industry," to accomplish color contrast of the horn symbol on the background of the steering wheel, despite the fact that the Alliance agrees that the lead time afforded by the May 2006 final rule is adequate "for compliance with this section in order to minimize the associated financial impact * * *";
- A "significant concern" is the "compatibility of materials that may be used to assure long term symbol identification durability and contrast * * *" and that this new combination of materials may "adversely affect airbag cover performance, requiring further engineering development. Environmental and manufacturing issues related to providing horn symbol

contrast cannot be assessed until the materials and processes are defined" and;

- The UN working group considering a GTR² on controls and displays is the appropriate forum to understand and discuss horn identification problems.

On October 17, 2006, the Alliance presented a data analysis to NHSTA staff of complaints regarding horn control identification on various member companies' vehicles. (The presentation has been placed in The DOT Docket at NHTSA-2006-23651.) The analysis revealed that as manufacturers have adopted membrane switches in the center of the steering wheel to activate the horn, consumer complaints about horn identification have decreased substantially.

IV. Grant of Petition for Reconsideration and Notice of Proposed Rulemaking

In a **Federal Register** document of October 4, 2007 (72 FR 56713), NHTSA stated that it has been persuaded by the Alliance's petition and accompanying data, and granted its petition for reconsideration regarding S5.4.3. NHTSA stated its belief that the Alliance's analysis provided on October 17, 2006 has merit. Driver confusion as to the location of the horn control has decreased as the horn control is returned where drivers intuitively expect to find it to the center of the steering wheel hub on more vehicles. If the horn control is located where most drivers expect it, NHTSA stated its belief that there is little safety benefit from the presence of the horn identifier. In fact, requiring the identifier on or adjacent to the control, may contribute to driver confusion as manufacturers opt to place the identifier adjacent to the control, rather than too close to the large, multi-colored, company logo displayed on many vehicles at the center of the wheel.

In the NPRM, NHTSA stated that at present, S5. *Requirements* of FMVSS No. 101 states: "Each passenger car, multipurpose passenger vehicle, truck and bus that is fitted with a control, a telltale or an indicator listed in Table 1 or Table 2 must meet the requirements of this standard for the location,

identification, color, and illumination of the control, telltale, or indicator." The horn control indicator is specified in Table 2. So that horn controls that are in the middle of the steering wheel would not have to meet S5., in the NPRM, we proposed to amend S5.4.3 of FMVSS No. 101 to read:

Each identifier used for the identification of a telltale, control or indicator must be in a color that stands out clearly against the background. However, no identifier is required for a horn control activated by the driver pressing on the center of the face plane of the steering wheel. For vehicles with a GVWR of under 4,536 kg (10,000 pounds), the compliance date for this provision is September 1, 2011.

The word "symbol" was proposed to be changed to "identifier" to more accurately include words and abbreviations as identifiers which are required to contrast with their backgrounds, as was done in the previous final rules to other sections of the standard. This was pointed out by the Alliance in its current petition.

NHTSA did not propose to amend FMVSS No. 101 with the Alliance's suggested language ("The identification required by Table 1 or Table 2 for a telltale, control or indicator shall contrast with the background.") because we stated our belief that the suggested language would allow non-contrasting identifiers for telltales, indicators and controls whenever they appear in the vehicle (such as the instrument panel).

At present, S5.2.1 states in part: "* * * No identification is required for any horn (i.e., audible warning signal) that is activated by a lanyard or for a turn signal * * *" To make S5.2.1 consistent with the changes to S5.4.3, in the October 2007 NPRM, we proposed to revise the fourth sentence in S5.2.1 to state in part: "* * * No identification is required for any horn (i.e., audible warning signal) that is activated by a lanyard or by the driver pressing on the center of the face plane of the steering wheel * * *"

V. Comments to the October 2007 NPRM and NHTSA Discussion of the Comments

In response to the NPRM, we received comments from the Alliance, the Association of International Automobile Manufacturers, Inc. (AIAM) and from Mr. Michael Tebbi, a private individual.

Mr. Tebbi stated that he agreed with the agency that the center of the steering wheel is where he expects the horn to be, and "therefore no icon is needed." However, he expressed concern about the possibility that horns placed in the centers of steering wheels could lead to injuries since "a consumer will be

²The United States participates in the United Nations/Economic Commission for Europe World Forum for Harmonization of Vehicle Regulations (also known as Working Party 29 or WP.29) under a 1990 agreement known as the 1998 Global Agreement. The 1998 Global Agreement provides for the establishment of global technical regulations (GTRs) regarding, among other things, the safety of motorized wheeled vehicles, equipment and parts. The Agreement contains procedures for establishing GTRs by either harmonizing existing regulations or developing new ones.

honking the car's horn as he collides with another vehicle. If the air bag deploys while the driver's hand is pressing against the center of the steering wheel, I believe there may be a possibility of injury to the driver's arm or shoulder." This rulemaking addresses requirements for identification of the horn control. Since the horn control is optional, we do not address where in a motor vehicle the horn control must be placed. However, based on normal body kinematics during a crash, we believe that it is very unlikely that in crashes with deceleration great enough to cause air bag deployment, that the driver's hand will still be on the air bag cover at the time of the deployment. Since the introduction of driver air bags, the usual location for the horn control has been under the air bag cover. No problems regarding horn use such as that described by Mr. Tebbi have come to NHTSA's attention.

The AIAM supported the proposed amendment to FMVSS No. 101. AIAM did not suggest changes to the proposed regulatory text. However, AIAM identified two related issues that it asked us to clarify in the preamble to the final rule. The first was, if a manufacturer provides a horn control activated by pressing on the center of the steering wheel³ and provides a second horn control "off-center, near the edge of the hub, to identify the supplemental horn control that operates by tilting the plane of the hub" whether the second control must meet the S5.4.3 requirement for color contrast. As a rationale for arguing that no identification should be required, AIAM stated that "[h]istorically, NHTSA has taken the position that voluntarily installed items (i.e., items not mandated by an FMVSS) are not subject to regulation by NHTSA so long as such items do not interfere with the operation of regulated systems or equipment." In support of its position, AIAM cited a January 28, 1992 letter to Honda and what it described as an "undated" letter to Mazda regarding redundant heating/ventilator controls. The date of the letter to Mazda is July 5, 1984.

NHTSA does not agree that the two cited interpretations are applicable to the rulemaking at issue. The 1992 letter to Honda interprets FMVSS No. 123, *Motorcycle controls and displays*, not FMVSS No. 101. Further, the letter addressed the nature of operation of a brake system, not the identification required for a control. The July 5, 1984 letter to Mazda, addresses a "secondary, redundant control placed in the rear

seat area facilitating operation of the heating/ventilation and audio system functions by rear seat passengers." In contrast, in the rulemaking at issue, all horn controls provided would be operable by the driver, not by "rear seat passengers." Thus, the Mazda letter does not apply to the rulemaking at issue.

While in some situations NHTSA has concluded that certain requirements do not apply to items that are voluntarily provided or redundant, this is not a general principle. In considering such an issue, the agency needs to consider the specific situation and purpose of a particular requirement.

AIAM argued that the second horn control would not be subject to FMVSS No. 101 because the second control is "voluntarily installed." All horn controls are "voluntarily installed," including those placed in the center of the face plane of the steering wheel hub. Moreover, while the second horn control would be redundant, unidentified controls in unexpected places, or controls identified in unfamiliar ways, may cause confusion to the driver. As a result of today's final rule, identification is not required for those horn controls that are placed in the center of the face plane of the steering wheel hub. All other horn controls must meet all FMVSS No. 101 requirements that apply to horns.

AIAM also argued that "since no identifier is required for a horn control that is operated at the center of the steering wheel, any identifier that is voluntarily affixed there" would not have to meet S5.2 of FMVSS No. 101. NHTSA does not agree with this position. The purpose of FMVSS No. 101 is to:

Assure the accessibility and visibility of motor vehicle controls and displays under daylight and nighttime conditions, in order to reduce the safety hazards caused by the diversion of the driver's attention from the driving task, and by mistakes in selecting controls.

Permitting manufacturer-chosen identifications of a control for which identification is specified in FMVSS No. 101 would not be consistent with the purpose of FMVSS No. 101. Such alternative horn designations (with each manufacturer possibly having a different designation) would result in drivers spending time trying to understand the meaning of the manufacturer-chosen identification and would divert the "driver's attention from the driving task." Such a result would not meet the need for safety. Therefore, in this final rule, a horn control placed in the center of the face plane of the steering wheel need not be identified. However, if

identification is voluntarily provided, the horn symbol identification in Table 2 or the word "horn" must be used.

We would agree, however, that a manufacturer could voluntarily use a horn symbol that is embossed, (i.e., without a contrasting color) to identify a horn control placed in the center of the face plane of the steering wheel. Since no identification would be required in this situation, and since the embossed horn symbol would not cause confusion, its use would be permissible.

The Alliance agreed with the proposal but suggested changes in the regulatory text as "technical corrections" to "clarify" the agency's intent. The Alliance asked for "clarification on the meaning of the term 'center of the face plane of the steering wheel' which could be narrowly interpreted and create potential questions of compliance." The Alliance therefore suggested that S5.2.1 be changed to read:

S5.2.1 No identification is required for any horn (i.e., audible warning signal) that is activated by a lanyard or by the driver pressing on the center area of the steering wheel hub * * *

NHTSA agrees that use of the word "hub" provides clarification as to where activation of the horn would occur. However, we believe the term "center" is clear, and decline to adopt "center area." There will be no compliance difficulty: The center of the hub is located, the driver presses, and if the horn sounds, the condition is met, and no identification is necessary.

The second issue raised by the Alliance is "the applicability of the proposed language when manufacturers voluntarily mark horn controls that are activated by pressing on the center area of the steering wheel hub * * * [I]f a manufacturer chooses to identify a horn control activated by pressing on the center area of the steering wheel hub, the proposed text could be interpreted to require the symbol to be a contrasting color." The Alliance offered the following change to S5.4.3 to "clarify this point."

S5.4.3 Each identifier used for the identification of a telltale, control or indicator must be in a color that stands out clearly against the background. This requirement does not apply to the identification of a horn control activated by the driver pressing on the center area of the steering wheel hub.

As earlier explained, we do not agree with changing "center" to "center area." As to horn controls placed in the center of the face plane of the steering wheel, we agree, also for reasons discussed earlier, that a manufacturer could use a

³ A location where it was proposed in the NPRM, that no horn identifier would be required.

horn symbol (or the word horn) that is embossed in this situation, *i.e.*, without a contrasting color.

VI. Leadtime

For vehicles under 10,000 pounds, the compliance date for S5.4.3 continues to be September 1, 2011. The compliance date for the extension of the standard's control, indicator, and telltale requirements to vehicles with at GVWR of 4,536 kg (10,000 pounds) or greater continues to be September 1, 2013. Optional early compliance is permitted as of the date the final rule is published.

VII. Rulemaking 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 or recipients thereof; or

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

We have considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed by the Office of Management and Budget under E.O. 12866, "Regulatory Planning and Review." The rulemaking action is also not considered to be significant under the Department's Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

For the following reasons, NHTSA concludes that this final rule will not have any quantifiable cost effect on motor vehicle manufacturers. The rule will not impose any new requirements but instead relieves a restriction. In this

final rule, NHTSA excludes horn controls activated by the driver pressing on the center of the face plane of the steering wheel from the standard's requirement that an identifier be provided. This final rule will have no measurable effect on safety. As discussed above, driver confusion as to the location of the horn control decreases as the horn control returns to the center of the steering wheel hub, where drivers intuitively expect to find it. If the horn control is located where drivers expect it, there is no apparent safety benefit from the presence of the horn identifier. As a result of this final rule, vehicle manufacturers are spared the costs of embossing a horn symbol in the center of the steering wheel hub and coloring in the symbol.

Because the economic effects of this final rule are minimal, no further regulatory evaluation is necessary.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity "which operates primarily within the United States." (13 CFR § 121.105(a)). No regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

I have considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and certify that this rule will not have a significant economic impact on a substantial number of small entities. The rule does not impose any new requirements but relieves a restriction.

For these reasons, and for the reasons described in our discussion on Executive Order 12866 and DOT Regulatory Policies and Procedures, NHTSA concludes that this final rule will not have a significant economic

impact on a substantial number of small entities.

C. National Environmental Policy Act

NHTSA has analyzed this rulemaking action 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.

D. Executive Order 13132 (Federalism)

NHTSA has examined today's final rule pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rule does not have federalism implications, because the rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Further, no consultation is needed to discuss the issue of preemption in connection with today's rule. The issue of preemption can arise in connection with NHTSA rules in at least two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemptive provision: "When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter." 49 U.S.C. 30103(b)(1). It is this statutory command that unavoidably preempts State legislative and administrative law, not today's rulemaking, so consultation would be unnecessary.

Second, the Supreme Court has recognized the possibility of implied preemption: In some instances, State requirements imposed on motor vehicle manufacturers, including sanctions imposed by State tort law, can stand as an obstacle to the accomplishment and execution of a NHTSA safety standard. When such a conflict is discerned, the Supremacy Clause of the Constitution makes the State requirements unenforceable. *See Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). However, NHTSA has considered the nature and purpose of today's rule and does not currently foresee any potential State requirements that might conflict

with it. Without any conflict, there could not be any implied preemption.

E. Executive Order 12988 (Civil Justice Reform)

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988, "Civil Justice Reform" (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) adequately defines key terms; and (7) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

Pursuant to this Order, NHTSA notes as follows. The issue of preemption is discussed above in connection with E.O. 13132. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

F. Paperwork Reduction Act

Under 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 Office of Management and Budget (OMB) control number. This final rule does not require any collections of information, or recordkeeping or retention requirements as defined by the OMB in 5 CFR Part 1320.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272) directs NHTSA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the Society of

Automotive Engineers (SAE). The NTTAA directs the agency to provide Congress, through the OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

After conducting a search of available sources, we have determined that there is no applicable voluntary consensus standard for this final rule.

H. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires Federal 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 in any one year (adjusted for inflation with base year of 1995). Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires NHTSA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows NHTSA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted.

This final rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of more than \$100 million annually. Accordingly, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

I. 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.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, and Tires.

■ In consideration of the foregoing, 49 CFR part 571 is amended as set forth below:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 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 571.101 is amended by revising the fourth sentence in S5.2.1, adding a fifth sentence to S5.2.1, and by revising S5.4.3, to read as follows:

§ 571.101 Standard No. 101, Controls, telltales, and indicators.

* * * * *

S5.2.1 * * * No identification is required for any horn (i.e., audible warning signal) that is activated by a lanyard or by the driver pressing on the center of the face plane of the steering wheel hub; or for a turn signal control that is operated in a plane essentially parallel to the face plane of the steering wheel in its normal driving position and which is located on the left side of the steering column so that it is the control on that side of the column nearest to the steering wheel face plane. However, if identification is provided for a horn control in the center of the face plane of the steering wheel hub, the identifier must meet Table 2 requirements for the horn.

* * * * *

S5.4.3 Each identifier used for the identification of a telltale, control or indicator must be in a color that stands out clearly against the background. However, this requirement does not apply to an identifier for a horn control in the center of the face plane of the steering wheel hub. For vehicles with a GVWR of under 4,536 kg (10,000 pounds), the compliance date for this provision is September 1, 2011. For vehicles with a GVWR of 4,536 kg (10,000 pounds) or over, the compliance date for this provision is September 1, 2013.

* * * * *

Issued on: August 7, 2009.

Ronald L. Medford,

Acting Deputy Administrator.

[FR Doc. E9-19396 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-59-P

Proposed Rules

Federal Register

Vol. 74, No. 155

Thursday, August 13, 2009

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AH42

[NRC-2008-0332]

Performance-Based Emergency Core Cooling System Acceptance Criteria

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking (ANPR) presents a conceptual approach that the Nuclear Regulatory Commission (NRC) is considering in a rulemaking effort to revise the acceptance criteria for emergency core cooling systems (ECCSs) for light-water nuclear power reactors as currently required by NRC regulations that govern domestic licensing of production and utilization facilities. Revised ECCS acceptance criteria would reflect recent research findings that indicate the current criteria should be re-evaluated for all fuel cladding materials in all potential conditions. Further, the NRC is considering an approach that would expand the applicability of the rule to all current and future cladding materials, modify the reporting requirements, and address the issues raised in a petition for rulemaking (PRM) regarding crud and oxide deposits and hydrogen content in fuel cladding. With this ANPR, the NRC seeks comment on specific questions and issues for consideration related to this proposed conceptual approach to revising the ECCS acceptance criteria.

DATES: Submit comments by October 27, 2009. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration of comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number RIN 3150-AH42 in the subject line of

your comments. Comments on rulemakings submitted in writing or electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submissions that you do not want to be publicly disclosed.

We request that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore they should not include any information in their comments that they do not want publicly disclosed. All commenters should ensure that sensitive or Safeguards Information is not contained in their responses or comments to this ANPR.

Federal e-Rulemaking Portal: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2008-0332. Address questions about NRC dockets to Carol Gallagher (301) 492-3668; e-mail Carol.Gallagher@nrc.gov.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1677.

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

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm during Federal workdays. (Telephone (301) 415-1677).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101. You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Public File Area Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

NRC's Agencywide Document Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available

electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are any problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at (800) 397-4209, (301) 415-4737, or by e-mail to PDR.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT:

Barry Miller, Mail Stop O-9E3, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-4117, or e-mail Barry.Miller@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR part 50—'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998 (ADAMS Accession number ML992870048), the NRC began to explore approaches to risk-informing its regulations for nuclear power reactors. One alternative (termed "Option 3") involved making risk-informed changes to the specific requirements in the body of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50. As the NRC began to develop its approach to risk-informing these requirements, it sought stakeholder input in public meetings. Two of the regulations identified by industry as potentially benefitting from risk-informed changes were 10 CFR 50.44 and 10 CFR 50.46. Section 50.44 specifies the requirements for combustible gas control inside reactor containment structures and § 50.46 specifies the requirements for light-water power reactor emergency core cooling systems. For § 50.46, the potential was identified for making risk-informed changes to requirements for both ECCS cooling performance and ECCS analysis acceptance criteria in § 50.46(b).

Additionally, on March 14, 2000, as amended on April 12, 2000, the Nuclear Energy Institute (NEI) submitted a PRM requesting that the NRC amend its regulations in §§ 50.44 and 50.46 (PRM-50-71). The NEI petition noted that these two regulations apply to only two specific zirconium-based fuel cladding alloys (Zircaloy and ZIRLO™). NEI

stated that reactor fuel vendors had subsequently developed new cladding materials other than Zircaloy and ZIRLO™ and that in order for licensees to use these new materials under the regulations, licensees had to request NRC approval of exemptions from §§ 50.44 and 50.46. On September 16, 2003, (68 FR 54123), the NRC amended § 50.44 to include new, risk-informed requirements for combustible gas control. The regulation was also modified to be applicable to all boiling or pressurized water reactors regardless of the type of fuel cladding material utilized.

On March 3, 2003, in response to SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)'"', the Commission issued a staff requirements memorandum (SRM) (ADAMS Accession number ML030910476) directing the NRC staff to move forward to risk-inform its regulations in a number of specific areas. Among other things, this SRM directed the NRC staff to modify the ECCS acceptance criteria to provide for a more performance-based approach to meeting the ECCS requirements in § 50.46.

Separately from the Commission's efforts to modify its regulations to provide a more risk-informed, performance-based regulatory approach, the NRC had also undertaken a fuel cladding research program intended to investigate the behavior of high exposure fuel cladding under accident conditions. This research program included an extensive loss-of-coolant accident (LOCA) research and testing program at Argonne National Laboratory (ANL), as well as jointly funded programs at the Kurchatov Institute and the Halden Reactor project, to develop the body of technical information needed to support the new regulations.

The effects of both alloy composition and fuel burnup (the extent to which fuel is used in a reactor) on cladding embrittlement (*i.e.*, loss of ductility) under accident conditions were studied in this research program. The research program identified new cladding embrittlement mechanisms and expanded the NRC's knowledge of

previously identified mechanisms. The research results revealed that alloy composition has a minor effect on embrittlement, but the cladding corrosion which occurs as fuel burnup increases has a substantial effect on embrittlement. One of the major findings of NRC's research program was that hydrogen, which is absorbed in the cladding during the burnup-related corrosion process under normal operation, has a significant influence on the embrittlement during a hypothetical accident. Increased hydrogen content increases both the solubility of oxygen in zirconium and the rate at which it is absorbed, thus increasing the amount of oxygen in the metal during high temperature oxidation in LOCA conditions. Oxygen is what ultimately causes embrittlement in zirconium, but hydrogen content is a good indicator of burnup embrittlement effects because of its ability to allow this increased oxygen absorption. Because of hydrogen's effect, the embrittlement thresholds can be correlated with the pre-accident hydrogen concentration. Further, the NRC's research program found that oxygen from the oxide fuel pellets enters the cladding from the inner surface if a bonding layer exists between the fuel pellet and the cladding, in addition to the oxygen that enters from the oxide layer on the outside of the cladding. Moreover, under conditions that might occur during a small-break LOCA [such as an extended time-at-temperature below 1000 degrees Centigrade (°C) (1832 degrees Fahrenheit (°F))], the accumulating oxide on the surface of the cladding can break up; this can allow large amounts of hydrogen to diffuse into the cladding, thus exacerbating the embrittlement process.

The research results also confirmed an older finding that if cladding rupture occurs during a LOCA, large amounts of hydrogen produced from the steam-cladding reaction can enter the cladding inside surface near the rupture location. These research findings have been summarized in Research Information Letter (RIL) 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46," (ADAMS Accession number ML081350225) and the detailed experimental results from the program at ANL are contained in NUREG/CR-6967, "Cladding Embrittlement during

Postulated Loss-of-Coolant Accidents" (ADAMS Accession number ML082130389).

In response to the research findings identified in RIL 0801, the NRC completed a preliminary safety assessment of currently operating reactors (ADAMS Accession number ML090340073). This assessment found that due to realistic fuel rod power history, measured cladding performance under LOCA conditions, and current analytical conservatisms, sufficient safety margin exists for operating reactors. Therefore, any changes to the ECCS acceptance criteria to account for the new findings can reasonably be addressed through rulemaking.

After the NRC publicly released the technical basis information in RIL 0801 on May 30, 2008, and NUREG/CR-6967, on July 31, 2008, it published a **Federal Register** (FR) document on July 31, 2008, (73 FR 44778), requesting that public stakeholders comment on the adequacy of the technical basis and identify issues that may arise with respect to experimental data development, regulatory costs, or impacts of potential new requirements. The comments received in response to this document can be found at <http://www.regulations.gov> by searching on docket ID NRC-2008-0332. On September 24, 2008, the NRC held a public workshop to discuss stakeholder comments on the adequacy of the technical basis and to give the public and industry another opportunity to provide further comment and input. The workshop included presentations and open discussion between representatives of the NRC, international regulatory and research agencies, domestic and international commercial power firms, fuel vendors, and the general public. The meeting summary, including a list of attendees and presentations, is available at ADAMS Accession number ML083010496.

Since 2002, the NRC has met with the Advisory Committee on Reactor Safeguards (ACRS) multiple times to discuss the progress of the LOCA research program and rulemaking proposals. Provided in the table below are the dates and ADAMS Accession numbers of the relevant ACRS meetings and associated correspondence.

Date	Meeting/letter	ADAMS accession number
October 9, 2002	Subcommittee Meeting	ML023030246 *
October 10, 2002	Full Committee Meeting	ML022980190 *
October 17, 2002	Letter from ACRS to NRC staff	ML022960640
December 9, 2002	Response letter from NRC staff to ACRS	ML023260357
September 29, 2003	Subcommittee Meeting	ML032940296 *

Date	Meeting/letter	ADAMS accession number
July 27, 2005	Subcommittee Meeting	ML052230093 *
September 8, 2005	Full Committee Meeting	ML052710235 *
January 19, 2007	Subcommittee Meeting	ML070390301 *
February 2, 2007	Full Committee Meeting	ML070430485 *
May 23, 2007	Letter from ACRS to NRC staff	ML071430639
July 11, 2007	Response letter from NRC staff to ACRS	ML071640115
December 2, 2008	Subcommittee Meeting	ML083520501 * & ML083530449
December 4, 2008	Full Committee Meeting	ML083540616 *
December 18, 2008	Letter from ACRS to NRC staff	ML083460310
January 23, 2009	Response letter from NRC staff to ACRS	ML0836640532

* ADAMS file is a transcript of the ACRS meeting.

On March 15, 2007, Mark Leye submitted to the NRC a PRM (ADAMS Accession number ML070871368). In the petition, which was docketed as PRM 50–84, the petitioner requested that all holders of operating licenses for nuclear power plants be required to operate such plants at operating conditions (e.g., levels of power production, and light-water coolant chemistries) necessary to effectively limit the thickness of crud¹ and/or oxide layers on fuel rod cladding surfaces. The petitioner requested the NRC to conduct rulemaking in the following three specific areas:

(1) Establish regulations that require licensees to operate light-water power reactors under conditions that are effective in limiting the thickness of crud and/or oxide layers on zirconium-clad fuel in order to ensure compliance with § 50.46(b) ECCS acceptance criteria;

(2) Amend Appendix K to 10 CFR part 50 to explicitly require that the steady-state temperature distribution and stored energy in the reactor fuel at the onset of a postulated LOCA be calculated by factoring in the role that the thermal resistance of crud deposits and/or oxide layers plays in increasing the stored energy in the fuel (these requirements also need to apply to any NRC-approved, best-estimate ECCS evaluation models used in lieu of Appendix K to Part 50, calculations); and

(3) Amend § 50.46 to specify a maximum allowable percentage of hydrogen content in [fuel rod] cladding.

¹ Crud is a foreign substance which may be deposited on the surface of fuel cladding which can impede the transfer of heat. Crud most frequently refers to deposits of iron or nickel metallic particles eroded from pipe and valve surfaces. These particles of stable isotopes may become “activated” when they are irradiated in the reactor and transform into radioactive isotopes such as cobalt-60. The NRC makes a distinction between crud and pure zirconium oxidation layers. Although both materials contain metal oxides, crud does not originate at the fuel rod, while zirconium oxide forms on fuel cladding when the cladding material reacts with oxygen.

On May 23, 2007, (72 FR 28902), the NRC published a notice of receipt for this petition in the FR and requested public comment on the petition. The public comment period ended on August 6, 2007. After evaluating the public comments, the NRC resolved the Leye petition by deciding that each of the petitioner’s issues should be considered in the rulemaking process. The NRC’s determination was published in the FR on November 25, 2008, (73 FR 71564).

Because the issues raised in PRM–50–84 pertain to ECCS analysis and acceptance criteria, the need for rulemaking to address the petitioner’s technical concerns will be addressed in this rulemaking. Technical details associated with the NRC’s evaluation of the rulemaking requests in PRM–50–84 are discussed in Section III.4 of this document.

II. Rulemaking Objectives

The scope of the rulemaking contemplated by this ANPR includes four separate rulemaking objectives:

Objective 1: Expand the applicability of § 50.46 to include any light-water reactor fuel cladding material:

In this rulemaking, the NRC is considering expansion of the rule’s applicability (which currently addresses only Zircaloy and ZIRLO™ cladding) to include any light-water reactor fuel cladding material. As used in this ANPR, the term “fuel cladding” (or simply “cladding”) refers only to the cylindrical material that surrounds and contains the nuclear fuel, not a fuel/cladding system. The rulemaking may clarify the general applicability of § 50.46 to require that all light-water nuclear power reactors must be provided with an ECCS designed so that after a postulated LOCA, a coolable core geometry would be maintained, excessive combustible gases would not be generated, and long-term cooling would be assured. The applicability expansion would also encompass the request in PRM–50–71, filed by NEI (see

65 FR 34599; May 31, 2000, and 73 FR 6600; November 6, 2008), to establish requirements that apply to all zirconium-based cladding alloys, including current and anticipated alloys. The NRC’s high-burnup fuel research program investigated cladding embrittlement in a number of different zirconium-based cladding alloys and concluded that the results were applicable equally to all of the zirconium-based alloys. Therefore, new zirconium-specific criteria can be formulated in a performance-based manner that would satisfy the request in PRM–50–71. Because this applicability expansion may also aim to encompass any potential new cladding materials developed in the future that are not zirconium-based, the NRC notes that such materials would still need an extensive technical foundation to receive NRC approval. However, this applicability expansion would eliminate the need for licensees to request, and the NRC to review and approve, exemptions from § 50.46 for these potential new non-zirconium cladding materials.

Objective 2: Establish performance-based requirements and acceptance criteria specific to zirconium-based cladding materials that reflect recent research findings:

The second objective of this rulemaking is to enhance the performance-based features of § 50.46 by replacing the current § 50.46(b) prescriptive analytical limits with fuel cladding performance requirements and acceptance criteria. These performance requirements, based upon the recent findings from the NRC’s high burnup research program, would ensure that an adequate level of cladding ductility is maintained throughout a postulated LOCA.

Objective 3: Revise the LOCA reporting requirements:

The third objective of this rulemaking is to amend § 50.46(a)(3)(i) to emphasize the importance of reporting reduction in margins to the acceptance criteria and

the periodic reporting of susceptibility to breakaway oxidation.

Objective 4: Address the issues raised in PRM-50-84, which relate to crud deposits and hydrogen content in fuel cladding:

The fourth objective of this rulemaking is to amend § 50.46 as necessary to address the technical issues on which the PRM-50-84 petitioner's three requests for rulemaking are based. The need for and extent of any changes that may be needed to address these issues will be determined during this rulemaking.

III. Specific Proposals

The NRC presents the following conceptual approach to revising 10 CFR 50.46 under the outlined objectives:

Objective 1: Expand the applicability of § 50.46 to include any light-water reactor fuel cladding material:

This first conceptual approach involves the applicability of the rule as defined in § 50.46(a)(1)(i). Currently, this provision is limited to fuel rods clad in Zircaloy or ZIRLO™. The recent LOCA research program conducted testing on a wide range of zirconium-based alloys such that research findings and future testing requirements are believed to be applicable to all zirconium-based alloys. Therefore, the NRC intends to expand the applicability of the rule to all zirconium-based alloys. This would allow the introduction of future, advanced zirconium-based alloys without the need for exemption requests. However, NRC approval would still be required.

In addition, the NRC is considering further expansion of the rule's applicability to include all light-water reactors (LWRs) without regard to the type of fuel cladding material utilized in the design. Currently, § 50.46 states that the ECCS must be designed so that its calculated cooling performance following postulated LOCAs conforms to the five criteria set forth in § 50.46(b). To accomplish such a change, the NRC is considering an approach where the proposed revision would specify that all fuel cladding material used in LWRs, without regard to its composition, must satisfy the three general conditions which currently exist as the criteria specified in § 50.46(b)(3) Maximum hydrogen generation, § 50.46(b)(4) Coolable geometry, and § 50.46(b)(5) Long-term cooling. The § 50.46(b)(3) criterion would be modified to limit generation of any combustible gas, rather than just hydrogen, with recognition that different cladding materials could potentially react to produce different combustible gases. Because the NRC's recent research

findings are only applicable to LWRs with zirconium-based cladding alloys, detailed ECCS acceptance criteria for different cladding materials could not now be specified in the regulations. Therefore, the NRC is considering a cladding-specific regulatory approach that would require applicants with non-zirconium cladding materials to propose specific detailed criteria to demonstrate how coolable core geometry, long-term cooling, and minimal generation of combustible gases would be ensured. In order to develop such cladding-specific criteria, applicants would need to fully develop and understand all of the material's degradation mechanisms, chemical and physical properties, and any other characteristics that may affect its behavior in the core during normal operation and under LOCA conditions. The NRC would review the applicant's proposed criteria and issue its approval only if the criteria ensure that the three general conditions are met, that the cladding-specific criteria can be demonstrated to be met during all credible LOCA scenarios, and that they are sufficient to ensure adequate protection of public health and safety. Section IV of this document requests comment on this conceptual approach to expanding the rule's applicability.

For LWRs using zirconium-based alloys, cladding-specific criteria can and will be specified in the regulations based on the results of the NRC's LOCA research program. These criteria will ensure adequate cladding ductility is maintained via specified performance requirements. A general discussion on the nature of these criteria is provided below under Objective 2.

Objective 2: Establish performance-based requirements and acceptance criteria specific to zirconium-based cladding materials that reflect recent research findings:

Cladding Ductility

In the current rule, the preservation of cladding ductility, via compliance with regulatory criteria on peak cladding temperature (§ 50.46(b)(1)) and local cladding oxidation (§ 50.46(b)(2)), ensures that the core remains amenable to cooling. The recent LOCA research program identified new cladding embrittlement mechanisms which demonstrated that the current combination of peak cladding temperature (2200 °F (1204 °C)) and local cladding oxidation (17 percent equivalent cladding reacted (ECR)) criteria do not always ensure post quench ductility (PQD). It is important to recognize that the loss of cladding ductility is the result of oxygen diffusion into the base metal and not

directly related to the growth of a zirconium dioxide layer on the cladding outside diameter. In the current provision, the peak local oxidation limit is used as a surrogate to limit time at elevated temperature and associated oxygen diffusion. This surrogate approach is possible because both oxidation and diffusion share a strong temperature dependence. In the recent LOCA research program, the Cathcart-Pawel (CP) weight gain correlation was used to quantify the time at elevated temperature at which ductility was lost (nil ductility). For this reason, the proposed amendment would include a requirement that local cladding oxidation (which is being used as a surrogate for limiting time-at-temperature) be calculated using the same Cathcart-Pawel correlation (see Regulatory Guide 1.157 regarding use of the Cathcart-Pawel oxidation correlation rather than the Baker-Just correlation cited in 10 CFR part 50, Appendix K, Part I.A.5).

To enhance the performance-based aspects of § 50.46 (and achieve an objective of this rulemaking), the limits on peak cladding temperature and local oxidation would be replaced with specific cladding performance requirements and acceptance criteria which ensure that an adequate level of cladding ductility is maintained throughout the postulated LOCA. For example, the rule may specify that retention of cladding ductility is defined as the accumulation of ≥ 1.00 percent permanent strain prior to failure during ring-compression loading at a temperature of 135 °C and a displacement rate of 0.033 millimeters per second (mm/sec). Section IV of this document requests comment on alternative ways to define an acceptable measure of ductility. This acceptance criterion would be used to define analytical limits for peak cladding temperature and local oxidation based on cladding performance during tests in which cladding specimens are exposed to double-sided steam oxidation up to a specified peak oxidation temperature and CP-ECR. Analytical limits would be calculated as a function of initial cladding hydrogen content (weight parts per million (wppm) in metal). The NRC intends to issue a regulatory guide detailing an acceptable experimental test methodology for defining analytical limits in accordance with these performance requirements. Included in this test methodology would be guidance for treating ring-compression test results which fail in such a way that permanent strain cannot be measured. The guidance would provide a

relationship of permanent strain to offset-displacement.

This ANPR also provides two possible approaches for determining the acceptability of current and future cladding alloys in accordance with the proposed performance requirements. Two approaches are described as follows, however the NRC recognizes there may be other alternatives.

Approach A—Analytical Limits Defined Within Regulatory Guidance:

The focal point of this approach would be a future regulatory guidance document which defines an acceptable, generically-applicable set of analytical limits for peak cladding temperature and maximum allowable time-at-temperature (expressed as calculated local oxidation, CP-ECR) as a function of pre-transient hydrogen content in the cladding metal, excluding hydrogen in the cladding oxide layer. These acceptable analytical limits would be based on the results of NRC's LOCA research program. Appendix A of this document outlines the conceptual path for approving both current and future cladding alloys using this approach.

Approach B—Cladding-Specific Analytical Limits Defined by an Applicant:

The second approach involves establishing cladding-specific and/or temperature-specific analytical limits for peak cladding temperature and maximum allowable time-at-temperature (expressed as calculated local oxidation, CP-ECR) as a function of pre-transient hydrogen content in the cladding metal, excluding hydrogen in the cladding oxide layer. This approach would provide optimum flexibility for defining more specific analytical limits to gain margin to the ECCS performance criteria. However, unlike citing analytical limits within a regulatory guide, this approach places the burden of proof on the applicant to validate their analytical limits and address experimental variability and repeatability. As a result, this approach would necessitate a larger number of PQD tests (relative to confirming the applicability of the regulatory guide). Analytical limits, along with the experimental procedures, protocols, and specimen test results used in their development, would be subject to NRC review and approval. Appendix B of this document includes further discussion to illustrate the possible implementation of this approach.

Cladding embrittlement is highly sensitive to both hydrogen content and peak oxidation temperature, and this relationship is applicable to both approaches. The discussion in the Appendices to this document describes

an approach that would demonstrate compliance with the proposed change and illustrate this relationship.

Implementing any hydrogen based analytical limits, similar to the descriptions contained in the Appendices, requires an accurate, alloy-specific hydrogen uptake model. Section IV of this document seeks comment on the development of these models and how best to deal with the axial, radial, and circumferential variability in hydrogen concentration.

Two-Sided Oxidation

Prompted by research which found that oxygen from the inside diameter fuel bonding layer present in high burnup fuel rods may diffuse into the base metal of the cladding, the NRC is proposing a new analytical requirement to specifically account for the potential diffusion of oxygen from the cladding inside diameter. Because the formation of a fuel bonding layer may depend on fuel rod design and power history, licensees would be required to develop and justify a burnup threshold above which this phenomenon would be specifically accounted for within local cladding oxidation calculations.

Breakaway Oxidation

The NRC may also propose new requirements addressing breakaway oxidation. The recent LOCA research program discovered that the protective cladding oxide layer will undergo a phase transformation, become unstable, and allow for the uptake of hydrogen into the base metal. The timing of this transformation is sensitive to many parameters including the cladding manufacturing process. Licensees would be responsible for ensuring that the timing of the oxide phase transformation is measured for each cladding alloy utilized in their core to determine susceptibility to early breakaway oxidation. The proposed rule would specify the required testing method, along with an acceptable measure of breakaway oxidation behavior. The NRC intends to issue a regulatory guide detailing an acceptable experimental methodology for defining new criteria under these requirements. For example, the proposed rule may specify that the minimum measured time until the onset of breakaway oxidation, defined as when hydrogen uptake reaches 200 wppm anywhere on a cladding segment subjected to high temperature steam oxidation ranging from 1200 °F to 1875 °F (649 °C to 1024 °C), shall remain greater than the calculated duration that cladding surface temperature anywhere on the fuel rod remains above 1200 °F (649 °C).

The measured timing of the oxide phase transformation for each cladding alloy, along with the experimental procedures and protocols used in their development, would be subject to NRC review and approval. Section IV of this document seeks public comment on a draft experimental methodology for conducting breakaway oxidation testing with zirconium-based cladding alloys.

Application of the proposed breakaway oxidation criterion would involve new analytical requirements, including an additional break spectrum analysis to identify the limiting combination of inputs that maximize the time above elevated temperatures which are susceptible to breakaway oxidation for the given cladding alloy (e.g., 1200 °F (649 °C)). Each licensee would be required to demonstrate that this calculated duration remained below the measured minimum time to breakaway oxidation. As an alternative, the NRC is considering tying breakaway oxidation to the rule's applicability statement. For example, the proposed revision would only be applicable to zirconium-based alloys which do not experience the breakaway phenomena within a specified time period. This approach would eliminate the need for each licensee to perform and maintain a current updated final safety analysis report (UFSAR) break spectrum analysis for breakaway oxidation. To set the specified time period within the proposed rule's applicability statement, the NRC is seeking information related to the maximum time span with cladding surface temperature above 1200 °F (649 °C) for the full range of piping break sizes and nuclear steam supply system (NSSS)/ECCS design combinations. If successful, this alternative approach would include a simpler pass/fail breakaway testing requirement up to this specified time period (as opposed to searching for and quantifying the limiting time to breakaway). Section IV of this document seeks to obtain this input.

Objective 3: Revise the LOCA reporting requirements.

Redefining a Significant Change or Error:

The reporting requirement in 10 CFR 50.46(a)(3)(i) currently defines a significant change or error as one that results in a calculated peak cladding temperature (PCT) different by more than 50 °F (28 °C) from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F (28 °C).

The NRC is considering revising the reporting requirements by redefining what constitutes a significant change or error in such a manner as to make the reporting requirements dependent upon the margin between the acceptance criteria limits and the calculated values of the respective parameters (*i.e.*, PCT or CP-ECR). The redefinition would aim to capture the importance of being close to the limits by making reporting of a change dependent upon the margin to the acceptance criteria. The NRC believes this redefinition should also expand the current reporting scope to include CP-ECR, in addition to PCT, as a parameter required for reporting. The timeliness requirements for reporting would remain the same (*i.e.*, 30 days for a significant change or error). The following definitions exemplify a specific approach the NRC is considering:

If the calculated parameter (PCT or CP-ECR) has margin greater than 5 percent of its acceptance criterion limit, then a significant change or error is one that results in:

- (i) A PCT change of 100 °F (56 °C) or greater,
- (ii) A CP-ECR change of 2 percent or greater, or
- (iii) An accumulation of changes and errors such that the sum of the absolute magnitudes of the changes and errors is greater than 100 °F (56 °C) or 2 percent, respectively.

If the calculated parameter (PCT or CP-ECR) is within 5 percent of its acceptance criterion limit, then a significant change or error is one that results in a calculated 10 percent or greater reduction in the remaining margin.

The following table gives an example for how the PCT criterion reporting would be "triggered" for a plant with a PCT limit of 2200 °F.

Calculated PCT	Reporting trigger
< 2090 (<i>i.e.</i> , not within 5 percent of 2200 °F limit).	Any change ≥ 100 °F.
2090–2099 °F	Any change ≥ 11 °F.
2100–2109 °F	Any change ≥ 10 °F.
2110–2119 °F	Any change ≥ 9 °F.
2120–2129 °F	Any change ≥ 8 °F.
2130–2139 °F	Any change ≥ 7 °F.
2140–2149 °F	Any change ≥ 6 °F.
2150–2159 °F	Any change ≥ 5 °F.
2160–2169 °F	Any change ≥ 4 °F.
2170–2179 °F	Any change ≥ 3 °F.
2180–2189 °F	Any change ≥ 2 °F.
2190–2199 °F	Any change ≥ 1 °F.

The NRC recognizes that there are other possible approaches for implementing the concept that the reporting obligation depends upon the

margin to the relevant acceptance criteria. Section IV of this document seeks specific comment on this approach to modifying the reporting requirements.

Breakaway Oxidation Susceptibility Reporting

The NRC is also considering reporting requirements related to breakaway oxidation. Different zirconium-based alloys have varying susceptibility to breakaway oxidation that is dependent on factors such as alloy content, manufacturing process, and surface preparation, among others. The NRC is concerned that during the life-cycle of an alloy used by a fuel vendor, both intentional and unintentional changes may be made in the aforementioned conditions. The effect of the changes can only be determined by testing samples throughout the life-cycle of an alloy of the current cladding material for breakaway oxidation potential. The NRC plans to propose to include periodic testing of cladding samples as part of the annual licensee report pertaining to the LOCA licensing basis. The new requirement would be consistent with the following concept: licensees would report to the NRC at least annually as specified in §§ 50.4 or 52.3, as applicable, results of testing of each type of zirconium-based cladding alloy employed in their reactor core for susceptibility to breakaway oxidation. If a cladding alloy is found to have greater susceptibility to breakaway oxidation than would be acceptable for the corresponding time-at-temperature of the ECCS performance analysis, the affected licensee would be required to propose immediate steps to reduce the impact of breakaway oxidation on their ECCS performance analysis. Section IV of this document seeks specific comment on this approach to modifying the reporting requirements.

Objective 4: Address the issues raised in PRM-50-84, which relate to crud deposits and hydrogen content in fuel cladding:

In this ANPR, the NRC addresses the three requests for rulemaking in PRM-50-84:

(1) Establish regulations that require licensees to operate light-water power reactors under conditions that are effective in limiting the thickness of crud and/or oxide layers on zirconium-clad fuel in order to ensure compliance with § 50.46(b) ECCS acceptance criteria;

(2) Amend Appendix K to 10 CFR part 50 to explicitly require that the steady-state temperature distribution and stored energy in the reactor fuel at the onset of a postulated LOCA be

calculated by factoring in the role that the thermal resistance of crud deposits and/or oxide layers plays in increasing the stored energy in the fuel (these requirements also need to apply to any NRC-approved, best-estimate ECCS evaluation models used in lieu of Appendix K to part 50, calculations); and

(3) Amend § 50.46 to specify a maximum allowable percentage of hydrogen content in [fuel rod] cladding.

PRM-50-84 Rulemaking Requests 1 and 2

Because the petitioner's first two requests for rulemaking are technically related, they are addressed together in the following discussion. When evaluating PRM-50-84, the NRC reviewed the technical information provided by the petitioner and by all public commenters. The NRC's detailed analysis of all public comments was published in the FR on November 25, 2008 (73 FR 71564). A summary of key comments that influenced the NRC's conclusions follows.

The NEI opposed granting PRM-50-84 because the petition relies heavily on atypical operating experiences at four plants: River Bend (1998–1999 and 2001–2003), Three Mile Island Unit 1 (1995), Palo Verde Unit 2 (1997), and Seabrook (1997), where thick crud layers developed during normal operation. NEI stated that the incidents cited by the petitioner were isolated operational events and would not have been prevented by imposing specific regulatory limits on crud thickness. NEI noted that the industry is actively pursuing root cause evaluations and has developed corrective actions to mitigate further cases of excessive crud formation.

NEI also stated that reactor licensees use approved fuel performance models to determine fuel rod conditions at the start of a LOCA. NEI stated that the impact of crud and oxidation on fuel temperatures and pressures may be determined explicitly or implicitly in the system of models used. NEI referenced the NRC review guidance in the Standard Review Plan (SRP) (NUREG-0800) noting that SRP Section 4.2 states that the impact of corrosion on thermal and mechanical performance should be considered in the fuel design analysis, when comparing to the design stress and strain limits. NEI and industry commenters in general opposed issuing new regulations related to crud, stating that the existing regulations and voluntary guidance regarding crud are sufficient.

The NRC agrees with NEI that new requirements imposing specific

regulatory limits on crud thickness would not necessarily have prevented the occurrences of heavy crud deposits that were the unexpected consequences of the operational events cited in PRM-50-84. Nevertheless, formation of cladding crud and oxide layers is an expected condition at nuclear power plants. Although the thickness of these layers is usually limited, the amount of accumulated crud and oxidation varies from plant to plant and from one fuel cycle to another. Intended or inadvertent changes to plant operational practices may result in unanticipated levels of crud deposition. The NRC agrees with the petitioner that crud and/or oxide layers may directly increase the stored energy in reactor fuel by increasing the thermal resistance of cladding-to-coolant heat transfer, and may also indirectly increase the stored energy through an increase in the fuel rod internal pressure.

As previously discussed, NEI commented that reactor licensees use approved fuel performance models to determine fuel rod conditions at the start of a LOCA and that the impact of crud and oxidation on fuel temperatures and pressures may be determined explicitly or implicitly by the system of models used. The NRC believes that to accurately model fuel performance during normal and postulated accident conditions, it is essential that fuel performance and LOCA evaluation models include the thermal effects of both crud and oxidation whenever their accumulation changes the calculated results. Recently, power reactor licensees have been submitting an increased number of license amendment applications requesting significant increases in licensed power levels. In some cases, these increases have reduced the margin between calculated ECCS performance and current ECCS acceptance criteria. This trend further supports the need to ensure that the effects of both crud and oxidation are properly accounted for in ECCS analyses. The technical concerns related to the thermal effects of oxidation and crud raised by the petitioner's rulemaking requests are addressed separately below.

Oxidation. The accumulation of cladding oxidation and its associated effects on fuel cladding acceptance criteria are being addressed by the ongoing work to revise the ECCS acceptance criteria. Thus, the concerns related to oxidation raised by the petitioner's rulemaking requests are encompassed by Objective 2 of this section.

Crud. 10 CFR 50.46 requires the licensee of a facility to perform LOCA

accident analyses to demonstrate that a nuclear reactor has an ECCS that is designed so its calculated performance meets the acceptance criteria in § 50.46(b) on peak clad temperature (2200 °F) and maximum local oxidation (17 percent). Licensees must evaluate a plant's ECCS by calculating its performance with an acceptable evaluation model. An acceptable model is one that either complies with the required and acceptable features in Appendix K to Part 50—ECCS Evaluation Models; or, for best-estimate models, complies with the § 50.46(a)(1)(i) requirement that there is a high level of probability that the calculated cooling performance will not exceed the acceptance criteria in § 50.46(b). The NRC reviews and approves all licensee evaluation models to determine if they are acceptable.

For best-estimate evaluation models, § 50.46(a)(1)(i) requires that "The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor coolant system during a loss-of-coolant accident." For Appendix K models, section I.B. of Appendix K to Part 50 states, "The calculations of fuel and cladding temperatures as a function on time shall use values for gap conductance and other thermal parameters as functions of temperature and other applicable time-dependent variables." Crud accumulation and its effects are not explicitly identified as required parameters to be included in best-estimate or Appendix K to Part 50 models.

However, based on these requirements, the NRC has prepared regulatory review guidance that addresses the accumulation of crud and oxidation deposits on fuel cladding surfaces. This guidance is in the format of review criteria in NUREG-0800, "Standard Review Plan (SRP)" which are used by the NRC staff to review licensees' evaluation models. SRP Section 4.2, "Fuel System Design," Section 4.3, "Nuclear Design," and Section 4.4, "Thermal and Hydraulic Design" all contain specific criteria related to the accumulation of crud and oxidation on fuel cladding surfaces. For example, on page 4.2-6 of SRP Section 4.2.2, fuel system damage acceptance criterion iv. states:

iv. Oxidation, hydriding, and the buildup of corrosion products (crud) should be limited, with a limit specified for each fuel system component. These limits should be established based on mechanical testing to demonstrate that each component maintains acceptable strength and ductility. The safety analysis report should discuss allowable

oxidation, hydriding, and crud levels and demonstrate their acceptability. These levels should be presumed to exist in items (i) and (ii) above. The effect of crud on thermal hydraulic considerations and neutronic (AOA)² considerations are reviewed as described in SRP Sections 4.3 and 4.4.

Page 4.2-15 of SRP Section 4.2 also states that the calculational models used to determine fuel temperature and stored energy should include phenomenological models addressing "Thermal conductivity of the fuel, cladding, crud and oxidation layers" and "Cladding oxide and crud layer thickness." Review criteria in SRP Section 4.4 specifically note that the thickness of oxidation layers and crud deposits must be accounted for in critical heat flux calculations and when determining the pressure drop throughout the reactor coolant system.

The NRC review guidance in the SRP supports interpreting § 50.46(a) and Appendix K to Part 50 to include crud as a required parameter in these analyses. However, because crud is not explicitly identified in the regulations and the regulatory guidance in the SRP is not an enforceable requirement, there is ambiguity in the current requirements. The NRC is considering amending its regulations to explicitly identify crud as one of the parameters that must be addressed in ECCS analysis models. This change would eliminate any ambiguity between the current rule language and the current SRP review guidance. Licensee evaluation models could be formulated to calculate the accumulation of crud or assume an expected maximum thickness. The resulting effects on fuel temperatures would be determined based on the predicted or assumed thickness of deposits.

The NRC also notes that licensees are required to operate their facilities within the boundaries of the calculated ECCS performance. During or immediately after plant operation, if actual crud layers on reactor fuel are implicitly determined or visually observed after shutdown to be greater than the levels predicted by or assumed in the evaluation model, licensees would be required to determine the effects of the increased crud on the calculated ECCS results. In many cases, engineering judgment or simple calculations could be used to evaluate the effects of increased crud levels; therefore, detailed LOCA reanalysis may not be required. In other cases, new analyses would be performed to determine the effect the new crud

² AOA means Axial Offset Anomaly.

conditions have on the final calculated results.

The NRC would consider the deposition of a previously unanalyzed amount of crud to be the same as making a change to or finding an error in an approved evaluation model or in the application of such a model. In these cases, § 50.46(a)(3)(i) requires licensees to determine if the change or error is significant. For significant changes, § 50.46(a)(3)(ii) requires licensees to provide, within 30 days, a report to the NRC including a schedule for providing a reanalysis or taking other action as may be needed to show compliance with the § 50.46 requirements. In situations when the § 50.46(b) acceptance criteria are not exceeded, the licensee could either change the ECCS analysis of record to conform to the new crud level or make changes to plant design or operation (e.g., adjust water coolant chemistry) to reduce crud deposits to the level assumed in the original analysis. Situations where a model change or error correction results in calculated ECCS performance that does not conform to the acceptance criteria in § 50.46(b) would be reportable events as described in §§ 50.55(e), 50.72, and 50.73. In these situations, the licensee would be required under § 50.46(a)(3)(ii) to propose immediate steps to demonstrate compliance or bring the plant design or operation into compliance with § 50.46 requirements.

In summary, to address the technical concerns related to crud in the PRM-50-84 petitioner's requests for rulemaking, the NRC is considering amending § 50.46(a) to specifically identify crud as a parameter to be considered in best-estimate and Appendix K to Part 50 ECCS evaluation models. Compliance with this requirement during plant operation would be determined by the process outlined in the scenarios above.

Under this approach, the NRC would propose new rule language defining crud as a foreign substance (other than zirconium oxide) which may be deposited on the surface of fuel cladding and which impedes the transfer of heat due to thermal resistance and/or flow area reduction. A requirement would be added stating that ECCS evaluation models must consider the effects of crud deposition on fuel cladding at the highest level of buildup expected during a fuel cycle. In addition, to ensure that plant-specific crud levels are bounded by the levels analyzed in the ECCS model, the NRC is considering adding a requirement that licensees inspect one or more fuel assemblies every fuel cycle to determine

the actual thickness of crud on the fuel. Section IV of this document requests comment on the potential addition of such a requirement.

PRM-50-84 Rulemaking Request 3

The petitioner's third request for rulemaking—that the NRC amend § 50.46 to specify a maximum allowable percentage of hydrogen content in cladding—pertains to the effects on fuel cladding embrittlement caused by hydrogen in the cladding. The cladding embrittlement issue will be technically resolved by revising the ECCS analysis embrittlement acceptance criteria under rulemaking Objective 2. These new acceptance criteria will address the embrittlement effects of cladding hydrogen content and other pertinent variables.

IV. Issues for Consideration

Based on the specific proposals and discussion above, the NRC requests comment on the following questions and issues. In submitting comments, the NRC asks that each comment be referenced to its corresponding question or issue number, as indicated below.

Applicability Considerations

1. Objective 1 describes a conceptual approach to expanding the applicability of § 50.46 to all fuel cladding materials. Should the rule be expanded to include any cladding material, or only be expanded to include all zirconium-based cladding alloys? The NRC also requests comment on the potential advantages and disadvantages of the specific approach described that would expand the applicability beyond zirconium-based alloys. Is there a better approach that could achieve the same objective?

2. The rulemaking objectives do not include expanding the applicability of § 50.46 to include fuel other than uranium oxide fuel (UO₂). Is there any need for, or available information to justify, expanding the applicability of this rule to mixed oxide fuel rods?

New Embrittlement Criteria Considerations

3. The NRC requests information related to the maximum time span with cladding surface temperature above 1200 °F (649 °C) for the full range of piping break sizes and NSSS/ECCS design combinations. This information may be used to set a specified minimum time to breakaway in the proposed rule's applicability statement.

4. The NRC requests comment on the two approaches to establishing analytical limits for cladding alloys, as described in Section III.2 of this

document and expanded upon in the Appendices, where limits on peak cladding temperature and local oxidation would be replaced with specific cladding performance requirements that define an adequate level of ductility which must be maintained throughout a postulated LOCA. In addition to general comments on these approaches, the NRC also seeks specific comment on the following related items:

a. The NRC requests any further PQD ring-compression test data that may be available to expand the empirical database as shown in Appendix A of this document.

b. Because no cladding segments tested in the NRC's LOCA research program exhibited an acceptable level of ductility beyond a hydrogen concentration of 550 wppm (metal), analytical limits may be restricted to terminate at this point. Are any further PQD ring-compression test data available at hydrogen concentrations beyond 550 wppm which exhibited an acceptable level of ductility?

c. Ring-compression tests conducted on cladding segments with identical hydrogen concentrations oxidized to the same CP-ECR often exhibited a range of measured offset displacement. The variability, repeatability, and statistical treatment of these test results must be evaluated for defining generic PQD analytical limits. The NRC requests comments on the variability, repeatability, and statistical treatment of ductility measurements from samples exposed to high-temperature steam oxidation.

5. Implementation of a hydrogen-dependent PQD criterion requires an NRC-approved hydrogen uptake model. The sensitivity of hydrogen pickup fraction to external factors (e.g., manufacturing process, proximity to dissimilar metals, plant coolant chemistry, oxide thickness, crud, burnup, etc.) must be properly calibrated in the development and validation of this model.

a. The NRC requests information on the size and depth of the current hot-cell hydrogen database(s) and the industry's ability to segregate the sensitivity of each cladding alloy to each external factor and to quantify the level of uncertainty.

b. Pre-test characterization of some irradiated cladding segments revealed significant variability in axial, radial, and circumferential hydrogen concentrations.

i. What information exists that could quantify this asymmetric distribution in the development of a hydrogen uptake model?

ii. What information exists that could inform the treatment of this asymmetric hydrogen distribution as a function of fuel rod burnup?

iii. This asymmetric hydrogen distribution could be addressed in future PQD ring compression tests on irradiated material by such requirements as orienting ring samples such that the maximum asymmetric hydrogen concentration is aligned with the maximum stress point or in pre-hydrided material by introducing asymmetric distribution during hydriding. The NRC requests comment on these or other methods to treat asymmetric hydrogen distribution.

Testing Considerations

6. A draft proposed cladding oxidation and PQD testing methodology is provided at ADAMS Accession number ML090900841.

a. The NRC requests comment on the details of the draft experimental methodology, including sample preparation and characterization, experimental protocols, laboratory techniques, sample size, statistical treatment, and data reporting.

b. The NRC requests information on any ongoing or planned testing programs that could exercise the draft experimental methodology to independently confirm its adequacy.

c. Unirradiated cladding specimens pre-charged with hydrogen appear to be viable surrogates for testing on irradiated cladding segments. However, the NRC's position remains that future testing to support cladding approval reviews include irradiated material without further confirmatory work to directly compare the embrittlement behavior of irradiated material to hydrogen pre-charged material at the same hydrogen level. The NRC's LOCA research program reports PQD test results on twenty irradiated fuel cladding segments of varying zirconium alloys and hydrogen concentrations that underwent quench cooling. The NRC requests information on any ongoing or planned testing aimed at replicating these twenty PQD tests for the purpose of validating a pre-hydrided surrogate.

d. The NRC is considering defining an acceptable measure of cladding ductility as the accumulation of ≥ 1.00 percent permanent strain prior to failure during ring-compression loading at a temperature of 135 °C and a displacement rate of 0.033 mm/sec. Recognizing the difficulty of measuring permanent strain, the NRC requests comment on alternative regulatory criteria defining an acceptable measure of cladding ductility.

7. The proposed revisions to § 50.46 include a new testing requirement related to breakaway oxidation. Due to the observed effects of manufacturing controlled parameters (*e.g.*, surface roughness, minor alloying, *etc.*) on the breakaway phenomena, the proposed approach would include periodic testing requirements to ensure that both planned and unplanned changes in manufacturing processes do not adversely affect the performance of the cladding under LOCA conditions.

a. The NRC requests comment on the testing frequency and sample size provided in the breakaway oxidation testing methodology (ADAMS Accession number ML090840258) and technical basis for the proposed breakaway oxidation testing requirement.

b. Is there any ongoing or planned testing to further understand the sensitivity of breakaway oxidation to parameters controlled during the manufacturing process?

Revised Reporting Requirements Considerations

8. The NRC requests comment on the proposed concept that the reporting obligation in § 50.46 depend upon the margin to the relevant acceptance criteria. Please also comment on the specific approach to implement this objective as described under Objective 3 in Section III of this document.

9. The NRC requests comment on the proposed concept of adding the results of breakaway oxidation susceptibility testing to the annual reporting requirement. Are there other implementation approaches that could help ensure that a zirconium-based alloy does not become more susceptible to breakaway during its manufacturing and production life-cycle?

Crud Analysis Considerations

10. The NRC requests comment on the proposed regulatory approach in which crud is required to be considered in ECCS evaluation models. If actual crud levels should exceed the levels considered in the evaluation model, the situation would be considered equivalent to discovering an error in the ECCS model. The licensee would then be subject to the reporting and corrective action process specified in § 50.46(a)(3) to resolve the discrepancy. The NRC also requests comment on the imposition of a requirement that one or more fuel assemblies be inspected at the end of each fuel cycle to demonstrate the validity of crud levels analyzed in the ECCS model.

11. What information exists to facilitate developing an acceptable crud deposition model that could correlate crud deposition with measured primary water coolant chemistry (*e.g.*, iron-oxide concentration)? For boiling water reactors, it is difficult to perform visual inspections or poolside measurements of fuel rod crud thickness without first removing the channel box. A crud deposition model would facilitate the confirmation of design crud layers assumed in the ECCS evaluations and provide an indicator to reactor operators when crud levels approach unanalyzed conditions. Are there ongoing or planned industry efforts to monitor water coolant chemistry for comparison to observed crud deposition? If so, what amount of success has been obtained? Could a properly correlated crud model be sufficiently accurate to preclude the need for crud measurements at the end of each fuel cycle?

Cost Considerations

12. The U.S. commercial nuclear power industry claims that implementation of the proposed rule would be a significant burden in both money and resources. The industry has discussed an implementation cost of approximately \$250 million (NRC–2008–0332–0008.1 at <http://www.regulations.gov>).

a. What options are available to reduce this implementation cost?

b. Are there changes in core operating limits, fuel management, or cladding material that would reduce the cost and burden of implementing the proposed hydrogen based PQD criterion without negatively impacting operations?

c. A staged implementation would be more manageable for both the NRC and industry. One potential approach involves characterizing the plants based upon safety margin and deferring implementation for the licensees with the largest safety margin (*e.g.*, lowest calculated CP–ECR). The NRC requests comment on this implementation approach.

Available Supporting Documents

The following documents provide additional background and supporting information regarding this rulemaking activity and corresponding technical basis. The documents can be found in the NRC's Agencywide Document Access and Management System (ADAMS). Instructions for accessing ADAMS were provided under the **ADDRESSES** section of this document.

Date	Document	ADAMS accession number
July 31, 2008	NUREG/CR-6967, "Cladding Embrittlement During Postulated Loss-of-Coolant Accidents".	ML082130389.
May 30, 2008	Research Information Letter (RIL) 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46".	ML081350225.
September 24, 2008	Public Meeting Summary	ML083010496.
February 23, 2009	Plant Safety Assessment of RIL 0801	ML090340073.
July 31, 2008	Federal Register Notice (73 FR 44778), "Notice of Availability and Solicitation of Public Comments on Documents Under Consideration To Establish the Technical Basis for New Performance-Based Emergency Core Cooling System Requirements".	Reference the Federal Register at 73 FR 44778.
March 30, 2009	Supplemental research material—additional PQD tests.	ML090690711.
March 30, 2009	Supplemental research material—additional breakaway testing.	ML090700193.
March 31, 2009	Draft proposed procedure for Conducting Oxidation and Post-Quench Ductility Tests With Zirconium-based Cladding Alloys.	ML090900841.
March 23, 2009	Draft proposed procedure for Conducting Breakaway Oxidation Tests With Zirconium-Based Cladding Alloys.	ML090840258.
January 8, 2009	Update on Breakaway Oxidation of Westinghouse ZIRLO Cladding.	ML091330334.
May 7, 2009	Impact of Specimen Preparation on Breakaway Oxidation (Non-Proprietary).	ML091350581.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

The authority citation for this document is 42 U.S.C. 2201.

Dated at Rockville, MD, this 29th day of July 2009.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

APPENDIX A

An Approach for Determining the Acceptability of Zirconium-Based Cladding Alloys: Analytical Limits Defined Within Regulatory Guidance

This approach would include a future regulatory guidance document that defines an acceptable, generically-applicable set of analytical limits for peak cladding temperature and maximum allowable time-at-temperature (expressed as calculated local oxidation, CP-ECR) as a function of pre-transient hydrogen content in the cladding

metal (excluding hydrogen in the cladding oxide layer). These acceptable analytical limits would be developed using NRC's empirical database with consideration of experimental variability and repeatability. Figure A shows the results of ring-compression tests conducted on as-fabricated, hydrogen charged, and irradiated specimens of Zircaloy-2, Zircaloy-4, ZIRLO™ and M5 cladding material (documented in NUREG/CR-6967). Note that hydrogen concentrations were slightly adjusted (± 5 wppm) to illustrate results of multiple ring-compression tests run at the same CP-ECR and hydrogen concentration. Peak oxidation temperature is identified for samples tested below 2200 °F (1204 °C).

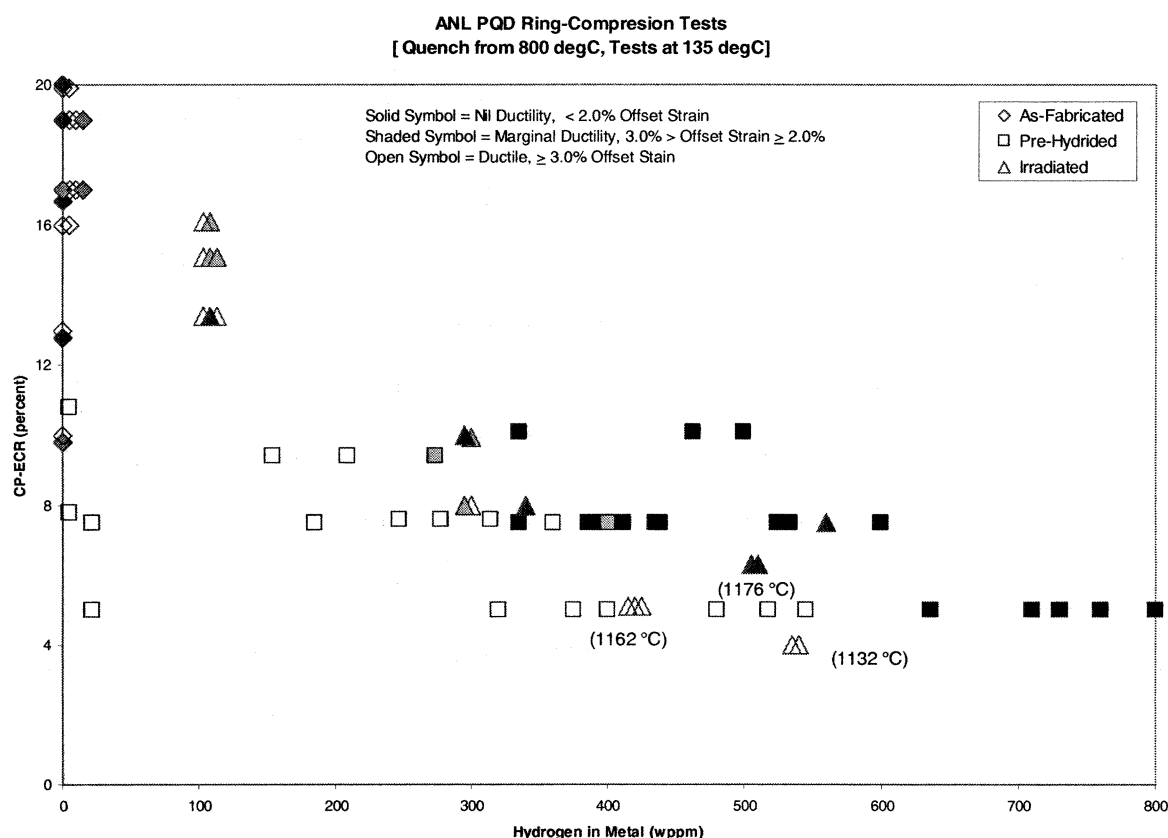


Figure A – Ring compression test results from as-fabricated, pre-hydrated and irradiated material. Samples were oxidized at ≤ 1200 °C and quenched at 800 °C. For high-burnup cladding with about 550 wppm hydrogen, embrittlement occurred during the heating ramp at 1160-1180 °C peak oxidation temperatures. Peak oxidation temperatures are indicated.

The analytical limit on PCT would be restricted to the peak oxidation temperature during testing of the cladding specimens used in the development of this limit. Furthermore, caveats on the applicability of the analytical limits may be required to capture limiting aspects of the steam oxidation temperature profile used during the testing. For example, if the calculated time at the specified PCT is less than the time at peak oxidation temperature of the supporting empirical database (for a given CP-ECR), or the calculated quench temperature is lower than 800 °C, then an applicability caveat may be required.

Existing Cladding Alloys

No PQD testing would be required to approve cladding alloys included in the NRC's LOCA research program. Under this approach, a fuel vendor would submit a topical report (TR) seeking NRC approval of each zirconium-based cladding alloy's analytical limits on PCT and time-at-temperature (CP-ECR, as a function of cladding hydrogen content). The TR would reference the acceptable analytical limits within the Regulatory Guide.

New Cladding Alloys

Under this approach, a fuel vendor would submit a TR which demonstrates that the results of PQD tests on a specific new alloy are applicable to the acceptable analytical

limits defined within the Regulatory Guide. A TR would need to include the results of testing, conducted in accordance with NRC's acceptable experimental methodology, which demonstrates that the embrittlement behavior of the new cladding alloy is consistent with the embrittlement behavior of the cladding alloys tested in NRC's LOCA research program by comparing test results to the defined analytical limit. This would likely require testing of the new cladding alloy with varying hydrogen contents, which are oxidized to calculated oxidation levels (CP-ECR) at or near the analytical limit for that hydrogen level as provided in regulatory guidance. Demonstrating ductile behavior in cladding samples with calculated oxidation levels at or near the analytical limit may serve to confirm the applicability of the analytical limit to a new cladding alloy. The range of hydrogen contents in test samples required may be limited by proposing cladding hydrogen design limits based on hot cell examinations of irradiated samples of the new cladding alloy following lead test assembly campaigns. Regulatory guidance would be provided to address the variability in measured offset strain of ring-compression test results. Section IV of this ANPR specifically seeks comment on the treatment of variability in ductility measurements of ring-compression tests.

For this description, it is assumed that sufficient justification for the use of hydrogen

charged cladding specimens has been accepted as a surrogate for testing on irradiated cladding segments. If sufficient justification for the use of hydrogen charged cladding specimens has not been accepted as a surrogate for testing on irradiated cladding segments, approving new cladding alloys would require PQD testing of irradiated material. Section IV of this ANPR requests information on any ongoing or planned testing aimed at validating this pre-hydrated surrogate.

APPENDIX B

An Approach for Determining the Acceptability of Zirconium-Based Cladding Alloys: Cladding-Specific Analytical Limits Defined by an Applicant

This approach involves establishing cladding-specific and/or temperature-specific analytical limits for peak cladding temperature and maximum allowable time-at-temperature (expressed as calculated local oxidation, CP-ECR) as a function of pre-transient hydrogen content in the cladding metal (excludes hydrogen in the cladding oxide layer). This approach would provide optimum flexibility for defining more specific analytical limits to gain margin to the ECCS performance criteria. However, unlike citing analytical limits within a regulatory guide, this approach places the burden of proof on the applicant to validate their analytical limits and address

experimental variability and repeatability. As a result, this approach would necessitate a larger number of PQD tests (relative to confirming the applicability of the regulatory guide). Analytical limits, along with the experimental procedures, protocols, and specimen test results used in their development, would be subject to NRC review and approval.

This approach would require that the PQD test results on irradiated cladding segments documented in NUREG/CR-6967 be considered in the development of analytical limits. Deviations in cladding performance relative to this empirical database must be identified and dispositioned.

Existing Cladding Alloys

In the case of existing cladding alloys, the rule may specify the following performance requirement to ensure an adequate retention of cladding ductility:

Accumulation of ≥ 1.00 percent permanent strain prior to failure during ring-compression loading at a temperature of 135 °C and a displacement rate of 0.033 mm/sec on a cladding specimen exposed to double-sided steam oxidation up to a specified peak oxidation temperature and CP-ECCR.

Analytical limits on allowable time-at-temperature (CP-ECCR) and peak cladding temperature would need to be defined as a function of initial cladding hydrogen content (wppm in metal) to demonstrate this performance requirement is met. A topical report (TR) would be generated to document the basis for the new analytical limits. Existing alloys which were included in the NRC high-burnup research program may reference the test results documented in NUREG/CR-6967 in the development of new analytical limits. This data was generated following experimental protocols acceptable to the NRC, so no further justification related to its validity would be required.

Using an approved hydrogen uptake model for an existing cladding alloy, the TR would provide the methodology to convert the hydrogen-based analytical limits to some unit of measure more readily applied within reload safety analyses (e.g., fuel rod burnup or fuel duty). Uncertainties related to hydrogen uniformity and uncertainties introduced by the conversion from hydrogen to another unit of measure would need to be addressed.

New Cladding Alloys

In the case of new cladding alloys, the rule may specify the following performance requirement to ensure an adequate retention of cladding ductility:

Accumulation of ≥ 1.00 percent permanent strain prior to failure during ring-compression loading at a temperature of 135 °C and a displacement rate of 0.033 mm/sec on a cladding specimen exposed to double-sided steam oxidation up to a specified peak oxidation temperature and CP-ECCR.

Analytical limits on allowable time-at-temperature (CP-ECCR) and peak cladding temperature would need to be defined as a function of initial cladding hydrogen content (wppm in metal) to demonstrate this performance requirement is met. A TR would be generated to document the basis for the

new analytical limits. The PQD test results on irradiated cladding segments documented in NUREG/CR-6967 would need to be considered in the development of analytical limits. PQD testing would be required to (1) establish analytical limits in accordance with the performance requirements that would be specified within the rule, and (2) demonstrate the applicability of the NUREG/CR-6967 empirical database. A TR could document that the PQD testing had been conducted to strictly adhere to the accepted experimental protocols documented in regulatory guidance documents, or if alternative testing procedures were used, then NRC review and approval of those laboratory procedures would be required.

For this approach, defining analytical limits for new cladding alloys would likely require testing at a range of hydrogen contents, with ring-compression test results at multiple calculated oxidation levels. Test samples with calculated oxidation levels sufficient to display brittle behavior, as well as test samples with calculated oxidation levels which display ductile behavior, would be necessary to define the transition from ductile to brittle behavior. Regulatory guidance would be provided to address the variability in measured offset strain of ring-compression test results. Section IV of this ANPR specifically seeks comment on the treatment of variability in ductility measurements of ring-compression tests. The range of hydrogen contents in test samples required may be limited by proposing cladding hydrogen design limits based on hot cell examinations of irradiated samples of the new cladding alloy following lead test assembly campaigns.

Multifaceted Analytical Limits

Recognizing that higher burnup fuel rods (with higher hydrogen concentrations) operate at a reduced power level (relative to lower burnup fuel rods), defining analytical limits for maximum allowable ECR at multiple peak oxidation temperatures would also be possible. For example, a TR could document the results of testing conducted at peak oxidation temperatures of 2200 °F (1204 °C), 2000 °F (1093 °C), and 1800 °F (982 °C), which are targeted at low burnup (low corrosion), medium burnup (medium corrosion), and high burnup (high corrosion) fuel rods, respectively. Testing to support these new limits would require testing at a range of hydrogen contents, with ring-compression test results at multiple calculated oxidation levels to define the transition from ductile to brittle behavior. In this case, it may be necessary to elect to strictly adhere to the accepted experimental protocols documented in regulatory guidance documents, thereby limiting regulatory exposure related to testing procedures and the validity of the data.

Implementation of the multifaceted analytical limits would require separating all of the fuel rods in the core into three categories and then ensuring that all fuel rods within each category satisfies their respective analytical limits on both CP-ECCR and PCT. While it is anticipated that this approach would provide flexibility, it would also necessitate a more complex LOCA analysis

and reload-by-reload confirmation. This approach also relies on tacit assumptions regarding the currently approved LOCA model's ability to accurately simulate the thermal-hydraulic conditions in every region of the reactor core (as opposed to simulating a core average response or pseudo hot channel location). Modeling uncertainties with respect to predicting local conditions throughout the reactor core would need to be addressed.

Using an approved hydrogen uptake model for a new cladding alloy, the TR would need to provide the methodology to convert the hydrogen-based analytical limits to some unit of measure more readily applied within reload safety analyses (e.g., fuel rod burnup or fuel duty). Uncertainties related to hydrogen uniformity and uncertainties introduced by the conversion from hydrogen to another unit of measure would need to be addressed.

For this description, it is assumed that sufficient justification for the use of hydrogen charged cladding specimens has been accepted as a surrogate for testing on irradiated cladding segments. If sufficient justification for the use of hydrogen charged cladding specimens has not been accepted as a surrogate for testing on irradiated cladding segments, approving new cladding alloys would require PQD testing of irradiated material. Section IV of this ANPR requests information on any ongoing or planned testing aimed at validating this pre-hydrated surrogate.

[FR Doc. E9-19423 Filed 8-12-09; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2009-0713; Directorate Identifier 2007-NM-303-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A318 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Some operators have reported airframe vibration under specific flight conditions including gusts.

Investigations have revealed that under such conditions, vibrations may occur when

the hinge moment of the elevator is close to zero, associated to elevator free-play.

* * * * *

The unsafe condition is excessive vibration of the elevators, which could result in reduced structural integrity and reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by September 14, 2009.

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

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Fax:** (202) 493-2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- **Hand Delivery:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2141; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2009-0713; Directorate Identifier 2007-NM-303-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the

closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2007-0163, dated June 11, 2007 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

Some operators have reported airframe vibration under specific flight conditions including gusts.

Investigations have revealed that under such conditions, vibrations may occur when the hinge moment of the elevator is close to zero, associated to elevator free-play.

* * * * *

The unsafe condition is excessive vibration of the elevators, which could result in reduced structural integrity and reduced controllability of the airplane. The corrective action includes inspecting the elevators for excessive freeplay and repairing the elevator or servo controls, if necessary. You may obtain further information by examining the MCAI in the AD docket.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

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

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA

policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD would affect about 11 products of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$80 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$1,760, or \$160 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Airbus: Docket No. FAA–2009–0713; Directorate Identifier 2007–NM–303–AD.

Comments Due Date

(a) We must receive comments by September 14, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A318 series airplanes; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 27: Flight Controls.

Reason

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

“Some operators have reported airframe vibration under specific flight conditions including gusts.

“Investigations have revealed that under such conditions, vibrations may occur when the hinge moment of the elevator is close to zero, associated to elevator free-play.”

* * * * *

The unsafe condition is excessive vibration of the elevators, which could result in reduced structural integrity and reduced controllability of the airplane. The corrective action includes inspecting the elevators for excessive freeplay, and repairing the elevator or servo controls, if necessary.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) At the later of the times specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD, inspect the elevators for excessive freeplay, using a load application tool and a spring scale assembly, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent). Repeat the inspection at intervals not to exceed 20 months.

Note 1: Guidance on the inspection procedures can be found in Task 27–34–00–

200–001 of the A318/A319/A320/A321 Aircraft Maintenance Manual (AMM).

(i) Within 20 months since the date of issuance of the original French, German, or EASA airworthiness certificate or the date of issuance of the original French, German, or EASA export certificate of airworthiness, or within 3 months after the effective date of this AD, whichever occurs later.

(ii) Within 20 months since the last inspection of the elevators for excessive freeplay performed in accordance with Task 27–34–00–200–001 of the Airbus A320 Airplane Maintenance Manual.

(2) If any inspection required by paragraph (f)(1) of this AD indicates that the freeplay in the elevator exceeds 7 millimeters, before further flight, repair the elevator or servo controls in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA (or its delegated agent).

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows:

(1) The EASA AD applies to Airbus Model A318, A319, A320, and A321 series airplanes, but the FAA AD applies only to Airbus Model A318 series airplanes. The actions required by the EASA AD for Airbus Model A319, A320, and A321 series airplanes are addressed in FAA AD 2001–16–09, amendment 39–12377, and FAA AD 2005–22–10 R1, amendment 39–14354.

(2) This FAA AD does not require modification of the elevator neutral setting as specified in paragraph 2. of the EASA AD because this modification is already part of the FAA-approved type design for Airbus Model A318 series airplanes.

(3) This FAA AD does not require a detailed inspection to determine the position of each tail cone triangle as specified in paragraph 3. of the EASA AD because that action was already accomplished on all Airbus Model A318 series airplanes during production.

Other FAA AD Provisions

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

(1) **Alternative Methods of Compliance (AMOCs):** The Manager, International Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

(2) **Airworthy Product:** For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority

(or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) **Reporting Requirements:** For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI EASA Airworthiness Directive 2007–0163, dated June 11, 2007, for related information.

Issued in Renton, Washington, on August 3, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–19419 Filed 8–12–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2009–0712; Directorate Identifier 2007–NM–152–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–100 and DHC–8–200 Series Airplanes, and Model DHC–8–301, –311, and –315 Airplanes

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

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier Model DHC–8–100 and DHC–8–200 series airplanes, and DHC–8–301, –311, and –315 airplanes. This proposed AD would require implementing a corrosion prevention and control program (CPCP) either by accomplishing specific tasks or by revising the maintenance inspection program to include a CPCP. This proposed AD results from the determination that, as airplanes age, they are more likely to exhibit indications of corrosion. We are proposing this AD to prevent structural failure of the airplane due to corrosion.

DATES: We must receive comments on this proposed AD by September 14, 2009.

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

• **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; e-mail thd.qseries@aero.bombardier.com; Internet <http://www.bombardier.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT:

Pong K. Lee, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7324; fax (516) 794-5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2009-0712; Directorate Identifier 2007-NM-152-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, notified us that an unsafe condition may exist on certain Bombardier Model DHC-8-100 and DHC-8-200 series airplanes, and Model DHC-8-301, -311, and -315 airplanes. TCCA advises that, as airplanes age, they are more likely to exhibit indications of corrosion. Operators must implement a Corrosion Prevention and Control Program (CPCP) that identifies specific areas to be inspected to minimize and control deterioration of the airplane from corrosion. This condition, if not corrected, could result in structural failure of the airplane.

Relevant Service Information

Bombardier has issued Part 1, Section 3, Structural Inspection Program, of the following de Havilland Dash 8 Maintenance Program MRB (Maintenance Review Board) Reports. In this proposed AD, we refer to these publications as the "manual."

- Program Support Manual (PSM) 1-8-7, Revision 22, dated November 1, 2008, for Bombardier Model DHC-8-100 series airplanes.
- PSM 1-82-7, Revision 13, dated November 1, 2008, for Bombardier Model DHC-8-200 series airplanes.
- PSM 1-83-7, Revision 22, dated November 1, 2008, for Bombardier Model DHC-8-300 series airplanes.

The manual provides a basic structural inspection schedule, which is intended to ensure continuous airworthiness. Only primary structures defined as Structurally Significant Items (SSIs) and secondary structures whose failure may adversely affect the systems' functions are included in the manual. Canadian airworthiness requirements state that the aircraft maintenance program must identify specific inspections under the CPCP. For the affected airplanes, the CPCP includes a complete re-analysis of the structural inspection program, supported by in-service engineering findings. New and revised tasks identified as CPCP are annotated in the manual as ED/CPCP. ED stands for "environmental damage."

TCCA mandated the service information and issued Canadian Airworthiness Directive CF-2007-06, dated April 10, 2007, to ensure the

continued airworthiness of these airplanes in Canada.

Levels of Corrosion

The Canadian Airworthiness Directive refers to levels of corrosion. For the purposes of this proposed AD, the levels are defined in Part 1 of the Bombardier (de Havilland) DHC-6 Twin Otter, Dash 7 & Dash 8 Corrosion Prevention and Control Manual PSM 1-GEN-5, Revision 3, dated November 30, 1998, as follows:

- *Level 1 corrosion:*
 1. Occurs between repetitive inspections, is local, and can be reworked within certain limits; or
 2. Is local but exceeds allowable limits and is attributed to an event not typical of the usage of the other airplanes in the operator's fleet; or
 3. Exceeds allowable limits but for which only light corrosion has been found in previous inspections.
- *Level 2 corrosion:*
 1. Occurs between repetitive inspections and exceeds allowable limits, necessitating a repair or complete replacement of a structural significant element; or
 2. Occurs between repetitive inspections, is widespread, and requires a rework approaching allowable limits.
- *Level 3 corrosion* is found during initial or repetitive inspections and is determined to be a potentially urgent unsafe condition necessitating expeditious action.

FAA's Determination and Requirements of the Proposed AD

These airplanes are manufactured in Canada and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCCA has kept the FAA informed of the situation described above. We have examined TCCA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require implementing a CPCP either by accomplishing specific tasks or by revising the maintenance inspection program to include a CPCP. The proposed AD would require you to use the manual described previously to perform these actions. The proposed AD also would require you to report findings of Level 3 corrosion to the airplane manufacturer and to the FAA.

Costs of Compliance

This proposed AD would affect about 154 airplanes of U.S. registry. There are between 16 and 17 specific inspections, depending on the applicable manual identified in Table 1 of this AD. The proposed inspections would take about 53 work hours per airplane, per inspection cycle, at an average labor rate of \$80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is \$652,960, or \$4,240 per airplane, per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

We have determined that this proposed AD would not have federalism

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the ADDRESSES section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:
Authority: 49 U.S.C. 106(g), 40113, 44701.

TABLE 1—APPLICABLE MANUALS

Bombardier model	Manual
(1) DHC–8–101, –102, –103, and –106 airplanes.	Part 1, Section 3, Structural Inspection Program, of the Dash 8 Maintenance Program MRB (Maintenance Review Board) Report Program Support Manual (PSM) 1–8–7, Revision 22, dated November 1, 2008.
(2) DHC–8–201 and DHC–8–202 airplanes	Part 1, Section 3, Structural Inspection Program, of the Dash 8 Maintenance Program MRB Report PSM 1–82–7, Revision 13, dated November 1, 2008.
(3) Model DHC–8–301, DHC–8–311, and DHC–8–315 airplanes.	Part 1, Section 3, Structural Inspection Program, of the Dash 8 Maintenance Program MRB Report PSM 1–83–7, Revision 22, dated November 1, 2008.

Inspections

(h) At the later of the times specified in paragraphs (h)(1) and (h)(2) of this AD, do each of the Environmental Damage/Corrosion Protection and Control Program (ED/CPCP) inspections, including re-protection tasks, as applicable, in accordance with the applicable manual identified in Table 1 of this AD. Except as provided by paragraph (i) of this AD, repeat each task thereafter at intervals not to exceed the compliance time specified in the “Repeat” column of the applicable manual identified in Table 1 of this AD.

- (1) Within 24 months after the effective date of this AD.
- (2) At the compliance time specified in the “Threshold” column of the applicable manual identified in Table 1 of this AD since the date of issuance of the original Canadian airworthiness certificate or the date of issuance of the original Canadian export certificate of airworthiness. If there is no value in the “Threshold” column, use the time specified in the “Repeat” column.
- (i) After accomplishment of each initial ED/CPCP task required by paragraph (h) of

§ 39.13 [Amended]

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

Bombardier, Inc. (Formerly de Havilland, Inc.): Docket No. FAA–2009–0712; Directorate Identifier 2007–NM–152–AD.

Comments Due Date

- (a) The FAA must receive comments on this AD action by September 14, 2009.

Affected ADs

- (b) None.

Applicability

(c) This AD applies to Bombardier Model DHC–8–101, DHC–8–102, DHC–8–103, DHC–8–106, DHC–8–201, DHC–8–202, DHC–8–301, DHC–8–311, and DHC–8–315 airplanes, certificated in any category; serial numbers 003 and subsequent.

Subject

(d) Air Transport Association (ATA) of America Codes 32: Landing Gear, 51: Standard Practices/Structures; 52: Doors; 53: Fuselage; 54: Nacelles/Pylons; 55: Stabilizers; and 57: Wings.

Unsafe Condition

(e) This AD results from the determination that, as airplanes age, they are more likely to exhibit indications of corrosion. We are issuing this AD to prevent structural failure of the airplane due to corrosion.

Compliance

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

Manual References

(g) This AD refers to the manuals listed in Table 1 of this AD.

this AD, the FAA may approve the incorporation into the operator’s approved maintenance/inspection program of the CPCP specified in the applicable manual identified in Table 1 of this AD; or the equivalent program that is approved in accordance with this AD. In all cases, the initial corrosion task for each airplane area must be completed by the initial compliance time specified in paragraph (h) of this AD.

(1) Any operator complying with paragraph (i) of this AD may use an alternative recordkeeping method to that otherwise

required by section 91.417 ("Maintenance records") or section 121.380 ("Maintenance recording requirements") of the Federal Aviation Regulations (14 CFR 91.417 or 14 CFR 121.380, respectively) for the actions required by this AD, provided that the recordkeeping method is approved by the FAA and is included in a revision to the maintenance/inspection program. For the purposes of this paragraph, "the FAA" is defined as the cognizant Principal Maintenance Inspector (PMI) for operators that are assigned a PMI (*i.e.*, part 121, 125, and 135 operators), and the cognizant Flight Standards District Office for other operators (*i.e.*, part 91 operators).

(2) After the initial accomplishment of the ED/CPCP tasks required by paragraph (h) of this AD, any extension of the repetitive intervals specified in the manual must be approved by the Manager, New York Aircraft Certification Office (ACO), FAA.

Corrective Actions

(j) If any corrosion is found during accomplishment of any action required by paragraph (h) of this AD: Before further flight, rework, repair, or replace, as applicable, in accordance with a method approved by either the Manager, New York ACO, FAA; or Transport Canada Civil Aviation (TCCA) (or its delegated agent).

Reporting Requirements for Level 3 Corrosion Findings

(k) If any Level 3 corrosion, as defined in Part 1 of the Bombardier (de Havilland) DHC-6 Twin Otter, Dash 7 & Dash 8 Corrosion Prevention and Control Manual PSM 1-GEN-5, Revision 3, dated November 30, 1998, is found during the accomplishment of any action required by this AD, do paragraphs (k)(1), (k)(2), and (k)(3) of this AD. Under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

(1) Within 3 days after the finding of Level 3 corrosion, report findings to the Manager, New York ACO, FAA, in accordance with the Bombardier (de Havilland) DHC-6 Twin Otter, Dash 7 & Dash 8 Corrosion Prevention and Control Manual PSM 1-GEN-5, Revision 3, dated November 30, 1998.

(2) Within 10 days after the finding of Level 3 corrosion, either submit a plan to the FAA to identify a schedule for accomplishing the applicable CPCP task on the remainder of the airplanes in the operator's fleet that are subject to this AD, or provide data substantiating that the Level 3 corrosion that was found is an isolated case. The FAA may impose a schedule other than that proposed in the plan upon finding that a change to the schedule is needed to ensure that any other Level 3 corrosion is detected in a timely manner. For the purposes of this paragraph, "the FAA" is defined as the cognizant Principal Maintenance Inspector (PMI) for operators that are assigned a PMI (*i.e.*, part 121, 125, and 135 operators), and the cognizant Flight Standards District Office for other operators (*i.e.*, part 91 operators).

(3) Within the time schedule approved in accordance with paragraph (k)(2) of this AD,

accomplish the applicable task on the remainder of the airplanes in the operator's fleet that are subject to this AD.

Limiting Future Corrosion Findings

(l) If corrosion findings that exceed Level 1 are found in any area during any repeat of any CPCP task after the initial accomplishment required by paragraph (h) of this AD: Within 60 days after such finding, implement a means approved by the FAA to reduce future findings of corrosion in that area to Level 1 or better. For the purposes of this paragraph, "the FAA" is defined as the cognizant PMI for operators that are assigned a PMI (*i.e.*, part 121, 125, and 135 operators), and the cognizant Flight Standards District Office for other operators (*i.e.*, part 91 operators).

Scheduling Corrosion Tasks for Transferred Airplanes

(m) Before any airplane subject to this AD is transferred and placed into service by an operator: Establish a schedule for accomplishing the CPCP tasks required by this AD in accordance with paragraph (m)(1) or (m)(2) of this AD, as applicable.

(1) For airplanes on which the CPCP tasks required by this AD have been accomplished previously at the schedule established by this AD: Perform the first CPCP task in each area in accordance with the previous operator's schedule, or in accordance with the new operator's schedule, whichever results in an earlier accomplishment of that CPCP task. After the initial accomplishment of each CPCP task in each area as required by this paragraph, repeat each CPCP task in accordance with the new operator's schedule.

(2) For airplanes on which the CPCP tasks required by this AD have not been accomplished previously, or have not been accomplished at the schedule established by this AD: The new operator must perform each initial CPCP task in each area before further flight or in accordance with a schedule approved by the FAA. For the purposes of this paragraph, "the FAA" is defined as the cognizant Principal Maintenance Inspector (PMI) for operators that are assigned a PMI (*i.e.*, part 121, 125, and 135 operators), and the cognizant Flight Standards District Office for other operators (*i.e.*, part 91 operators).

Alternative Methods of Compliance (AMOCs)

(n)(1) The Manager, New York ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Pong K. Lee, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7324; fax (516) 794-5531.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District

Office. The AMOC approval letter must specifically reference this AD.

Related Information

(o) Canadian airworthiness directive CF-2007-06, dated April 10, 2007, also addresses the subject of this AD.

Issued in Renton, Washington, on August 3, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-19420 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2009-0745; Directorate Identifier 2009-CE-036-AD]

RIN 2120-AA64

Airworthiness Directives; American Champion Aircraft Corp. Models 7ECA, 7GCAA, 7GCBC, 7KCAB, 8KCAB, and 8GCBC Airplanes

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

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all American Champion Aircraft Corp. Models 7ECA, 7GCAA, 7GCBC, 7KCAB, 8KCAB, and 8GCBC airplanes, manufactured prior to 1989 and equipped with folding rear seat backs. This proposed AD would require inspection of the rear seat back hinge areas for cracking and excessive elongation of the rear seat hinge bolt hole and, if cracking or excessive elongation is found, replacement of the rear seat frame. This proposed AD results from an occurrence of the rear seat hinge area failing in flight. We are proposing this AD to detect and correct cracking of the rear seat back hinge area and excessive elongation of the rear seat hinge bolt hole, either of which could result in failure of the seat back. This failure could lead to a rear-seated pilot or passenger inadvertently interfering with the control stick while attempting to not roll to the rear of the airplane upon seat back failure. Consequently, this failure could result in loss of control.

DATES: We must receive comments on this proposed AD by September 28, 2009.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

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

For service information identified in this proposed AD, contact American Champion Aircraft Corporation, P.O. Box 37, 32032 Washington Ave., Rochester, Wisconsin 53167; telephone: (262) 534–6315; fax: (262) 534–2395; Internet: <http://www.amerchampionaircraft.com/Technical/Technical.html>.

FOR FURTHER INFORMATION CONTACT: Wess Rouse, Aerospace Engineer, 2300 East Devon Avenue, Room 107, Des Plaines, Illinois 60018; telephone: (847) 294–8113; fax: (847) 294–7834.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments regarding this proposed AD. Send your

comments to an address listed under the **ADDRESSES** section. Include the docket number, “FAA–2009–0745; Directorate Identifier 2009–CE–036–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

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

Discussion

We received information that during a training flight on an American Champion Aircraft Corp. Model 8KCAB airplane the rear seat hinge failed. While performing spins, with the student pilot in the front seat and the instructor pilot in the rear seat, the rear seat hinge broke, which resulted in the rear seat back failing. The instructor pilot partially fell into the baggage area. The student and the instructor were able to recover from the spins and landed safely at the airport.

The Models 7GCAA, 7GCBC, 7KCAB, and 8GCBC airplanes incorporate the same or similar seat configuration.

This condition, if not corrected, could result in failure of the rear seat back. This failure could lead to a rear-seated

pilot or passenger inadvertently interfering with the control stick while attempting to not roll to the rear of the airplane upon seat back failure. Consequently, this failure could result in loss of control.

Relevant Service Information

We have reviewed American Champion Aircraft Corp. Service Letter No. 431, dated July 20, 2009.

The service information describes procedures for inspecting the rear seat hinge areas for cracking and excessive elongation of the rear seat hinge bolt and, if cracking or excessive elongation is found, replacing the rear seat frame.

FAA’s Determination and Requirements of the Proposed AD

We are proposing this AD because we evaluated all information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design. This proposed AD would require inspecting the rear seat back hinge areas for cracking and excessive elongation of the rear seat hinge bolt hole and, if cracking or excessive elongation is found, replacing the rear seat frame.

Costs of Compliance

We estimate that this proposed AD would affect 2,000 airplanes in the U.S. registry.

We estimate the following costs to do the proposed inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
.5 work-hour × \$80 per hour = \$40	Not applicable	\$40	\$80,000

We estimate the following costs to do any necessary replacements that would

be required based on the results of the proposed inspection. We have no way of

determining the number of airplanes that may need this replacement:

Labor cost	Parts cost	Total cost per airplane
1.5 work-hours × \$80 per hour = \$120	Remanufactured seat \$200, New standard seat \$645, New wide seat \$765.	Remanufactured seat \$320, New standard seat \$765, New wide seat \$885.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

Examining the AD Docket

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

American Champion Aircraft Corp.: Docket No. FAA-2009-0745; Directorate Identifier 2009-CE-036-AD.

Comments Due Date

- (a) We must receive comments on this airworthiness directive (AD) action by September 28, 2009.

Affected ADs

- (b) None.

Applicability

(c) This AD applies to Models 7ECA, 7GCAA, 7GCBC, 7KCAB, 8KCAB, and 8GCBC airplanes, all serial numbers, that are:

- (1) Manufactured prior to 1989;
- (2) Equipped with folding rear seat backs; and
- (3) Certificated in any category.

Unsafe Condition

(d) This AD results from an occurrence of the rear seat frame failing in flight. We are proposing this AD to detect and correct cracking of the rear seat back hinge area and excessive elongation of the rear seat hinge bolt hole, which could result in failure of the rear seat back. This failure could lead to a rear-seated pilot or passenger inadvertently interfering with the control stick while attempting to not roll to the rear of the airplane upon seat back failure. Consequently, this failure could result in loss of control.

Compliance

- (e) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) Inspect the rear seat back hinge area for cracking and elongation of the rear seat hinge bolt hole.	Within the next 25 hours time-in-service (TIS) after the effective date of this AD and repetitively thereafter at intervals not to exceed every 100 hours TIS or every 12 months, whichever occurs first.	Follow American Champion Aircraft Corp. Service Letter No. 431, dated July 20, 2009.
(2) If cracking or excessive elongation of the rear seat bolt hole is found during any inspection required in paragraph (e)(1) of this AD, replace the seat frame with a factory remanufactured seat frame, a new part number (P/N) 7-1500 (standard) seat frame, or a new P/N 7-1501 (wide) seat frame. Replacement of the seat frame terminates the repetitive inspections requirements of this AD.	Before further flight after the inspection where cracking or excessive elongation of the rear seat bolt hole is found.	Follow American Champion Aircraft Corp. Service Letter No. 431, dated July 20, 2009.
(3) You may at any time replace the rear seat frame with a factory remanufactured seat frame, a new part number (P/N) 7-1500 (standard) seat frame, or a new P/N 7-1501 (wide) seat frame to terminate the repetitive inspection requirements of this AD.	Not applicable	Follow American Champion Aircraft Corp. Service Letter No. 431, dated July 20, 2009.

Alternative Methods of Compliance (AMOCs)

(f) The Manager, Chicago Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Wess Rouse, Aerospace Engineer, 2300 East Devon Avenue, Room 107, Des Plaines, Illinois 60018; telephone: (847) 294-8113; fax: (847) 294-7834. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(g) To get copies of the service information referenced in this AD, contact American Champion Aircraft Corporation, P.O. Box 37, 32032 Washington Ave., Rochester, Wisconsin 53167; telephone: (262) 534-6315; fax: (262) 534-2395; Internet: <http://www.amerchampionaircraft.com/Technical/Technical.html>. To view the AD docket, go to U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at <http://www.regulations.gov>.

Issued in Kansas City, Missouri, on August 7, 2009.

Scott A. Horn,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-19448 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1112

[CPSC Docket No. CPSC–2009–0061]

Audit Requirements for Third Party Conformity Assessment Bodies

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Consumer Product Safety Commission (“CPSC” or “Commission”) is proposing to issue regulations establishing requirements for the periodic audit of third party conformity assessment bodies as a condition for their continuing accreditation. The proposed rule would implement section 14(d) of the Consumer Product Safety Act (“CPSA”), as amended by section 102(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”).

DATES: Submit written or electronic comments on the proposed rule by October 13, 2009. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 14, 2009, (see the “Paperwork Reduction Act” section of this document).

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2009–0061, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or

other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Randy Butturini, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; 301–504–7562; e-mail: RButturini@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 14(a)(1) of the CPSA (15 U.S.C. 2063(a)(1)), as amended by the CPSIA (Pub. L. 110–314, 122 Stat. 3016), requires that the manufacturer (including the importer) and the private labeler, if any, of a product that is subject to an applicable consumer product safety rule under the CPSA, or any similar rule, ban, standard, or regulation under any other Act enforced by the CPSC, issue a certificate which certifies “based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under this Act or any other Act enforced by the Commission” and specifies each rule, ban, standard, or regulation applicable to the product. This requirement applies to any such product manufactured on or after November 12, 2008. Section 14(a)(4) of the CPSA gives the CPSC the authority to designate, by rule, one or more of these parties to issue the required certificate and to relieve the other parties enumerated in section 14 of the CPSA from the requirement to furnish certificates. The CPSC issued a final rule in the **Federal Register** on November 18, 2008 (73 FR 68328) pertaining to such certificates of compliance.

Section 14(a)(2) of the CPSA establishes a third party testing requirement for children’s products that are subject to a children’s product safety rule. In general, section 14(a)(2) of the CPSA states, in part, that every manufacturer or private labeler (if the children’s product bears a private label) of such products shall submit sufficient samples of the product, or samples that are identical in all material respects to the product, to an accredited third party conformity assessment body to be tested for compliance with such children’s product safety rule. Section 14(a)(3) of the CPSA establishes various time lines for accreditation and requires the Commission to publish notice of the requirements for accreditation of third

party conformity assessment bodies to assess conformity with specific laws or regulations, and the Commission has published several notices of requirements in the **Federal Register** (see 73 FR 54564 (September 22, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with part 1301 of Title 16, Code of Federal Regulations)); 73 FR 62965 (October 22, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1508, Part 1509, and/or Part 1511 of Title 16, Code of Federal Regulations)); 73 FR 67838 (November 17, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With part 1501 of Title 16, Code of Federal Regulations); and 73 FR 78331 (December 22, 2008) (Notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with the 600 parts per million (“ppm”) and 300 ppm lead content limits in metal and metal alloy parts of children’s metal jewelry established by the Consumer Product Safety Improvement Act of 2008)).

Section 14(d)(1) of the CPSA, as added by the CPSIA, requires the Commission to establish “requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation of such conformity assessment bodies” under section 14(a)(3)(C) of the CPSA.

This proposed rule, if finalized, would implement section 14(d)(1) of the CPSA.

II. Description of the Proposed Rule

The proposal would create a new part 1112, titled “Audit Requirements for Third Party Conformity Assessment Bodies,” in Title 16 of the Code of Federal Regulations.

A. Proposed § 1112.1—Purpose

Proposed § 1112.1 would describe the purpose behind the new part 1112. In brief, proposed § 1112.1 would state that part 1112 “establishes the audit requirements for third party conformity assessment bodies pursuant to section 14(d)(1) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(d)(1)).” Under section 14(d)(1) of the CPSA, compliance with the requirements in part 1112 would be a condition for the continuing accreditation of such third party conformity assessment bodies.

Section 14(f)(2)(C) of the CPSA, “Testing and Certification of Art Materials and Products,” states that a certifying organization as defined in 16

CFR 1500.14(b)(8), Appendix A, “(or any successor regulation or ruling) meets the requirements of [section 14(f)(2)(A) of the CPSA] with respect to the certification of art material and art products required under this section or by regulations prescribed under the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.).” These certifying organizations certify that art materials conform to the requirements of ASTM D-4236 under the Labeling of Hazardous Art Materials Act (LHAMA), 15 U.S.C. 1277, which provided that the provisions of ASTM D-4236 shall be deemed a regulation issued by the Commission. Those requirements are codified at 16 CFR 1500.14(b)(8).

LHAMA and the standard it mandated provide certain requirements for art materials. Under these requirements, the producer or repackager of an art material must submit the product’s formulation or reformulation to a toxicologist who will review the formulation to determine if the art material has potential to produce chronic adverse health effects through customary or reasonably foreseeable use. If the toxicologist does determine that the art material has this potential, the toxicologist will recommend appropriate chronic hazard labeling, and the producer or repackager must use suitable precautionary labeling on the product. If the art material presents an acute hazard, the labeling also must contain an acute hazard warning.

Under LHAMA, the producer or manufacturer of the art material must submit to the Commission a written description of the criteria the toxicologist uses to determine whether the producer/repackager’s product has the potential to produce chronic adverse health effects and a list of art materials that require chronic hazard warning labels. A conformance statement indicating that the product has been reviewed in accordance with the standard as required must appear either on the product, at point of sale, or on an invoice. Furthermore, the “Guidelines for a Certifying Organization,” which can be found as Appendix A to 16 CFR 1500.14(b)(8), state, in part, that an “advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board” should conduct periodic reviews of a toxicologist’s reviews and that, “In cases where there is a disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist’s decision can

be presented to the advisory board for arbitration.”

Thus, because section 14(f)(2)(A) of the CPSA considers organizations that follow the guideline listed at Appendix A to 16 CFR 1500.14(b)(8) to be third party conformity assessment bodies and because the “Guidelines for a Certifying Organization” establish a mechanism for reviewing the toxicologist’s work (either periodically or in response to a disagreement), the proposed rule would not subject these certifying organizations to the audit requirements in part 1112.

B. Proposed § 1112.3—Definitions

Proposed § 1112.3 would define various terms used in part 1112.

Proposed § 1112.3(a) would define “accreditation” as: A procedure by which an authoritative body gives formal recognition that a third party conformity assessment body is competent to perform specific tasks. Accreditation recognizes a third party conformity assessment body’s technical competence and is usually specific for tests of the systems, products, components, or materials for which the third party conformity assessment body claims proficiency.

The proposed definition is based on a description used by the International Organization for Standardization (ISO) in relation to ISO Standard ISO/IEC 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories” (see International Organization for Standardization, “Accreditation,” accessed on the Internet at http://www.isoiec17025.com/wst_page4.html), except that it uses the term “third party conformity assessment body” instead of “lab” and refers to “technical competence” instead of “technical capability.” The term “third party conformity assessment body” is used in section 14(a)(3)(C) of the CPSA. The Commission is aware that ISO/IEC 17025, by reference, incorporates the definitions set forth in ISO/IEC 17000:2004, “Conformity Assessment—Vocabulary and General Principles,” but ISO/IEC 17000’s definition of “accreditation” incorporates several other definitions by implied reference. Therefore, the proposed rule would adopt a more explanatory definition rather than adopt a definition from ISO/IEC 17000 whose terms necessitate additional definition themselves.

Proposed § 1112.3(b) would define “accreditation body” as “an entity that accredits or has accredited a third party conformity assessment body as meeting, at a minimum, the International Organization for Standardization (ISO)

Standard ISO/IEC 17025:2005, ‘General Requirements for the Competence of Testing and Calibration Laboratories’” and any test methods or consumer product safety requirements specified in the relevant notice of requirements issued by the Commission and is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement. The proposed definition of “accreditation body” reflects the basic elements the Commission has specified in its notices of requirements for the accreditation of third party conformity assessment bodies. Additionally, the phrase “at a minimum” recognizes that some accreditation bodies may, as part of the accreditation process, demand that a third party conformity assessment body demonstrate its conformance with specific methods or programs in addition to demonstrating conformance with ISO/IEC 17025 and with any test methods identified in the relevant notices of requirements issued by the Commission.

ISO/IEC 17025 incorporates by reference the definitions in ISO/IEC 17000, and ISO/IEC 17000 defines “accreditation body” as an “authoritative body that performs accreditation.” However, for purposes of the proposed rule, the Commission believes that the proposed definition is more explanatory and, in this instance, more consistent with the notices of requirements for the accreditation of third party conformity assessment bodies.

Proposed § 1112.3(c) would define “audit” as “a systematic, independent, documented process for obtaining records, statements of fact, or other relevant information, and assessing them objectively to determine the extent to which specified requirements are fulfilled.” The proposed definition is almost identical to the definition of “audit” in ISO/IEC 17000. Proposed § 1112.3(c) also would explain that, for purposes of part 1112, an audit is composed of two parts: (1) An examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation (a process known more commonly as a “reassessment” and which the remainder of this preamble will refer to as a “reassessment”); and (2) the resubmission of the “Consumer Product Conformity Assessment Body Acceptance Registration Form” (CPSC Form 223) by the third party conformity assessment body and the CPSC’s examination of the resubmitted CPSC Form 223 (which the remainder of this preamble will refer to as an

“examination” by the CPSC). For example, assume that a third party conformity assessment body is accredited as conforming to ISO/IEC 17025 and to the testing pertaining to 16 CFR part 1501 (which pertains to “Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts”). The “reassessment” portion of the audit, in this example, would consist of the assessment or reassessment of the third party conformity assessment body by the accreditation body relative to ISO/IEC 17025 and the testing pertaining to 16 CFR part 1501. The “examination” portion of the audit would consist of the third party conformity assessment body re-registering at the CPSC through the completion of a new CPSC Form 223 and the CPSC’s review of the information in the resubmitted form. If the third party conformity assessment body is a “firewalled” conformity assessment body or a government-owned or government-controlled conformity assessment body, the CPSC’s examination may include verification to ensure that the entity continues to meet the appropriate statutory criteria pertaining to such conformity assessment bodies. (A “firewalled” conformity assessment body is a conformity assessment body that is “owned, managed, or controlled by a manufacturer or private labeler,” and such conformity assessment bodies are subject to certain statutory requirements and are accredited by the Commission by order (see section 14(f)(2)(D) of the CPSA). Section 14(f)(2)(B) of the CPSA also allows a third party conformity assessment body to be “owned or controlled in whole or in part by a government” under certain statutory conditions or requirements. The statutory requirements for “firewalled” and government-owned or government-controlled conformity assessment bodies are in addition to those pertaining to third party conformity assessment bodies generally.)

Proposed § 1112.3(d) would define “Commission” as meaning the Consumer Product Safety Commission.

Proposed § 1112.3(e) would define “quality manager” as an individual “(however named) who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times and has direct access to the highest level of management at which decisions are made on the conformity assessment body’s policy or resources.” This

definition is patterned after the explanation of the quality manager’s role in ISO/IEC 17025, section 4.1.5.

Proposed § 1112.3(f) would explain that, unless otherwise stated, the definitions of section 3 of the CPSA and additional definitions in the CPSIA apply for purposes of part 1112 of this title. Thus, for example, the CPSIA’s definition of “third party conformity assessment body,” which includes independent conformity assessment bodies, government-owned or government-controlled conformity assessment bodies (subject to certain requirements in section 14(f)(2)(B) of the CPSA), and “firewalled” conformity assessment bodies (subject to certain requirements in section 14(f)(2)(D) of the CPSA), would apply to part 1112, and the term “third party conformity assessment body” in part 1112 would be understood as including all three types of conformity assessment bodies.

C. Proposed § 1112.5—Who Is Subject to These Audit Requirements?

Proposed § 1112.5 would explain that the requirements in part 1112 apply to third party conformity assessment bodies operating pursuant to section 14(a)(2) of the CPSA and would reiterate that third party conformity assessment bodies must comply with the audit requirements as a continuing condition of the Commission’s acceptance of their accreditation. However, as explained earlier in part II.A of this preamble, certifying organizations described in Appendix A to 16 CFR 1500.14(b)(8) (pertaining to LHAMA and the certification of art material and art products) are not subject to the audit requirements.

D. Proposed § 1112.7—What Must an Audit Address or Cover? Who Conducts the Audit?

As described earlier in part II.B of this document, proposed § 1112.3(c) would explain that, for purposes of part 1112, an audit is composed of two parts: (1) An examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation (the “reassessment” portion of the audit); and (2) the resubmission of the “Consumer Product Conformity Assessment Body Acceptance Registration Form” (CPSC Form 223) by the third party conformity assessment body and the CPSC’s examination of the resubmitted CPSC Form 223. If the third party conformity assessment body is a “firewalled” conformity assessment body or a government-owned or government-controlled conformity assessment body,

the CPSC’s examination may include verification to ensure that the entity continues to meet the appropriate statutory criteria pertaining to such conformity assessment bodies.

Under proposed § 1112.7(a), the reassessment portion of the audit may cover the management systems, specific tests, types of tests, calibrations, or types of calibrations that are the subject of the third party conformity assessment body’s accreditation. For example, if an accreditation body accredited a third party conformity assessment body on the latter’s conformity with ISO/IEC 17025 and additional method(s) or programs from the accreditation body or tests identified in the relevant notice of requirements issued by the Commission, the reassessment portion of the audit could have the accreditation body assess the third party conformity assessment body’s conformity with ISO/IEC 17025 and assess whether the third party conformity assessment body is qualified to use the specific method(s) or programs from the accreditation body or the tests identified in the relevant notice of requirements. The examination portion of the audit conducted by the CPSC would consist of the third party conformity assessment body’s resubmission of a CPSC Form 223, the CPSC’s examination of the resubmitted form, and a check by the CPSC to see whether the third party conformity assessment body continues to meet the statutory requirements applicable to it.

It is important to note that, with one exception, the proposed rule would not specify the precise scope of a reassessment by an accreditation body. The Commission recognizes that accrediting bodies often have the flexibility to determine whether a third party conformity assessment body continues to conform with its accreditation requirements and to decide what systems or test methods to examine as part of the reassessment process. Thus, the proposed rule would state that the reassessment portion of the audit “may” (rather than “must”) cover the management systems, specific tests, types of tests, calibrations, or types of calibrations that are the subject of the third party conformity assessment body’s accreditation. Proposed § 1112.7(a) would, however, expressly require each reassessment to examine the third party conformity assessment body’s management systems to ensure that the third party conformity assessment body is free from any undue influence regarding its technical judgment. Such an examination would be consistent with ISO/IEC 17025, section 4.1, “Organization,” and note 2 to section 4.1.4 states that:

If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger trust in its independence of judgment and integrity in relation to its testing or calibration activities.

(See International Organization for Standardization, ISO/IEC 17025: 2005(E), "General Requirements for the Competence of Testing and Calibration Laboratories," at page 2.) Such an examination also would be consistent with section 14(f)(2)(D)(ii) of the CPSA, which requires "firewalled" conformity assessment bodies to have established procedures to ensure that:

(I) Its test results are protected from undue influence by the manufacturer, private labeler or other interested party;

(II) The Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and

(III) Allegations of undue influence may be reported confidentially to the Commission.

Proposed § 1112.7(b) would require the third party conformity assessment body to have the accreditation body that accredited the third party conformity assessment body perform the reassessment portion of the audit. For example, if a third party conformity assessment body was accredited by an accreditation body named AB-1, then AB-1 would conduct the reassessment. If, however, the same third party conformity assessment body changes its accreditation, so that it becomes accredited by a different accreditation body named AB-2, then AB-2 would conduct the reassessment.

The proposed rule contemplates that accrediting bodies performing a reassessment will conform to ISO/IEC 17011, "Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." Certain provisions in ISO/IEC 17011, notably sections 7.11, "Reassessment and Surveillance," 7.12, "Extending Accreditation," and 7.13, "Suspending, Withdrawing, or Reducing Accreditation," may be particularly relevant when conducting a reassessment.

As for the examination portion of the audit, proposed § 1112.7(c) would explain that the third party conformity assessment body must have the examination portion of the audit conducted by the Commission. The examination portion of the audit would consist of resubmission of CPSC Form 223 by the third party conformity

assessment body to the CPSC and the CPSC's examination of the resubmitted form. As explained later in part II.E of this document, resubmission of the CPSC Form 223 would occur in two ways: (1) There would be a continuing obligation to ensure that the information submitted on CPSC Form 223 is current, such that a third party conformity assessment body would submit a new CPSC Form 223 whenever the information changes; and (2) in the absence of any changes that would necessitate the submission of a new CPSC Form 223, the third party conformity assessment body would re-register at the CPSC every two years using CPSC Form 223.

Additionally, proposed § 1112.7(c) would contain specific requirements for the CPSC's examination of "firewalled" and government-owned or government-controlled conformity assessment bodies. For "firewalled" conformity assessment bodies, proposed § 1112.7(c)(1) would state that the examination portion of the audit conducted by the CPSC may include verification to ensure that the "firewalled" conformity assessment body continues to meet the criteria set forth in section 14(f)(2)(D) of the CPSA. Section 14(f)(2)(D) of the CPSA states that:

Upon request, the Commission may accredit a conformity assessment body that is owned, managed, or controlled by a manufacturer or private labeler as a third party conformity assessment body if the Commission by order finds that—

(i) Accreditation of the conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body; and

(ii) The conformity assessment body has established procedures to ensure that—

(I) Its test results are protected from undue influence by the manufacturer, private labeler or other interested party;

(II) The Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and

(III) Allegations of undue influence may be reported confidentially to the Commission.

Thus, for example, under proposed § 1112.7(c)(1), the CPSC could examine whether a "firewalled" conformity assessment body's established procedures continue to exist and examine its mechanisms for confidential reporting of allegations of undue influence. For government-owned or government-controlled conformity assessment bodies, proposed § 1112.7(c)(2) would state that the examination portion of the audit

conducted by the CPSC may include verification that the government-owned or government-controlled conformity assessment body continues to meet the five criteria set forth in section 14(f)(2)(B) of the CPSA. In brief, section 14(f)(2)(B) of the CPSA states that the term "third party conformity assessment body" may include a government-owned or government-controlled entity if:

(i) Private labelers located in any nation are permitted to choose conformity assessment bodies that are not owned or controlled by the government of that nation;

(ii) The entity's testing results are not subject to undue influence by any other person, including another governmental entity;

(iii) The entity is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited under [section 14 of the CPSA];

(iv) The entity's testing results are accorded no greater weight by other governmental authorities than those of other third party conformity assessment bodies accredited under [section 14 of the CPSA]; and

(v) The entity does not exercise undue influence over other governmental authorities on matters affecting its operations or on decisions by other governmental authorities controlling distribution of products based on outcomes of the entity's conformity assessments.

Thus, for example, under proposed § 1112.7(c)(2), the CPSC could examine whether a government-owned conformity assessment body has procedures in place to ensure that its testing results are not subject to undue influence by any other person. CPSC staff is considering whether to specify the types of documents government-owned or government-controlled conformity assessment bodies should have to demonstrate compliance with section 14(f)(2)(B) of the CPSA; however, because such details may be more appropriately considered to be part of the accreditation or acceptance of accreditation processes rather than part of an "audit," the Commission may amend the previously-published notices of requirements and/or include such information in any future notices of requirements.

E. Proposed § 1112.9—When Must an Audit Be Conducted?

Proposed § 1112.9(a) would state that, at a minimum, each third party conformity assessment body must be reassessed at the frequency established by its accreditation body for reassessments of the accreditation. For example, if the accreditation body would conduct a reassessment to reexamine a third party conformity

assessment body's accreditation after two years, the minimum reassessment frequency for that third party conformity assessment body, under proposed § 1112.9(a), would be two years.

Third party conformity assessment bodies are free to have themselves reassessed more frequently (such as annually or on any other predetermined schedule) and may wish to consider having reassessments conducted if a change has occurred that may affect their capabilities. For example, if a third party conformity assessment body desires to perform an additional method, it may wish to consider being reassessed at an earlier date so that the reassessment examines the third party conformity assessment body's conformance with ISO/IEC 17025 and all methods covered by the accreditation(s). As another example, accreditation bodies themselves may have shorter intervals between initial accreditation and a reassessment or allow for another type of action called "surveillance." Section 7.11.3 of ISO/IEC 17011 discusses various dates for reassessment and/or surveillance of a third party conformity assessment body's accreditation. ISO/IEC 17011 defines "surveillance" as a "set of activities, except reassessment, to monitor the continued fulfillment by accredited [conformity assessment bodies] of requirements for accreditation." "Surveillance," therefore, is distinct from "reassessment." Section 7.11.3 of ISO/IEC 17011 directs accreditation bodies to design a plan for reassessment and surveillance and recommends that the first on-site surveillance be conducted "no later than 12 months from the date of initial accreditation."

As for the examination portion of the audit conducted by the CPSC, proposed § 1112.9(b)(1) would require each third party conformity assessment body to ensure that the information it submitted on CPSC Form 223 is current and to submit a new CPSC Form 223 whenever the information, such as the third party conformity assessment body's address, telephone number, or ownership, changes. This will ensure that the information available to CPSC reflects the most current information for a particular third party conformity assessment body. In the absence of any changes that would necessitate the submission of a new CPSC Form 223, proposed § 1112.9(b)(2) would require the third party conformity assessment body to re-register at the CPSC every two years using CPSC Form 223. This re-registration requirement may help CPSC identify third party conformity

assessment bodies that have gone out of business or discontinued testing of products subject to the CPSC's jurisdiction and remove such third party conformity assessment bodies from its list of accredited third party conformity assessment bodies.

If a third party conformity assessment body has registered more than once with the CPSC, has registered at different times, and has no changes in information that would warrant the submission of a new CPSC Form 223, the first examination portion of the audit, under proposed § 1112.9(b)(3), would be performed two years after the last registration date, and then every two years thereafter. For example, assume that a third party conformity assessment body registers in 2009 to test for lead paint and later registers in 2010 to test for small parts. The examination portion of the audit would occur in 2012, and subsequent examination portions of the audit would be at 2014, 2016, etc. If the third party conformity assessment body has made changes that warranted the submission of a new CPSC Form 223, then, under proposed § 1112.9(b)(4), the first examination portion of the audit would be performed two years after the submission of the new CPSC Form 223.

F. Proposed § 1112.11—What Must a Third Party Conformity Assessment Body Do After an Audit?

In general, once the accreditation body has conducted its reassessment of a third party conformity assessment body, the accreditation body will present its initial findings along with any supporting evidence to the quality manager for the third party conformity assessment body. The accreditation body may give the third party conformity assessment body's personnel the opportunity to present any objections they have to the initial findings. The accreditation body may then adjust its findings in response to any valid objections.

When the accreditation body presents its findings to the third party conformity assessment body, proposed § 1112.11(a) would require the third party conformity assessment body's quality manager to receive the findings and, if necessary, to initiate corrective action in response to the findings. Proposed § 1112.11(b) would require the quality manager to prepare a resolution report; the resolution report would identify the corrective actions taken and any follow-up activities. If immediate corrective action is necessary (as may be the case if the findings identify problems associated with incorrect procedures, invalid actions, or the creation or use of

invalid data), proposed § 1112.11(b) would require the quality manager to document that he/she notified the relevant parties within the third party conformity assessment body to take immediate corrective action and also document the action(s) taken.

Proposed § 1112.11(c) would require the quality manager to notify the CPSC if the accreditation body decides to reduce, suspend, or withdraw the third party conformity assessment body's accreditation, and the reduction, suspension, or withdrawal of accreditation is relevant to the third party conformity assessment body's activities pertaining to a CPSC regulation or test method. For example, assume that a third party conformity assessment body is accredited by its accreditation body to perform lead paint testing and to perform tests to detect the presence of a specific substance (which this example will refer to as Test 2), where the latter test is not done to determine whether children's products conform to an applicable children's product safety rule and also is not within the scope of the CPSC's acceptance of the accreditation for the third party conformity assessment body. Assume further that the accreditation body finds the third party conformity assessment body to remain competent to conduct the lead tests, but withdraws accreditation with respect to Test 2. Under this example, the quality manager would not have to notify the CPSC that the accreditation body has withdrawn accreditation for Test 2 because Test 2 was not relevant to the third party conformity assessment body's testing of children's products.

In circumstances when a notification is required, the notification would be sent to the Assistant Executive Director, Office of Hazard Identification and Reduction, within five business days of the accreditation body's notification to the third party conformity assessment body. This provision will help ensure that the CPSC is notified about third party conformity assessment bodies that have their accreditation suspended or withdrawn or have the scope of their accreditation reduced after a reassessment. If a third party conformity assessment body does not notify the CPSC as proposed § 1112.11(c) would require, such non-compliance may be grounds for withdrawal of acceptance of the accreditation by the Commission itself under section 14(e)(1)(B) of the CPSA for failure to "comply with an applicable * * * requirement established by the Commission" under the audit regulations.

Proposed § 1112.11(d) would explain that the CPSC will notify the third party

conformity assessment body if the CPSC finds that the third party conformity assessment body no longer meets the conditions contained in CPSC Form 223 or in the relevant statutory provisions applying to that third party conformity assessment body. The CPSC also will identify the condition or statutory provision that is no longer met and specify a time by which the third party conformity assessment body must notify the CPSC of the steps that it intends to take to correct the deficiency and when it will complete such steps. Proposed § 1112.11(d) also would require the quality manager to document that he/she notified the relevant parties within the third party conformity assessment body to take corrective action and also document the action(s) taken.

Proposed § 1112.11(e) would describe the possible consequences if a third party conformity assessment body fails to remedy the deficiency in a timely fashion. In brief, proposed § 1112.11(e) would state that the CPSC “shall take whatever action it deems appropriate under the circumstances, up to and including withdrawing the CPSC’s accreditation of the third party conformity assessment body or the CPSC’s acceptance of the third party conformity assessment body’s accreditation.”

G. Proposed § 1112.13—What Records Should a Third Party Conformity Assessment Body Retain Regarding an Audit?

Proposed § 1112.13 would require a third party conformity assessment body to retain all records relating to an audit and all records pertaining to the third party conformity assessment body’s resolution of or plans for resolving nonconformities identified by the audit. Such nonconformities could be identified through a reassessment by an accreditation body or through an examination by the CPSC. The proposal also would require third party conformity assessment bodies to retain

records relating to the last three reassessments (or however many reassessments have been conducted if the third party conformity assessment body has been reassessed less than three times) and to make such records available to the CPSC upon request.

The Commission also proposes to require third party conformity assessment bodies to retain records relating to the last three reassessments because such records may reveal whether a pattern of problems with accreditation exists and how quickly such problems are addressed and resolved.

III. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This part of the preamble to the proposed rule describes the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

The Commission invites comments on: (1) Whether the collection of information is necessary for the proper performance of the CPSC’s functions, including whether the information will have practical utility; (2) the accuracy of the CPSC’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: Audit Requirements for Third Party Conformity Assessment Bodies.

Description: The proposed rule would require third party conformity assessment bodies to comply with the audit requirements. As part of these requirements, the proposed rule would, if finalized, require the third party conformity assessment bodies to complete an on-line form to begin the examination portion of the audit process. This form asks for certain identifying information pertaining to the third party conformity assessment body, information concerning whether the third party conformity assessment body is owned, managed, or controlled by manufacturers or private labelers of children’s products, whether the third party conformity assessment body is owned or controlled by a government entity, the laboratory accreditation certificate for the third party conformity assessment body, and, for “firewalled” conformity assessment bodies, training materials. Additionally, the proposed rule would require third party conformity assessment bodies to retain records relating to a reassessment and all records pertaining to the third party conformity assessment body’s resolution or plans for resolving nonconformities identified by the reassessment. The proposal also would require third party conformity assessment bodies to retain such records relating to the last three reassessments (or however many reassessments have been conducted if the third party conformity assessment body has been reassessed less than three times). Proposed § 1112.13 would require the third party conformity assessment body to make such records available to the CPSC upon request.

Description of Respondents: Persons who are third party conformity assessment bodies pursuant to section 14(a) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)).

The CPSC estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total hours
1112.9(b)(1)	150	1	150	1	150
1112.9(b)(2)	3	1	3	0.25	0.75
1112.13	150	1	150	4	600
Total					750.75

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

Our estimates are based on the following information:

- As of June 5, 2009, 153 third party conformity assessment bodies had registered with the CPSC. However,

because the CPSC expects to receive additional registrations and because section 14(a)(3)(B)(vi) of the CPSA

requires the Commission to issue a notice of requirement for “all other children’s product safety rules,” it is anticipated that many more third party conformity assessment bodies will register. Therefore, the Commission tentatively estimates the number of third party conformity assessment bodies to be 300.

- Under proposed § 1112.9(b)(1), third party conformity assessment bodies would be required to resubmit CPSC Form 223. At a minimum, assuming there are no changes to the information that a third party conformity assessment body has submitted previously in its CPSC Form 223, the resubmission would occur every two years from the date of the previous submission. As all third party conformity assessment bodies have not submitted their first CPSC Form 223s at the same time, only some would be expected to resubmit a CPSC Form 223 in any one year. The percentage of third party conformity assessment bodies that will resubmit a CPSC Form 223 in a given year cannot be determined at this time, so, for purposes of this analysis, the CPSC will assume that half of the third party conformity assessment bodies will resubmit a CPSC Form 223 in any given year. Thus, the estimated number of respondents for proposed § 1112.9(b)(1) is 150 (300 total third party conformity assessment bodies $\times$ 0.5 resubmissions annually per third party conformity assessment bodies = 150 resubmissions annually). Furthermore, the CPSC estimates the burden hour for each resubmission to be one hour, so the total burden associated with proposed § 1112.9(b)(1) would be 150 hours (150 resubmissions $\times$ 1 hour per resubmission = 150 hours).

- Under proposed § 1112.9(b)(2), third party conformity assessment bodies would be required to ensure that the information submitted on CPSC Form 223 is current and to submit a new CPSC Form 223 whenever the information changes. Based on current experience with third party conformity assessment bodies, the CPSC estimates that only one percent of third party conformity assessment bodies will revise or update their information, so the estimated number of respondents is 3 (300 third party conformity assessment bodies $\times$ 0.01 revisions per conformity assessment body = 3 revisions per year).

- Under proposed § 1112.13, third party conformity assessment bodies will have to retain records pertaining to an audit and their resolution of or plans for resolving nonconformities identified through a reassessment by an accrediting body or through an

examination by the CPSC. The proposal also would require third party conformity assessment bodies to retain records relating to the last three reassessments (or however many reassessments have been conducted if the number of reassessments is less than three). The number of third party conformity assessment bodies to be reassessed in a given year cannot be determined at this time, but, for purposes of this analysis, the CPSC will assume that half will be reassessed in any given year. Thus, the estimated number of respondents is 150 (300 third party conformity assessment bodies $\times$ 0.5 reassessments annually per third party conformity assessment bodies = 150 reassessments annually). As for the time required to retain such records, it is difficult to estimate such time with precision because the amount of time is likely to vary among the third party conformity assessment bodies. Third party conformity assessment bodies that are accredited in more than one field or that have scopes that include a large number of tests are likely to require more time to manage the records generated during an audit than those who are accredited in only one field or whose scopes are limited to only a few tests. It is also likely that third party conformity assessment bodies at which a large number of nonconformities are discovered during a reassessment audit will require more time to maintain the records since more records are likely to be generated in correcting the nonconformities. Nevertheless, the CPSC tentatively estimates that it will take 4 hours per third party conformity assessment body, so the overall recordkeeping burden will be 600 hours (150 reassessments per year $\times$ 4 hours per record per reassessment = 600 hours). Most respondents probably will need less time to maintain records, but some can be expected to require more time due to factors such as the number of nonconformities found that might require the preparation of additional documents.

The total burden, therefore, is 750.75 hours, which the CPSC will round up to 751 hours.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the CPSC has submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by September 14, 2009, to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

IV. Regulatory Flexibility Act

The CPSC has examined the impacts of the proposed rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the required information is minimal and the costs associated with the audits are low, the Commission certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

A. Objectives and Legal Basis for the Draft Proposed Rule

Section 102(b) of the CPSIA requires the Commission to establish requirements for the periodic audit of the third party conformity assessment bodies in order for them to maintain their accreditation. The draft proposed rule would implement the CPSIA’s audit requirement. The purpose of a periodic audit is to ensure that an accredited third party conformity assessment body is still competent to perform the testing services for which it has been accredited. In the case of accredited third party conformity assessment bodies that are owned, managed, or controlled by a manufacturer (or “firewalled” conformity assessment bodies) or that are owned or controlled in whole or in part by a government entity, the audit requirements provide the Commission with an opportunity to ensure that the third party conformity assessment body continues to comply with the CPSIA’s requirements for “firewalled” and government-owned or government-controlled conformity assessment bodies.

B. Firms Subject to the Requirement for Periodic Audits

The requirement for periodic audits will only affect those third party conformity assessment bodies that seek to be able to provide the CPSIA-required third-party conformity assessment services for manufacturers or private labelers of children’s products. Third party conformity assessment bodies that do not intend to offer third party conformance testing for children’s products are not affected by the requirements for accreditation or periodic audits.

As of June 5, 2009, the CPSC had accepted the accreditations of 153 third party conformity assessment bodies. Of these, 40 are located within the United States. Of the third party conformity assessment bodies located in the United

States, six of the locations are owned by very large, foreign-based companies; nine are affiliated with large, United States-based companies; and the balance or 25 (about 63 percent) are affiliated with companies that could be small businesses according to the criteria established by the Small Business Administration (SBA), which for a testing laboratory (NAICS code 541380) is a company with less than \$12.5 million in annual revenue.

It is likely that the number of third party conformity assessment bodies with CPSC-accepted accreditations will increase over the next several months or years as the CPSIA's third party testing requirements are implemented or become effective. (The Commission, in a notice published in the **Federal Register** on February 9, 2009 (74 FR 6396), announced a stay of enforcement pertaining to certain provisions of section 14(a) of the CPSA; those provisions, in general, required testing and issuance of certificates of compliance by manufacturers, and the stay is to remain in effect until February 10, 2010. Additionally, section 14(a)(3)(B) of the CPSA establishes a timeline for accreditation and directs the CPSC to publish "notices of requirements" for accreditation of third party conformity assessment bodies; as more notices of requirements issue, it is reasonable to expect that the number of third party conformity assessment bodies seeking accreditation will increase.) Therefore, it is not possible to state with certainty how many third party conformity assessment bodies will ultimately be accredited. CPSC staff believes that the number of third party conformity assessment bodies in the United States that are ultimately accredited for testing children's products may reach 120. If 63 percent of these meet the SBA criteria for a small business, then about 76 small U.S. businesses would be affected by this proposed rule.

C. Requirements of the Draft Proposed Rule and Possible Impacts on Small Businesses

The notices of requirements issued by the CPSC for the accreditation of third party conformity assessment bodies state that, as a baseline requirement, third party conformity assessment bodies must be accredited by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement (ILAC—MRA). ILAC is an international cooperation of laboratory accreditation bodies that seeks to harmonize laboratory accreditation procedures so as to

facilitate the acceptance of the testing results of accredited laboratories both within and across national boundaries. The ILAC—MRA includes requirements for the initial assessment of laboratories and periodic reassessments. Laboratories that do not submit to the periodic reassessments lose their accredited status.

Under the proposed rule, the periodic audit of a third party conformity assessment body would consist of two parts. The first part would be a reassessment by the accrediting body to determine whether it continues to meet the conditions for accreditation. The second part of the audit would be the resubmission to the CPSC of CPSC Form 223 and its review by the CPSC.

All signatories to the ILAC—MRA have requirements for the periodic reassessment of accredited laboratories. The ILAC—MRA harmonized procedures for surveillance and reassessment of accredited laboratories (available on the Internet at http://www.ilac.org/documents/ILAC_G10_1996_harm_proced_for_surve_and_reass_of_accred_labs.pdf) recommend that the time between reassessments be no more than 60 months provided that the accrediting body undertakes somewhat less comprehensive surveillance visits at least every 18 months. However, many accrediting bodies opt to undertake more frequent full reassessments rather than conduct surveillance visits. According to ISO/IEC 17011, if an accreditation body does not conduct surveillance visits, full reassessments of accredited laboratories must take place at least once every two years.

The resubmission of CPSC Form 223 is intended to give the CPSC an opportunity to ensure that the third party conformity assessment body is still accredited by an ILAC—MRA signatory and still complies with the requirements of section 102 of the CPSIA with respect to "firewalled" and government-owned or government-controlled conformity assessment bodies. The CPSC is proposing that CPSC Form 223 be kept current or that, in the absence of any changes to the information that a third party conformity assessment body has previously submitted, be resubmitted every two years.

The cost of the periodic audit includes the cost of the time of the accrediting body's assessor to conduct the assessment, the cost of the assessor's travel to the site, and the cost of lodging and meals while the assessor is conducting the reassessment. According to a representative of an accrediting body, a reassessment will typically take two to three days, and the cost charged

to the third party conformity assessment body usually will be \$3,000 to \$4,000 per field (e.g., chemical, electrical, or mechanical testing) in which the third party conformity assessment body is accredited. Therefore, a third party conformity assessment body that is accredited for testing conformance to both chemical and mechanical standards could expect an assessment or reassessment to cost \$6,000 to \$8,000.

Another cost of a reassessment by an accrediting body is the cost of the time that third party conformity assessment body personnel spend cooperating with the assessors. This includes the time required to prepare or assemble documents needed by the auditors and to explain or demonstrate the procedures used at the third party conformity assessment body. No empirical estimates of this cost were found, but one might expect that the amount of time spent by third party conformity assessment body personnel during a reassessment would be close to the amount of time spent by the assessor. If the average reassessment takes 2.5 days (or 20 hours) and the wage of the employees involved is about \$44 an hour, then the cost of the time of the third party conformity assessment body's personnel spent cooperating with the reassessment would be about \$880. (The median hourly wage of architecture and engineering occupations in testing laboratories (NAICS code 541380) is \$31.65 (U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2008 (data extracted on June 17, 2009 from <http://www.bls.gov/data/>). In 2008, wages and salaries represented about 71.9 percent of total compensation for professional and related occupations in private industry (U.S. Department of Labor, Bureau of Labor Statistics, *Employer cost for Employee Compensation* (data extracted on June 17, 2009)).) The cost could be higher if a reassessment took longer than 2.5 days or higher paid employees were involved in the reassessment.

Another requirement would be the resubmission of CPSC Form 223, which must be done every two years. The cost to resubmit this form is probably low for most third party conformity assessment bodies, unless there have been significant changes in the third party conformity assessment body's ownership or internal practices since the last time it submitted the form. On average, the CPSC estimates that it will take one hour to complete this form and submit it electronically. If the form is completed by a manager, the cost would average \$68, assuming the median

hourly compensation for a general or operations manager in a testing laboratory. (The median hourly wage of a general or operations managers in testing laboratories (NAICS code 541380) is \$48.73 (U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2008 (data extracted on June 17, 2009 from <http://www.bls.gov/data/>)). In 2008, wages and salaries represented about 71.9 percent of total compensation for professional and related occupations in private industry (U.S. Department of Labor, Bureau of Labor Statistics, *Employer cost for Employee Compensation* (data extracted on June 17, 2009)).) The cost could be somewhat higher than average for “firewalled” and government-owned or government-controlled conformity assessment bodies. “Firewalled” conformity assessment bodies will need to provide the CPSC staff with the updated information and documents that describe the training that the “firewalled” conformity assessment body employees receive for reporting to the CPSC any allegation of an attempt by a manufacturer, private labeler, or other interested party to hide or exert undue influence over test results. Government-owned or government-controlled conformity assessment bodies might need to provide updated information to demonstrate that the government entity does not exert undue influence on the operation of the third party conformity assessment body or the testing results and that the third party conformity assessment body is not treated more favorably than other accredited third party conformity assessment bodies in the same nation.

The draft proposed rule also would require that third party conformity assessment bodies keep the information on CPSC Form 223 current. Based on the experience to date, the CPSC staff expects that about one percent of the third party conformity assessment bodies will need to provide updates to the form during the year. These updates should take about 15 minutes to complete online.

The periodic audits that would be required would cost third party conformity assessment bodies about \$4,000 to \$5,000 (rounded to the nearest thousand) per field in which the third party conformity assessment body is accredited. This cost includes the cost of the accrediting body’s assessors as well as the time of the third party conformity assessment body personnel that is spent on the audit, and other costs, such as the cost of providing the materials required of “firewalled”

conformity assessment bodies. The time periods between audits will vary to some degree between accrediting bodies, but a typical period is about every two years. Therefore, the annual average cost of the periodic audits would be approximately \$2,000 to \$2,500 per field in which the third party conformity assessment body is accredited. Therefore, the annual cost to a third party conformity assessment body accredited in three fields (e.g., chemical, mechanical, and electrical) would be approximately \$6,000 to \$7,500.

As noted earlier, the SBA considers a testing laboratory to be a small business if its annual revenue is less than \$12.5 million. According to the 2002 Economic Census, a very high percentage of testing laboratories would be considered to be small businesses. In 2002, almost 97 percent of all testing laboratories had revenue of less than \$10 million, and almost 50 percent had revenue of less than \$500,000 (see U.S. Department of Commerce, Bureau of the Census, 2002 Economic Census (release date November 15, 2005); accessed at http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0254SSSZ4&-NAICS2002=541380 (June 4, 2008)). Also, about 63 percent of the third party conformity assessment bodies that have been accredited so far for testing children’s products appear to be small businesses. Therefore, it is likely that the proposed rule will impact a substantial number of small businesses. However, it is unlikely that the rule will have significant adverse impact on many third party conformity assessment bodies. The only third party conformity assessment bodies that will seek accreditation for testing children’s products are those that expect to receive substantial revenue from the testing required by the CPSIA. Those third party conformity assessment bodies that do not expect substantial revenue from the testing required by the CPSIA will not seek to be accredited for the testing or they will not renew their accreditation if they had initially sought accreditation, but the expected revenue did not materialize.

D. Alternatives Considered to the Draft Proposed Rule

Given that the CPSC is relying upon accrediting bodies that are signatories to the ILAC–MRA to accredit and reassess the third party conformity assessment bodies, there are no realistic alternatives to the draft proposed rule that would substantially lower the cost of the periodic audits. The frequency of the reassessments of the third party

conformity assessment bodies is determined by the accrediting bodies, not the CPSC. The CPSC could reduce the frequency that CPSC Form 223 must be resubmitted. However, it probably takes a third party conformity assessment body an average of 1 hour to review and resubmit CPSC Form 223 and any supplemental materials. Therefore, reducing the frequency that this form has to be resubmitted would not significantly lower the cost of the periodic audits.

V. Environmental Considerations

This proposed rule falls within the scope of the Commission’s environmental review regulations at 16 CFR 1021.5(c)(2) which provide a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

VI. Effective Date

The Commission is proposing that any final rule based on this proposal become effective 60 days after its date of publication in the **Federal Register**.

List of Subjects in 16 CFR Part 1112

Consumer protection, Third party conformity assessment body, Audit.

For the reasons stated above, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding a new part 1112 to read as follows:

PART 1112—AUDIT REQUIREMENTS FOR THIRD PARTY CONFORMITY ASSESSMENT BODIES

Sec.

1112.1 Purpose.

1112.3 Definitions.

1112.5 Who Is Subject to These Audit Requirements?

1112.7 What Must an Audit Address or Cover? Who Conducts the Audit?

1112.9 When Must an Audit be Conducted?

1112.11 What Must a Third Party Conformity Assessment Body Do After an Audit?

1112.13 What Records Should a Third Party Conformity Assessment Body Retain Regarding an Audit?

Authority: Public Law 110–314, Sec. 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

§ 1112.1 Purpose.

This part establishes the audit requirements for third party conformity assessment bodies pursuant to section 14(d)(1) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(d)(1)). Compliance with these requirements is a condition for the continuing accreditation of such third party conformity assessment bodies pursuant

to section 14(a)(3)(C) of the CPSA. However, this part does not apply to certifying organizations under the Labeling of Hazardous Art Materials Act even if such organizations are third party conformity assessment bodies.

§ 1112.3 Definitions.

The following definitions apply for purposes of this part:

(a) “Accreditation” means a procedure by which an authoritative body gives formal recognition that a third party conformity assessment body is competent to perform specific tasks. Accreditation recognizes a third party conformity assessment body’s technical capability and is usually specific for tests of the systems, products, components, or materials for which the third party conformity assessment body claims proficiency.

(b) “Accreditation body” means an entity that:

(1) Accredits or has accredited a third party conformity assessment body as meeting, at a minimum, the International Organization for Standardization (ISO) Standard ISO/IEC 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories” and any test methods or consumer product safety requirements specified in the relevant notice of requirements issued by the Commission; and

(2) Is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement.

(c) “Audit” means a systematic, independent, documented process for obtaining records, statements of fact, or other relevant information, and assessing them objectively to determine the extent to which specified requirements are fulfilled. An audit, for purposes of this part, is composed of two parts:

(1) An examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation (a process known more commonly as a “reassessment”); and

(2) The resubmission of the “Consumer Product Conformity Assessment Body Acceptance Registration Form” (CPSC Form 223) by the third party conformity assessment body and the Consumer Product Safety Commission’s (“CPSC’s”) examination of the resubmitted CPSC Form 223. If the third party conformity assessment body is owned, managed, or controlled by a manufacturer or private labeler (also known as a “firewalled” conformity assessment body) or is a government-owned or government-

controlled conformity assessment body, the CPSC’s examination may include verification to ensure that the entity continues to meet the appropriate statutory criteria pertaining to such conformity assessment bodies.

(d) “CPSC” means the Consumer Product Safety Commission.

(e) “Quality manager” means an individual (however named) who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times and has direct access to the highest level of management at which decisions are made on the conformity assessment body’s policy or resources.

(f) Unless otherwise stated, the definitions of section 3 of the CPSA and additional definitions in the Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, apply for purposes of part 1112 of this title.

§ 1112.5 Who Is Subject to These Audit Requirements?

Except for certifying organizations described in 16 CFR 1500.14(b)(8), these audit requirements apply to third party conformity assessment bodies operating pursuant to section 14(a)(2) of the CPSA. Third party conformity assessment bodies must comply with the audit requirements as a continuing condition of the CPSC’s acceptance of their accreditation.

§ 1112.7 What Must an Audit Address or Cover? Who Conducts the Audit?

(a) The reassessment portion of an audit may cover the management systems, specific tests, types of tests, calibrations, or types of calibrations that are the subject of the third party conformity assessment body’s accreditation. Each reassessment portion of an audit also must examine the third party conformity assessment body’s management systems to ensure that the third party conformity assessment body is free from any undue influence regarding its technical judgment.

(b) The third party conformity assessment body must have the reassessment portion of the audit conducted by the same accreditation body that accredited the third party conformity assessment body. For example, if a third party conformity assessment body was accredited by an accreditation body named AB–1, then AB–1 would conduct the reassessment. If, however, the same third party conformity assessment body changes its accreditation, so that it becomes accredited by a different accreditation

body named AB–2, then AB–2 would conduct the reassessment.

(c) The third party conformity assessment body must have the examination portion of the audit conducted by the CPSC. The examination portion of the audit will consist of resubmission of the “Consumer Product Conformity Assessment Body Acceptance Registration Form” (CPSC Form 223) by the third party conformity assessment body and the CPSC’s examination of the resubmitted CPSC Form 223.

(1) For “firewalled” conformity assessment bodies, the CPSC’s examination may include verification to ensure that the “firewalled” conformity assessment body continues to meet the criteria set forth in section 14(f)(2)(D) of the CPSA.

(2) For government-owned or government-controlled conformity assessment bodies, the CPSC’s examination may include verification to ensure that the government-owned or government-controlled conformity assessment body continues to meet the criteria set forth in section 14(f)(2)(B) of the CPSA.

§ 1112.9 When Must an Audit be Conducted?

(a) At a minimum, each third party conformity assessment body must be reassessed at the frequency established by its accreditation body.

(b) For the examination portion of the audit, which is conducted by the CPSC:

(1) Each third party conformity assessment body must ensure that the information it submitted on CPSC Form 223 is current and submit a new CPSC Form 223 whenever the information changes.

(2) In the absence of any changes that would necessitate the submission of a new CPSC Form 223, the third party conformity assessment body must re-register at the CPSC every two years using CPSC Form 223.

(3) If the third party conformity assessment body has registered more than once with the CPSC, has registered at different times, and has no changes in information that would warrant the submission of a new CPSC Form 223, the first examination portion of the audit should be performed two years after the last registration date, and then every two years thereafter.

(4) If the third party conformity assessment body has made changes that warranted the submission of a new CPSC Form 223, then the first examination portion of the audit would be performed two years after the submission of the new CPSC Form 223.

§ 1112.11 What Must a Third Party Conformity Assessment Body Do After an Audit?

(a) When the accreditation body presents its findings to the third party conformity assessment body, the third party conformity assessment body's quality manager must receive the findings and, if necessary, initiate corrective action in response to the findings.

(b) The quality manager must prepare a resolution report identifying the corrective actions taken and any follow-up activities. If findings indicate that immediate corrective action is necessary, the quality manager must document that he/she notified the relevant parties within the third party conformity assessment body to take immediate corrective action and also document the action(s) taken.

(c) If the accreditation body decides to reduce, suspend, or withdraw the third party conformity assessment body's accreditation, and the reduction, suspension, or withdrawal of accreditation is relevant to the third party conformity assessment body's activities pertaining to a CPSC regulation or test method, the quality manager must notify the CPSC. Such notification must be sent to the Assistant Executive Director, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814, within five business days of the accreditation body's notification to the third party conformity assessment body.

(d) If the CPSC finds that the third party conformity assessment body no longer meets the conditions specified in CPSC Form 223 or in the relevant statutory provisions applicable to that third party conformity assessment body, the CPSC will notify the third party conformity assessment body, identify the condition or statutory provision that is no longer met, and specify a time by which the third party conformity assessment body shall notify the CPSC of the steps it intends to take to correct the deficiency and when it will complete such steps. The quality manager must document that he/she notified the relevant parties within the third party conformity assessment body to take corrective action and also document the action(s) taken.

(e) If the third party conformity assessment body fails to remedy the deficiency in a timely fashion, the CPSC shall take whatever action it deems appropriate under the circumstances, up to and including withdrawing the CPSC's accreditation of the third party conformity assessment body or the

CPSC's acceptance of the third party conformity assessment body's accreditation.

§ 1112.13 What Records Should a Third Party Conformity Assessment Body Retain Regarding an Audit?

A third party conformity assessment body must retain all records relating to an audit and all records pertaining to the third party conformity assessment body's resolution of or plans for resolving nonconformities identified through a reassessment by an accreditation body or through an examination by the CPSC. A third party conformity assessment body also must retain such records relating to the last three reassessments (or however many reassessments have been conducted if the third party conformity assessment body has been reassessed less than three times) and make such records available to the CPSC upon request.

Dated: August 7, 2009.

Todd A. Stevenson,

Secretary.

[FR Doc. E9-19443 Filed 8-12-09; 8:45 am]

BILLING CODE 6355-01-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 190

RIN 3038-AC82

Account Class

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (the "Commission") proposes amending its regulations (the "Regulations") to create a sixth and separate "account class," applicable only to the bankruptcy of a commodity broker that is a futures commission merchant ("FCM"), for positions in cleared over-the-counter ("OTC") derivatives (and money, securities, and/or other property margining, guaranteeing, and securing such positions). In general, the concept of "account class" governs the manner in which the trustee calculates the net equity (*i.e.*, claims against the estate) and the allowed net equity (*i.e.*, *pro rata* share of the estate) for each customer of a commodity broker in bankruptcy. The Commission further proposes amending the Regulations to codify the appropriate allocation, in a bankruptcy of any commodity broker, of positions in commodity contracts of one account class (and the money, securities, and/or

other property margining, guaranteeing, or securing such positions) that are commingled with positions in commodity contracts of the futures account class (and the money, securities, and/or other property margining, guaranteeing, or securing such positions), pursuant to an order issued by the Commission.

DATES: Submit comments on or before September 14, 2009.

ADDRESSES: You may submit comments, identified by RIN number, by any of the following methods:

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

- **Agency Web Site:** <http://www.cftc.gov>. Follow the instructions for submitting comments on the Web site.

- **E-mail:** secretary@cftc.gov. Include the RIN number in the subject line of the message.

- **Fax:** 202-418-5521.

- **Mail:** David A. Stawick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

- **Hand Delivery/Courier:** Same as mail above.

FOR FURTHER INFORMATION CONTACT:

Robert B. Wasserman, Associate Director, Division of Clearing and Intermediary Oversight, 202-418-5092, rwasserman@cftc.gov; or Nancy Schnabel, Attorney-Advisor, Division of Clearing and Intermediary Oversight, 202-418-5344, nschnabel@cftc.gov; Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Net Equity

A. Authority of Commission To Define "Net Equity" and To Prescribe Procedures for Its Calculation

The Commission is empowered by Section 20 of the Commodity Exchange Act (the "Act"),¹ (i) to define the "net equity" of a customer of a commodity broker² in bankruptcy, and (ii) to prescribe, by rule or regulation,³ the procedures for calculating such "net

¹ 7 U.S.C. 24.

² Section 101(6) of the Bankruptcy Code (11 U.S.C. 101(6)) defines "commodity broker" as a "futures commission merchant, foreign futures commission merchant, clearing organization, leverage transaction merchant, or commodity options dealer, as defined in section 761 of this title, with respect to which there is a customer, as defined in section 761 of this title."

³ The regulations of the Commission can be found at 17 CFR Chapter 1.

equity.” Moreover, Section 761(17) of the Bankruptcy Code⁴ subjects the definition of “net equity” in the case of a commodity broker to “such rules and regulations as the Commission promulgates under the Act.”⁵ Section 20 of the Act states, in pertinent part, that:

Notwithstanding title 11 of the United States Code, the Commission may provide, with respect to a commodity broker that is a debtor under chapter 7 of title 11 of the United States Code, by rule or regulation—
* * * (5) how the net equity of a customer is to be determined.⁶

The Commission has exercised its power under Section 20 of the Act in promulgating Regulation 190.07(b), which defines “net equity” as:

[T]he total claim of a customer against the estate of the debtor based on the commodity contracts held by the debtor for or on behalf of such customer less any indebtedness of the customer to the debtor.⁷

In addition, the Commission has exercised its power under Section 20 of the Act in promulgating the remainder of Regulation 190.07 (Calculation of Allowed Net Equity). According to the proposing release for Regulation Part 190 (the “Proposing Release”),⁸ the Commission intended Regulation 190.07 to constitute a “step-by-step method for calculating the estate’s liability to a customer (*i.e.*, the customer’s net equity) and of the pro rata share of the assets available to pay that claim (*i.e.*, the customer’s allowed net equity claim).”⁹ To further such intent, the Commission set forth the concept of “account class” in Regulation 190.07, and defined the term “account class” in Regulation 190.01(a).

B. Account Class

1. Definition

Regulation 190.01(a) currently defines “account class” as follows:

Each of the following types of customer accounts which must be recognized as a separate class of account by the trustee: [i] futures accounts, [ii] foreign futures accounts, [iii] leverage accounts, [iv] commodity option accounts and [v] delivery accounts as defined in § 190.05(a)(2): *Provided, however*, That to the extent that the equity balance, as defined in § 190.07, of a customer in a commodity option, as defined

in § 1.3(hh) of this chapter, may be commingled with the equity balance of such customer in any domestic commodity futures contract pursuant to regulations under the Act, the aggregate shall be treated for purposes of this part as being held in a futures account.¹⁰

2. Rationale for the Concept of Account Class

In general, the Regulations apply different requirements to the treatment of positions in different types of commodity contracts (and to the money, securities, and/or other property margining, guaranteeing, or securing such positions) based on the underlying characteristics of those contracts. For example, the segregation requirements in Regulations 1.20 through 1.30¹¹ would generally apply to positions in commodity futures contracts that are traded on a designated contract market (*i.e.*, futures contracts), and to the money, securities, and/or other property margining, guaranteeing, or securing such positions. In contrast, the requirements in Regulation 30.7¹² would generally apply to positions in commodity futures contracts that are traded on foreign boards of trade (*i.e.*, foreign futures or foreign options contracts), and to the money, securities, and/or other property margining, guaranteeing, or securing such positions.¹³

Under the Regulations, requirements for the treatment of positions (and the money, securities, and/or other property margining, guaranteeing, or securing such positions) may differ in stringency, and therefore in the degree of protection that they afford customers of a commodity broker in bankruptcy. For example, the segregation requirements in Regulations 1.20 through 1.30 are more stringent than the requirements in Regulation 30.7.¹⁴ Thus, the

Commission created the concept of “account class,” in order to ensure that, in a bankruptcy of a commodity broker, customers that hold positions in commodity contracts (and deposit money, securities, and/or other property to margin, guarantee, or secure such positions) subject to one requirement would benefit from the specific protections afforded by such requirement. As the Commission stated in the Proposing Release:

The reason for identifying classes of customer accounts is to permit the implementation of the principle of pro rata distribution so that the differing segregation requirements with respect to different classes of accounts benefit customer claimants based on the class of account for which they were imposed.¹⁵

As the Commission further stated in the Proposing Release:

Obviously, much of the benefit of segregation would be lost if property segregated on behalf of a particular account class could be allocated to pay the claims of customers of a different account class for which less stringent segregation requirements were in effect.¹⁶

The Commission codified the aforementioned intent by promulgating Regulation 190.08(c), which states:

[P]roperty held by or for the account of a customer, which is segregated on behalf of a specific account class * * * must be allocated to the customer estate of the account class for which it is segregated.
* * * 17

C. The Use of Account Class in the Calculation of Net Equity and Allowed Net Equity

As mentioned above, the concept of “account class” governs the manner in which the trustee calculates the net equity and the “allowed net equity” for each customer of a commodity broker in bankruptcy.

In general, Regulation 190.07(b) requires a trustee to calculate net equity separately for each account class.¹⁸ Specifically, Regulation 190.07(b)(2) directs the trustee to “aggregate the credit and debit equity balances of all accounts of the same class held by a customer in the same capacity” while calculating net equity.¹⁹

¹⁵ Proposing Release, *supra*, note 9 at 57536.

¹⁶ *Id.* at 57554.

¹⁷ 17 CFR 190.08(c).

¹⁸ 17 CFR 190.07(b).

¹⁹ 17 CFR 190.07(b)(2).

Regulation 190.07(b)(3) (17 CFR 190.07(b)(3)) provides a limited exception to Regulation 190.07(b)(2), by permitting the trustee, while calculating net equity, to offset “[a] negative equity balance with respect to one customer account class” against “a positive equity balance in any other

Continued

⁴ Section 761(17) of the Bankruptcy Code (11 U.S.C. 761(17)) is one provision in Subchapter IV of Chapter 7 of the Bankruptcy Code (11 U.S.C. 761 *et seq.*), which governs commodity broker liquidations (“Subchapter IV”).

⁵ 11 U.S.C. 761(17).

⁶ 7 U.S.C. 24.

⁷ 17 CFR 190.07(a).

⁸ See Proposed Rulemaking: 17 CFR Part 190 (Bankruptcy), 46 FR 57535 (November 24, 1981).

⁹ *Id.* at 57546.

¹⁰ 17 CFR 190.01(a).

¹¹ 17 CFR 1.20–1.30.

¹² 17 CFR 30.7.

¹³ As discussed in further detail below, the Commission has the power under Section 4d of the Act (7 U.S.C. 6d) to issue an order permitting positions in foreign futures contracts (and the money, securities, and/or property margining, guaranteeing, or securing such positions), to be commingled, in either an FCM or DCO account, with positions in futures contracts (and the money, securities, and/or other property margining, guaranteeing, or securing such positions).

¹⁴ When the Commission promulgated Regulation Part 190 in 1983, the Regulations had no requirements for the treatment of money, securities, and/or other property that were used to margin, guarantee, or secure commodity futures contracts traded on foreign boards of trade. In 1987, however, the Commission promulgated Regulation 30.7, which applies different and less stringent requirements to such money, securities, and/or other property than the segregation requirements in Regulations 1.20 through 1.30.

Regulation 190.07(a) states that “allowed net equity” shall “be equal to the aggregate of the funded balances of such customer’s net equity claim for each account class plus or minus” certain adjustments.²⁰ Regulation 190.07(c), in turn, defines “funded balance” as: “* * * a customer’s pro rata share of the customer estate with respect to each account class available as of the primary liquidation date for distribution to customers of the same class.”²¹

As this definition provides, Regulation 190.07(c) requires a trustee to calculate funded balance separately for each account class. Specifically, Regulation 190.07(c)(1) requires the trustee to calculate, with respect to a particular account class held by a particular customer of a commodity broker in bankruptcy, the ratio between (i) the net equity of such customer for such account class, and (ii) the net equity of all customers for such account class. Regulation 190.07(c)(1) then requires the trustee to multiply such ratio against the value of any money, securities or other property that the commodity broker held on behalf of commodity contracts in such account class. Finally, to calculate allowed net equity, Regulation 190.07(a) requires the trustee to aggregate the funded balances across account classes, and to make certain adjustments, thus generating the total amount that each customer is entitled to recover from all money, securities, and/or other property held on behalf of such customer.

II. Proposed Amendments To Include Cleared OTC Derivatives as a Separate Account Class

A. Description

As mentioned above, Regulation 190.01(a) currently sets forth five separate account classes: (i) Futures accounts; (ii) foreign futures accounts; (iii) leverage accounts; (iv) commodity option accounts; and (v) delivery accounts. The Commission is proposing to amend Regulation 190.01(a) to designate “cleared OTC derivatives” as a sixth and separate account class with respect to the bankruptcy of a commodity broker that is an FCM. The Commission is also proposing to make certain conforming changes to Regulation 190.07(b)(2)(viii) and Form 4 (Proof of Claim) in Appendix A to Regulation Part 190 (Bankruptcy Forms).²² As described below, the

account class of such customer held in the same capacity.”

²⁰ 17 CFR 190.07(a).

²¹ 17 CFR 190.07(c).

²² 17 CFR pt. 190, app. A, form 4.

Commission does not intend for “cleared OTC derivatives” to constitute a sixth and separate account class with respect to a bankruptcy of a commodity broker that is not an FCM.

The Commission is also proposing to amend Regulation 190.01 to define “cleared OTC derivatives.” In its Interpretative Statement, dated September 26, 2008 (the “Statement on Cleared OTC Derivatives”), the Commission defined “cleared-only contracts” as those contracts that “although not executed or traded on a Designated Contract Market or a Derivatives Transaction Execution Facility, are subsequently submitted for clearing through a Futures Commission Merchant * * * to a Derivatives Clearing Organization.”²³ In the definition of “cleared OTC derivatives” in the proposed amendment to Regulation 190.01, the Commission is proposing to incorporate the definition for “cleared-only contracts” from the Statement on Cleared OTC Derivatives. However, consistent with the intentions specified in the Proposing Release,²⁴ the Commission proposes to limit “cleared OTC derivatives” to only those positions in “cleared-only contracts” that (along with the money, securities, and/or other property margining, guaranteeing, or securing such positions) are required to have been (i) segregated in accordance with a rule, regulation, or order issued by the Commission, or (ii) held in a separate account for “cleared-only contracts” in accordance with the rules or bylaws of a DCO. The Commission does not intend to specify substantive requirements for the treatment of cleared OTC derivatives (and the money, securities, and/or other property margining, guaranteeing, or securing such derivatives). Rather, the Commission proposes to define “cleared OTC derivatives” in such a manner as to specify the sources from which such substantive requirements may originate. Moreover, by including contracts that “are required to be segregated * * * or to be held in a separate account” for “cleared-only contracts,” the Commission seeks to avoid the need to engage in fact-intensive post-bankruptcy inquiries regarding compliance with such requirements.

B. Rationale

As detailed further below, the Commission is proposing these amendments (i) to reflect the extension

of Subchapter IV (and, in turn, Regulation Part 190) to cleared OTC derivatives under the Commodity Futures Modernization Act of 2000 (the “CFMA”),²⁵ and (ii) to address a scenario that the Statement on Cleared OTC Derivatives did not reference. The Commission is proposing the amendments at this time because of increased interest among DCOs in clearing OTC derivatives, and the need to enhance certainty regarding the treatment of cleared OTC derivatives in the bankruptcy of a commodity broker that is an FCM.

1. To Reflect the Extension of Subchapter IV to Cleared OTC Derivatives

The Commission promulgated the current version of Regulation 190.01(a) in 1983. At that time, cleared OTC derivatives, if they existed, were not “commodity contracts” within the meaning of Section 761(4) of the Bankruptcy Code.²⁶ Therefore, neither Subchapter IV nor Regulation Part 190 applied to cleared OTC derivatives.

The CFMA, however, created the opportunity for OTC derivatives to be cleared.²⁷ In addition, the CFMA extended Subchapter IV (and, in turn, Regulation Part 190) to cleared OTC derivatives. As mentioned in the Statement on Cleared OTC Derivatives, Section 761(4)(A) of the Bankruptcy Code defines “commodity contract,” with respect to an FCM, as a “contract for the purchase or sale of a commodity for future delivery on, or subject to the rules of, a contract market or board of trade.”²⁸ The CFMA amended the definition of “contract market” in Section 761(7) of the Bankruptcy Code to include reference to a “registered entity.” As mentioned in the Statement on Cleared OTC Derivatives, Section 761(8) of the Bankruptcy Code incorporates by reference the definition of “registered entity” in the Act.²⁹ Therefore, the CFMA first permitted cleared OTC derivatives, which are subject to the rules of a DCO, to become “commodity contracts” within the meaning of Section 761(4) of the Bankruptcy Code, specifically with respect to a commodity broker that is an FCM.

²⁵ Appendix E of Pub. L. 106–554, 114 Stat. 2763 (2000).

²⁶ 11 U.S.C. 761(4).

²⁷ See Sections 2(d) and 2(e) of the Act (7 U.S.C. §§ 2(d), (e)).

²⁸ *Id.*

²⁹ 11 U.S.C. 761(8). The term “registered entity” is defined in Section 1a(29) of the Act (7 U.S.C. § 1a(29)) to include “(iii) a derivatives clearing organization registered under Section 5b * * *.”

²³ 73 FR 65514 (November 4, 2008).

²⁴ See *supra* notes 16 and 17, and the corresponding quotations from the Proposing Release in the text of this preamble.

As detailed in the Statement on Cleared OTC Derivatives, in a bankruptcy of a commodity broker that is an FCM, claims arising out of cleared OTC derivatives should be included in the determination of net equity (and therefore, by inference, in the determination of allowed net equity), for purposes of Subchapter IV and Regulation Part 190.³⁰ Consequently, the Commission is proposing amendments to provide a regulatory framework to accomplish this goal.

2. To Address a Scenario Not Referenced in the Statement on Cleared OTC Derivatives

In the Statement on Cleared OTC Derivatives, the Commission explained that, for purposes of Regulation Part 190:

A claim arising out of a cleared-only contract, or the property margining such a contract, would be includable in the futures account class, where, pursuant to Commission Order, the contract or property is included in an account segregated in accordance with Section 4d of the Act.³¹

However, the Commission did not address the treatment, under Regulation Part 190, of positions in cleared OTC derivatives (and the money, securities, and/or other property margining, guaranteeing, or securing such positions), in a scenario where there is no applicable Section 4d Order (as such term is defined below). Therefore, as mentioned above, the Commission is proposing amendments to create, only with respect to the bankruptcy of a commodity broker that is an FCM, a sixth and separate account class, to which cleared OTC derivatives (as well as the money, securities, and/or other property margining, guaranteeing, or securing such derivatives) could be allocated. By creating such an account class, the Commission is effectively specifying the manner in which the trustee in the bankruptcy of a commodity broker that is an FCM must treat, in the absence of an applicable Section 4d Order, claims arising out of cleared OTC derivatives when determining net equity and allowed net equity.

III. Proposed Amendment To Clarify Appropriate Allocation of Collateral to Certain Account Classes

The Commission has the power under Section 4d of the Act³² to issue an order (a "Section 4d Order") permitting positions in commodity contracts of one account class (and the money,

securities, and/or other property margining, guaranteeing or securing such positions), to be commingled with (and, therefore, to be accorded the same protections in bankruptcy as) positions in commodity contracts of the futures account class (and the money, securities, and/or other property margining, guaranteeing or securing such positions), in either an FCM or DCO account. Specifically, Section 4d of the Act states that:

In accordance with such terms and conditions as the Commission may prescribe by rule, regulation, or order, * * * money, securities, and property of the customers of such futures commission merchant may be commingled and deposited * * * with any other money, securities, and property received by such futures commission merchant and required by the Commission to be separately accounted for and treated and dealt with as belonging to the customers of such futures commission merchant.

The Commission has issued two interpretations stating that, for purposes of Regulation Part 190, if positions in commodity contracts (and relevant money, securities, and/or other property) of one account class, are, pursuant to a Commission order, commingled with positions in commodity contracts (and relevant money, securities, and/or other property) of the futures account class, then, the former positions (and relevant money, securities, and/or other property) shall be treated as part of the futures account class. First, the Commission issued an Interpretative Statement on October 21, 2004 (the "Statement on Commingling Foreign Futures Positions"), stating that "collateral supporting foreign futures placed in domestic segregation pursuant to Commission Order should be treated as in a futures account, not a foreign futures account, for purposes of Part 190."³³ In the Statement on Commingling Foreign Futures Positions, the Commission indicated that it would accord similar treatment to positions in other commodity contracts (and the relevant money, securities, and/or other property) that are placed in domestic segregation. Specifically, the Commission stated that:

In a situation whereby Commission order or direction, customers are required or allowed to contribute to a Commission Regulation 1.20 segregated account, those customers also should benefit from the distribution of that account proportionately to their contributions in the event of insolvency. Such claims should be treated as encompassed within the futures account

class as opposed to the foreign futures account class or another account class.³⁴

As mentioned above, the Commission subsequently issued the Statement on Cleared OTC Derivatives, which extends the conclusion in the Statement on Commingling Foreign Futures Positions to cover cleared OTC derivatives that have been placed in domestic segregation pursuant to Commission order. Specifically, the Commission stated that:

[I]n October 2004, the Commission issued an interpretation regarding the appropriate account class for funds attributable to contracts traded on non-domestic boards of trade, and the assets margining such contracts, that are included in accounts segregated in accordance with Section 4d of the Act pursuant to Commission Order. In that context, the Commission concluded that the claim is properly against the Section 4d account class because customers whose assets are deposited in such an account pursuant to Commission Order should benefit from that pool of assets. The same rationale supports the Commission's conclusion that a claim arising out of a cleared-only contract, or the property margining such a contract, would be includable in the futures account class, where, pursuant to Commission Order, the contract or property is included in an account segregated in accordance with Section 4d of the Act.³⁵

The Commission is proposing to codify explicitly, in Regulation 190.01(a), a generalized version of the Statement on Commingling Foreign Futures Positions and the Statement on Cleared OTC Derivatives. This version shall apply to positions in all commodity contracts (and money, securities, and/or other property margining, guaranteeing, or securing such positions). The Commission believes that these amendments would remove any concerns regarding whether the Statement on Commingling Foreign Futures Positions and the Statement on Cleared OTC Derivatives would be limited to the specific factual patterns addressed therein. To be clear, it is the belief of the Commission that the Statement on Commingling Foreign Futures Positions and the Statement on Cleared OTC Derivatives are nonetheless effective without such explicit codification.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")³⁶ requires Federal agencies, in promulgating regulations, to consider the impact of those regulations on small

³⁰ 73 FR 65514, 65515 (November 4, 2008).

³¹ 73 FR 65514, 65516 (November 4, 2008).

³² 7 U.S.C. 6d.

³³ 69 FR 69510, 69511 (November 30, 2004).

³⁴ *Id.*

³⁵ 73 FR 65514, 65516 (November 4, 2008).

³⁶ 5 U.S.C. 601 *et seq.*

businesses. The amendments proposed herein will affect only FCMs and DCOs. The Commission has previously established certain definitions of “small entities” to be used by the Commission in evaluating the impact of its regulations on small entities in accordance with the RFA.³⁷ The Commission has previously determined that FCMs³⁸ and DCOs³⁹ are not small entities for the purpose of the RFA. Accordingly, pursuant to 5 U.S.C. 605(b), the Chairman, on behalf of the Commission, certifies that the amendments will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act (“PRA”)⁴⁰ imposes certain requirements on Federal agencies in connection with their conducting or sponsoring any collection of information as defined by the PRA. The amendments do not require the new collection of information on the part of any entities subject to such amendments. Accordingly, for purposes of the PRA, the Commission certifies that the amendments, if promulgated in final form, would not impose any new reporting or recordkeeping requirements.

C. Cost-Benefit Analysis

Section 15(a) of the Act requires that the Commission, before promulgating a regulation under the Act or issuing an order, consider the costs and benefits of its action. By its terms, Section 15(a) of the Act does not require the Commission to quantify the costs and benefits of a new regulation or determine whether the benefits of the regulation outweigh its costs. Rather, Section 15(a) of the Act simply requires the Commission to “consider the costs and benefits” of its action.

Section 15(a) of the Act further specifies that costs and benefits shall be evaluated in light of the following considerations: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. Accordingly, the Commission could, in its discretion, give greater weight to any one of the five considerations and could determine that, notwithstanding its costs, a particular regulation was

necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

The Commission has evaluated the costs and benefits of the amendments, in light of the specific considerations identified in Section 15(a) of the Act, as follows:

1. Protection of Market Participants and the Public

The amendments would benefit FCMs and DCOs, as well as customers of the futures and options markets, by providing greater certainty (i) in a bankruptcy of a commodity broker that is an FCM, regarding the treatment of cleared OTC derivatives, and (ii) in a bankruptcy of any commodity broker, regarding the allocation of positions in commodity contracts (and relevant money, securities, and/or other property) of one account class that are commingled in an FCM or DCO account, pursuant to an order from the Commission, with positions in commodity contracts (and relevant money, securities, and/or other property) of the futures account class.

2. Efficiency and Competition

The amendments are not expected to have an effect on efficiency or competition.

3. Financial Integrity of Futures Markets and Price Discovery

The amendments would enhance the protection, in the bankruptcy of a commodity broker that is an FCM, of customers with positions in cleared OTC derivatives, by providing an account class in which to hold such positions (and relevant money, securities, and/or other property). The amendments would enhance certainty regarding the treatment, in a bankruptcy of any commodity broker, of customers with positions (and relevant money, securities, and/or other property) subject to a Section 4d Order, by removing concerns regarding whether the Statement on Commingling Foreign Futures Positions and the Statement on Cleared OTC Derivatives would be limited to the specific factual patterns addressed therein. Thus, the proposed regulations would contribute to the financial integrity of the futures and options markets as a whole.

4. Sound Risk Management Practices

The amendments would reinforce the sound risk management practices already required of FCMs and DCOs, by (i) providing an account class in which to hold positions in cleared OTC derivatives (and relevant money,

securities, and/or other property), and (ii) providing certainty to FCMs and DCOs regarding the allocation between account classes, in a commodity broker bankruptcy, of customer positions (and relevant money, securities, and/or other property) subject to a Section 4d Order.

5. Other Public Considerations

Recent market events, including disruptions in global credit markets, render it prudent to enhance certainty regarding the treatment of customer positions (and relevant money, securities, and/or other property) in a commodity broker bankruptcy.

Accordingly, after considering the five factors enumerated in the Act, the Commission has determined to propose the regulations set forth below.

List of Subjects in 17 CFR Part 190

Bankruptcy, Brokers, Commodity Futures.

For the reasons stated in the preamble, the Commission proposes to amend 17 CFR part 190 as follows:

PART 190—BANKRUPTCY

1. The authority citation for part 190 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4a, 6c, 6d, 6g, 7a, 12, 19, and 24, and 11 U.S.C. 362, 546, 548, 556, and 761–766, unless otherwise noted.

2. In § 190.01, revise paragraph (a) and add paragraph (oo) to read as follows:

§ 190.01 Definitions.

* * * * *

(a) *Account class* means each of the following types of customer accounts which must be recognized as a separate class of account by the trustee: futures accounts, foreign futures accounts, leverage accounts, commodity option accounts, delivery accounts as defined in § 190.05(a)(2), and, only with respect to the bankruptcy of a commodity broker that is a futures commission merchant, cleared OTC derivatives accounts; *Provided, however*, That to the extent that the equity balance, as defined in § 190.07, of a customer in a commodity option, as defined in § 1.3(hh) of this chapter, may be commingled with the equity balance of such customer in any domestic commodity futures contract pursuant to regulations under the Act, the aggregate shall be treated for purposes of this part as being held in a futures account; *Provided, further*, that, if positions in commodity contracts of one account class (and the money, securities, and/or other property margining, guaranteeing, or securing such positions), are, pursuant to a Commission order,

³⁷ 47 FR 18618 (Apr. 30, 1982).

³⁸ *Id.* at 18619.

³⁹ 66 FR 45604, 45609 (Aug. 29, 2001).

⁴⁰ 44 U.S.C. 3501 *et seq.*

commingled with positions in commodity contracts of the futures account class (and the money, securities, and/or other property margining, guaranteeing, or securing such positions), then the former positions (and the relevant money, securities, and/or other property) shall be treated, for purposes of this part, as being held in an account of the futures account class.

* * * * *

(oo) *Cleared OTC derivatives* shall mean positions in commodity contracts that have not been entered into or traded on a contract market (as such term is defined in § 1.3(h) of this chapter) or on a derivatives transaction execution facility (within the meaning of Section 5a of the Act), but which nevertheless are submitted by a commodity broker that is a futures commission merchant (as such term is defined in § 1.3(p) of this chapter) for clearing by a clearing organization (as such term is defined in this section), along with the money, securities, and/or other property margining, guaranteeing, or securing such positions, which are required to be segregated, in accordance with a rule, regulation, or order issued by the Commission, or which are required to be held in a separate account for cleared OTC derivatives only, in accordance with the rules or bylaws of a clearing organization (as such term is defined in this section).

4. In § 190.07, revise paragraph (b)(2)(viii) to read as follows:

§ 190.07 Calculation of allowed net equity.

(b) * * *

(2) * * *

(viii) Subject to paragraph (b)(2)(ix) of this section, the futures accounts, leverage accounts, options accounts, foreign futures accounts, and cleared OTC derivatives accounts of the same person shall not be deemed to be held in separate capacities: *Provided, however,* That such accounts may be aggregated only in accordance with paragraph (b)(3) of this section.

* * * * *

5. Amend “bankruptcy appendix form 4—proof of claim” in Appendix A to Part 190 by revising paragraph a in section III to read as follows:

Appendix A to Part 190—Bankruptcy Forms

* * * * *

Bankruptcy Appendix Form 4—Proof of Claim

* * * * *

III. * * *

a. Whether the account is a futures, foreign futures, leverage, option (if an option

account, specify whether exchange-traded or dealer), “delivery” account, or, only with respect to a bankruptcy of a commodity broker that is a futures commission merchant, a cleared OTC derivatives account. A “delivery” account is one which contains only documents of title, commodities, cash, or other property identified to the claimant and deposited for the purposes of making or taking delivery on a commodity underlying a commodity contract or for payment of the strike price upon exercise of an option.

* * * * *

Issued in Washington, DC, on July 31, 2009, by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E9-18853 Filed 8-12-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

[SATS No. MT-029-FOR; Docket ID: OSM-2008-0022]

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

Montana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: We are announcing the receipt of revisions pertaining to a previously proposed amendment to the Montana regulatory program (hereinafter, the “Montana program”) under the Surface Mining Control and Reclamation Act of 1977 (“SMCRA” or “the Act”). Montana proposes additions of rules and revisions to the Administrative Rules of Montana (ARM) concerning Normal Husbandry Practices. Montana intends to revise its program to improve operational efficiency.

This document gives the times and locations that the Montana program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., mountain daylight time September 14, 2009. If requested, we will hold a public hearing on the amendment on September 8, 2009. We will accept requests to speak until 4 p.m., mountain daylight time, on August 28, 2009.

ADDRESSES: You may submit comments, identified by “MT-029-FOR” or Docket ID number OSM-2008-0022, using any of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. The proposed rule has been assigned Docket ID OSM-2008-0022. If you would like to submit comments via the Federal eRulemaking portal, go to <http://www.regulations.gov> and do the following. Click on the “Advanced Docket Search” button on the right side of the screen. Type in the Docket ID “OSM-2008-0022” and click on the “Submit” button at the bottom of the page. The next screen will display the Docket Search Results for the rule making. If you click on “OSM-2008-0022”, you can view the proposed rule and submit a comment. You can also view supporting material and any comments submitted by others.

- **Mail, Hand Delivery/Courier:** Jeff Fleischman, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, 150 East B Street, Room 1018, Casper, WY 82601-1018, (307) 261-6550. Fax: (307) 261-6552.

Instructions: All submissions received must include the agency name and MT-029-FOR. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Comment Procedures” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: Access to the docket to review copies of the Montana program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, may be obtained at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting the Office of Surface Mining Reclamation and Enforcement’s (OSM’s) Casper Field Office. In addition, you may review a copy of the amendment during regular business hours at the following locations:

Jeff Fleischman, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, 150 East B Street, Room 1018, Casper, WY 82601-1018, Telephone: (307) 261-6550, E-mail: jfleischman@osmre.gov.

Neil Harrington, Chief, Industrial and Energy Minerals Bureau, Montana Department of Environmental Quality, P.O. Box 200901, Helena, MT 59620-0901, Telephone: (406) 444-2544, E-mail: neharrington@mt.gov.

Or anytime at: <http://www.regulations.gov>, Docket ID OSM–2008–0022.

FOR FURTHER INFORMATION CONTACT: Jeff Fleischman (307) 261–6550.

SUPPLEMENTARY INFORMATION:

- I. Background on the Montana Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Montana Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the Montana program in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions concerning Montana’s program and program amendments at 30 CFR 926.15, 926.16, and 926.30.

II. Description of the Proposed Amendment

By letter dated July 3, 2008, Montana sent us a proposed amendment to its program (SATS No. MT–029–FOR) under SMCRA (30 U.S.C. 1201 *et seq.*). Montana sent the amendment to include changes made at its own initiative. The full text of the original program amendment is available for you to read at the locations listed above under **ADDRESSES**.

We announced receipt of the proposed amendment in the November 10, 2008, **Federal Register** (73 FR 66569), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (Administrative Record No. OSM–2008–0022–0001). Because no one requested a public hearing or meeting, none was held. The public comment period ended on December 10, 2008. We received one comment that was not relevant to the amendment proposal.

During our review of the amendment, we identified concerns with regard to

the proposed revisions for Normal Husbandry Practices that would be used for erosion and settling repair and landscaping activities. We notified Montana of our concerns by letter dated April 16, 2009 (Administrative Record No. OSM–2008–0022–0009). Montana responded in a letter dated May 12, 2009, by submitting a revised amendment proposal (Administrative Record No. OSM–2008–0022–0010). The full text of the revised program amendment is also available for you to read at the locations listed above under **ADDRESSES**.

In response to our concerns, Montana made the following changes to its July 3, 2008, amendment proposal. OSM expressed concerns regarding Guideline Number 7, *Erosion and settling repair*. Guidance concerning the repair of rills and gullies is found in the September 2, 1983, **Federal Register** notice (48 FR 40157). In this FR notice, OSM states that the regulatory authority could allow the repair of rills and gullies as a husbandry practice without restarting the liability period only if the general standards of 30 CFR 816.116(c)(4) are met and after consideration of the normal conservation practices within the region.

To clarify the intent of Guideline Number 7, *Erosion and settling repair*, Montana removed National Resource Conservation Standard (NRCS) No. 578 (stream crossings) from its list of applicable NRCS standards. In our April 16, 2009, letter to Montana, OSM advised the state to justify why stream crossings would be applicable to all crossing types cited in the incorporated NRCS reference, at any time during the liability period without extending the period of responsibility, or define reasonable limits. OSM was particularly concerned about large projects, such as a bridge associated with a road crossing that may be installed near the end of the liability period. We believe that in general, stream crossings should be restricted and clearly stated under what conditions, and what types of stream crossings should be included, or at least which would be prohibited. OSM requested that Montana also include a reasonable time limit to demonstrate the stability of such crossings; and that no negative consequences are reasonably likely after Phase III bond release. The type of stream crossings allowed, under what conditions, and time period restrictions should be supported by appropriate literature references.

Montana omitted stream crossings from the list of standard practices that can be employed for erosion and sediment control. Montana explained that stream crossings was deleted

because it is essentially irrelevant to reclamation activities at Montana coal mines.

OSM also expressed concerns about the use of fertilization and other facilitating practices, *i.e.* irrigation, that were mentioned in the incorporated NRCS reference for Critical Area Planting (342) or elsewhere (*e.g.* 412—Grassed Waterway). Montana must demonstrate that fertilization and other facilitating practices will only be allowed where these practices can be expected to continue as part of the postmining land use; or if the practices discontinue after the liability period expires, the probability of permanent vegetation success will not be reduced.

To clarify the use and intent of fertilizers for erosion and settling repair, Montana added language stating that “the use of fertilization or other facilitating practices (*i.e.* irrigation), as mentioned in some normal husbandry practices (*e.g.* 342—Critical Area Planting and 412—Grassed Waterway) will not be approved unless it can be demonstrated that the practice will continue as part of the postmining land use or if discontinuance of the practice after the liability period expires will not reduce the probability of permanent vegetation success.” OSM is satisfied with Montana’s edits to the July 3 amendment proposal regarding erosion and settling repair.

For Guideline Number 9, *Agricultural activities*, Montana omitted NRCS standard numbers 441 (micro-irrigation system), 442 (sprinkler irrigation system), 443 (surface and subsurface irrigation systems), and 449 (irrigation water management) for consistency, since these practices were omitted from Guideline Number 7 (*Erosion and settling repair*) and Guideline Number 10 (*Landscaping activities*) to satisfy OSM’s concerns.

To clarify the intent of Guideline Number 10 (*Landscaping activities*), Montana removed numbers 422 (hedgerow planting), 441 (micro-irrigation system), 442 (sprinkler irrigation system), 449 (irrigation water management), 578 (stream crossing), 657 (wetland restoration), 658 (wetland creation), and 659 (wetland enhancement) from its list of applicable NRCS standards.

In our April 16, 2009, letter to Montana, OSM expressed concerns regarding the NRCS standard conservation practices for irrigation, specifically micro-irrigation systems (441), sprinkler irrigation systems (442), surface and subsurface irrigation systems (443), and irrigation water management (449). 30 CFR 816.116(c)(4) specifically excludes augmentative

irrigation as being approved as a husbandry practice. However, the preamble to the 1979 revegetation regulations (44 FR 15238, March 13, 1979) clearly states that “the augmented seeding, fertilizing and irrigation does not apply to cropland and pastureland that can be expected to have a similar postmining use and which should be managed in accordance with acceptable local agricultural practices”. OSM explained in the September 7, 1988, **Federal Register** (FR 53 3640) that “the preamble to the 1979 revegetation regulations which explained that fertilization, seeding and irrigation in accordance with local agricultural practices on cropland or pasture land is not considered a prohibited augmentative practice”. Furthermore, 30 CFR 816.116(c)(4) specifically requires that any approved husbandry practice must be expected to continue as part of the postmining land use, or if the practices are discontinued after the liability period expires, cessation will not reduce the probability of permanent vegetation success.

OSM requested that Montana justify why irrigation would be applicable to all land uses without extending the period of responsibility, or define when and on what land use such irrigation practices would be applicable under the constraints cited in the regulations, thereby specifying when such irrigation practices could be reasonably considered to be a normal husbandry practice.

In response, Montana removed the following NRCS standard practices from the list of approved normal husbandry practices for *Landscaping activities*: 422 (hedgerow planting), 441 (micro irrigation system), 442 (sprinkler irrigation system), 449 (irrigation water management), 578 (stream crossing), 657 (wetland restoration), 658 (wetland creation), and 659 (wetland enhancement). Montana explained that a proposal for the use of irrigation systems will be addressed during the permitting or permit revision process and will be required to address OSM’s limitations on the use of irrigation.

Regarding wetland related work, OSM expressed concerns that any activity that requires more than minor stabilization, interseeding, or replanting would need to be completed at least six (6) years prior to Phase III bond release. In response to this, Montana omitted numbers 657 (wetland restoration), 658 (wetland creation), and 659 (wetland enhancement) from its list of applicable NRCS standards used for *Landscaping activities*. Montana will address these items through normal reclamation practices and time frames.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Montana program.

Electronic or Written Comments

Send your written comments to OSM at the addresses given above. Your comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent Tribal or Federal laws or regulations, technical literature, or other relevant publications.

We will not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see Dates). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Casper Field Office may not be logged in.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., mountain daylight time on August 28, 2009. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold the hearing. If only one person expresses an interest, a public meeting rather than a hearing may be held, with the results included in the docket for this rulemaking.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

IV. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of

SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA. Section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally recognized Indian Tribes and have determined that the rule does not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. The rule does not involve or affect Indian Tribes in any way.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior 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.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2) of the Small Business Regulatory Enforcement Fairness Act. This rule:

- a. Does not have an annual effect on the economy of \$100 million.
- b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 926

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 12, 2009.

Allen D. Klein,

Regional Director, Western Region.

[FR Doc. E9–19365 Filed 8–12–09; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0348]

RIN 1625–AA09

Drawbridge Operation Regulations; East River, New York City, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the drawbridge operating regulations governing the operation of the Roosevelt Island Bridge, mile 6.4, across the East River at New York City, New York. This proposed rule would allow the Roosevelt Island Bridge to remain in the closed position for eleven months to facilitate a major rehabilitation of the bridge.

DATES: Comments and related material must be received by the Coast Guard on or before September 14, 2009.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2009–0348 using any one of the following methods:

(1) *Federal Rulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building ground floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand Delivery:* Same as address above, between 9 a.m. and 5 p.m., Monday through Friday, except, Federal holidays. The telephone number is (202) 366–9329.

To avoid duplication, please use only one of these methods. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. Joe Arca, Project Officer, First Coast Guard District, telephone 212–668–7165, joe.arca@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–0348), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material on line (<http://www.regulations.gov>), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the content. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the “submit a comment” box, which will then become highlighted in blue. In the “Document Type” drop down menu select “Proposed Rules” and insert “USCG–2009–0348” in the “Keyword” box. Click “Search” then click on the balloon shape in the “Actions” column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2009–0348” and click “Search.” Click the

“Open Docket Folder” in the “Actions” column. You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of 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 a Privacy Act, system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Roosevelt Island Bridge has a vertical clearance of 40 feet at mean high water, and 47 feet at mean low water in the closed position. The existing drawbridge operating regulations listed at 33 CFR 117.781, require the bridge to open on signal if at least a two hour advance notice is given.

The bridge owner, New York City Department of Transportation, has requested a temporary rule to facilitate electrical and mechanical rehabilitation at the Roosevelt Island Bridge.

Under this temporary rule the Roosevelt Island Bridge would remain in the closed position from October 1, 2009 through August 31, 2010.

Discussion of Proposed Rule

This proposed change would amend 33 CFR 117.781 by suspending paragraph (c) and adding a new temporary paragraph (d) that would list the drawbridge operation regulations for the Roosevelt Island Bridge.

This proposed change would allow the Roosevelt Island Bridge to need not open for the passage of vessel traffic from October 1, 2009 through August 31, 2010. Vessels that can pass under

the draw in the closed position may do so at all times. This temporary rule is necessary to facilitate the rehabilitation construction at the Roosevelt Island Bridge. Vessel traffic should not be adversely affected since they may transit around the other side of Roosevelt Island as an alternate traffic route.

Regulatory Analysis

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

Regulatory Planning and Review

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

This proposed rule is not a significant regulatory action. This conclusion is based upon the fact that vessel traffic will still be able to transit the East River using the alternate route around the island.

Small Entities

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

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

This conclusion is based on the fact that vessel traffic will still be able to transit the East River using the alternate route round the island.

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

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact, Commander (dpb), First Coast Guard District, Bridge Branch, One South Street, New York, NY, 10004. The telephone number is (212) 668–7165. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 0023.1, and Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1(g); Department of Homeland Security Delegation No. 0170.1.

2. From, October 1, 2009 through August 31, 2010, § 117.781 is amended by suspending paragraph (c) and adding a temporary paragraph (d) to read as follows:

§ 117.781 East River.

* * * * *

(d) The draw of the Roosevelt Island Bridge at mile 6.4, at New York City, need not open for the passage of vessel traffic from October 1, 2009 through August 31, 2010.

Dated: July 6, 2009.

Dale G. Gabel,

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

[FR Doc. E9–19435 Filed 8–12–09; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2007–1129; FRL–8942–1]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Consumer Products Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request submitted by the Ohio Environmental Protection Agency (Ohio EPA) on October 5, 2007, to revise the Ohio State Implementation Plan (SIP) under the Clean Air Act. The State has submitted new volatile organic compounds (VOCs) control rules for approval under Chapter 3745–112 of the Ohio Administrative Code (OAC). The rules include OAC 3745–112–01 to OAC 3745–112–08 and are intended to assist the State in achieving and/or maintaining the national 8-hour ground level ozone standard through the regulation of VOCs in consumer products.

DATES: Comments must be received on or before September 14, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–1129, by one of the following methods:

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

2. *E-mail*: mooney.john@epa.gov.

3. *Fax*: (312) 692–2551.

4. *Mail*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Final Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0258, chang.andy@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial

submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to this rule, we do not contemplate taking any further action. If EPA receives adverse comments, we will withdraw the direct final rule, and will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule, which is located in the Final Rules section of this **Federal Register**.

Dated: July 28, 2009.

Walter W. Kovalick, Jr.,

Acting Regional Administrator, Region 5.

[FR Doc. E9–19306 Filed 8–12–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0591; FRL–8941–5]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revised Motor Vehicle Emission Budgets for the York-Adams Counties 8-Hour Ozone Maintenance Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania for the purpose of amending the 8-hour ozone maintenance plan for the York-Adams 8-Hour Ozone Maintenance Area. This revision amends the maintenance plan's 2009 and 2018 motor vehicle emissions budgets (MVEBs) by unequally dividing the overall MVEBs into two sub-regional MVEBs for each county comprising the area. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A

detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 14, 2009.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2008–0591 by one of the following methods:

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

B. *E-mail*: febbo.carol@epa.gov.

C. *Mail*: EPA–R03–OAR–2008–0591, Carol Febbo, Chief, Energy, Radiation and Indoor Environment Branch, Mailcode 3AP23, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery*: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2008–0591. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any

disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the Commonwealth submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Martin Kotsch, (215) 814-3335, or by e-mail at kotsch.martin@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the Rules and Regulations section of this **Federal Register** publication.

Dated: July 28, 2009.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. E9-18865 Filed 8-12-09; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09-1755; MB Docket No. 08-110; RM-11453]

Television Broadcasting Services; Flagstaff, AZ

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Multimedia Holdings Corporation ("MHC"), the permittee of station KNAZ-TV, channel 2, Flagstaff, Arizona. MHC is currently operating on its allotted pre-transition DTV channel 22 pursuant to Special Temporary Authority ("STA"). MHC requests the substitution of channel 22 for channel 2 at Flagstaff.

DATES: Comments must be filed on or before August 28, 2009, and reply comments on or before September 8, 2009.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Marnie Sarver, Esq., Wiley Rein LLP, 1776 K Street, NW., Washington, DC 20006

FOR FURTHER INFORMATION CONTACT:

Joyce L. Bernstein,
joyce.bernstein@fcc.gov, Media Bureau,
(202) 418-1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 08-110, adopted August 4, 2009, and released August 5, 2009. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC, 20554. This document will also be available via ECFS (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-478-3160 or via e-mail www.BCPIWEB.com. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to fcc504@fcc.gov or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document does not contain proposed information collection

requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622(i) [Amended]

2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Arizona, is amended by adding DTV channel 22 and removing DTV channel 2 at Flagstaff.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E9-19330 Filed 8-12-09; 8:45 am]

BILLING CODE 6712-01-P

Notices

Federal Register

Vol. 74, No. 155

Thursday, August 13, 2009

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

August 10, 2009.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to

the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: 7 CFR part 1786, Prepayment of RUS Guaranteed and Insured Loans to Electric and Telephone Borrowers.

OMB Control Number: 0572-0088.

Summary of Collection: The Rural Electrification (RE) Act of 1936, as amended, authorizes and empowers the Administrator of RUS to make loans in the States and Territories of the United States for rural electrification and for the purpose of furnishing and improving electric and telephone service in rural areas and to assist electric borrowers to implement demand side management, energy conservation programs, and on-grid and off-grid renewable energy systems. 7 CFR part 1786, subparts E and F are authorized by this section.

Need and Use of the Information: The information will be collected from borrowers requesting to prepay their notes and to determine that the borrower is qualified to prepay under the authorizing statutes. The overall goal of subparts E and F is to allow RUS borrowers to prepay their RUS loan and the overall goal of subpart G is to refinance.

Description of Respondents: Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 5.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 16.

Rural Utilities Service

Title: 7 CFR 1703, subparts D, E, F, and G, Distance Learning and Telemedicine Loan and Grant Program.

OMB Control Number: 0572-0096.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the Department of Agriculture and is authorized by Chapter 1 of subtitle D of the Food, Agriculture, Conservation and Trade Act of 1990. The purpose of the Distance Learning and Telemedicine Loan and Grant Program is to improve telemedicine services and distance learning services in rural areas through the use of telecommunications, computer networks, and related advanced technologies by students, teachers, medical professionals and rural residents.

Need and Use of the Information: The various forms and narrative statements required are collected from eligible applicants that are public and private, for-profit and not-for-profit rural community facilities, schools, libraries, hospitals, and medical facilities. The purpose of this information is to determine such factors as: eligibility of the applicant; the specific nature of the proposed project; the purposes for which loan and grant funds will be used; project financial and technical feasibility; and compliance with applicable laws and regulations.

Description of Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 230.

Frequency of Responses:

Recordkeeping; Reporting: On occasion.

Total Burden Hours: 13,451.

Rural Utilities Service

Title: 7 CFR part 1703-H, Deferments of RUS Loan Payments for Rural Development Projects.

OMB Control Number: 0572-0097.

Summary of Collection: Subsection (b) of section 12 of the Rural Electrification Act (RE Act) of 1936, as amended (7 U.S.C. 912), a Rural Utilities Service (RUS) electric or telephone borrower may defer the payment of principal and interest on any insured or direct loan made under the RE Act invest the deferred amounts in rural development projects. The Deferment program is used to encourage borrowers to invest in and promote rural development and rural job creation projects that are based on sound economic and financial analyses.

Need and Use of the Information: RUS will collect information to determine eligibility; specific purposes for which the deferment amount will be utilized; the term of the deferment the borrower will receive; the cost of the total project and degree of participation in the financing from other sources; verification that the purposes will not violate limitations established in 7 CFR 1703-H. If the information were not collected, RUS would be unable to determine eligibility for a project.

Description of Respondents: Not-for-profit; Business or other for-profit.

Number of Respondents: 1.

Frequency of Responses:

Recordkeeping; Reporting: On occasion.

Total Burden Hours: 11.

Rural Utilities Service

Title: Lien Accommodations and Subordinations 7 CFR part 1717, subparts R and S.

OMB Control Number: 0572-0100.

Summary of Collection: The Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901 *et seq.*, as amended, authorizes and empowers the Administrator of the Rural Utilities Service (RUS) to make loans in the several States and Territories of the United States for rural electrification and the furnishing electric energy to persons in rural areas who are not receiving central station service. The RE Act also authorizes and empowers the Administrator of RUS to provide financial assistance to borrowers for purposes provided in the RE Act by accommodating or subordinating loans made by the National Rural Utilities Cooperative Finance Corporation, the Federal Financing Bank, and other lending agencies.

Need and Use of the Information: RUS will use the information to determine an applicant's eligibility for a lien accommodation or lien subordination under the RE Act; facilitates an applicant's solicitation and acquisition of non-RUS loans as to converse available Government funds; monitor the compliance of borrowers with debt covenants and regulatory requirements in order to protect loan security; and subsequently to granting the lien accommodation of lien subordination, administer each so as to minimize its cost to the Government. If the information were not collected, RUS would not be able to accomplish its statutory goals.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 15.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 290.

Rural Utilities Service

Title: 7 CFR 1751 subpart B/State Telecommunications Modernization Plan.

OMB Control Number: 0572-0104.

Summary of Collection: The Rural Electrification Loan Restructuring Act (RELRA, Pub. L. 103-129), November 1, 1993, amended the Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.* (the RE Act). RELRA required that a State Telecommunications Modernization Plan (Modernization Plan or Plan), meet all the statutory requirements of RELRA (part 1751, Subpart B). The plan at a minimum must provide for: (1) The elimination of party line service; (2) the

availability of telecommunications services for improved business, educational, and medical services; (3) must encourage computer networks and information highways for subscribers in rural areas; (4) must provide for subscribers in rural areas to be able to receive through telephone lines: (a) conference calling; (b) video images; and (c) data at a rate of 1 million bits of information per second; and, the proper routing of information to subscribers.

Need and Use of the Information: The Rural Utilities Service (RUS) telecommunications program staff will review the Modernization Plan and approve the plans, if it complies with the requirements of the regulation. If the proposed Modernization Plan is approved, RUS will notify the developer of the approval. If not, RUS will make specific written comments and suggestions for modifying the proposed Modernization Plan so that it will comply with the requirements of the regulation. If the information is not collected, RUS' authority to make loans under the Rural Electrification Act will be restricted.

Description of Respondents: Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 1.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 350.

Rural Utilities Service

Title: 7 CFR part 1721, Extensions of Payments of Principal and Interest.

OMB Control Number: 0572-0123.

Summary of Collection: The Rural Utilities Service (RUS) electric program provides loans and loan guarantees to borrowers at interest rates and on terms that are more favorable than those generally available from the private sector. Procedures and conditions which borrowers may request extensions of the payment of principal and interest are authorized, as amended, in section 12 of the Rural Electrification Act of 1936, and section 236 of the Disaster Relief Act of 1970. As a result of obtaining Federal financing, RUS borrowers receive economic benefits that exceed any direct economic costs associated with complying with (RUS) regulations and requirements.

Need and Use of the Information: The collection of information occurs only when the borrower requests an extension of principal and interest. Eligible purposes include financial hardship, energy resource conservation loans, renewable energy project, and contributions-in-aid of construction. The collections are made to provide

needed benefits to borrowers while also maintaining the integrity of RUS loans and their repayment of taxpayer's monies.

Description of Respondents: Not-for-profit institutions.

Number of Respondents: 45.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 424.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E9-19427 Filed 8-12-09; 8:45 am]

BILLING CODE 3410-15- P

DEPARTMENT OF AGRICULTURE**Submission for OMB Review; Comment Request**

August 10, 2009.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to

the collection of information unless it displays a currently valid OMB control number.

Office of the Assistant Secretary for Civil Rights

Title: USDA/1994 Tribal Scholars Program.

OMB Control Number: 0503-0016.

Summary of Collection: The USDA/1994 Tribal Scholars Program, within the Office of the Assistant Secretary for Civil Rights, Office of Outreach and Diversity, is an annual joint human capital initiative between USDA and the Nation's thirty-two 1994 Land-Grant Tribal Colleges and Universities (1994 TCUs). The purpose of the USDA/1994 Tribal Scholars Program is to: (1) Strengthen the long-term partnership between USDA and the 1994 Land-Grant Tribal Colleges and Universities Institutions; (2) Increase the number of students studying agriculture, food, natural resources sciences, or other related disciplines; and (3) Offer career opportunities to USDA/1994 Tribal Scholars at the U.S. Department of Agriculture. Tribal Scholars are required to study in the food and agricultural and related sciences, so defined by the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (U.S.C. 3103 (8)).

Need and Use of the Information: This program offers a combination of work experience and academic study leading to career positions within USDA through a Student Career Experience Program designed to integrate classroom study with paid work experience. Without the information, USDA would be unable to award scholarships to students.

Description of Respondents: Individuals or households.

Number of Respondents: 1,440.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 4,320.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. E9-19428 Filed 8-12-09; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

Okanogan-Wenatchee National Forest, Washington; Forest-Wide Site-Specific; Invasive Plant Management Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement.

SUMMARY: The USDA Forest Service will prepare an Environmental Impact Statement (EIS) to document and disclose the potential environmental effects of proposed invasive plant treatments. The Proposed Action is to apply a combination of herbicide, mechanical, manual, cultural and biological treatment methods to control invasive plants on approximately 15,246 acres on the Okanogan-Wenatchee National Forest in Washington. The proposed action includes treatment of invasive species on 216 acres within congressionally designated wilderness areas on the Forest. The Proposed Action would also establish criteria for responding to the spread of infestations into currently unoccupied areas.

DATES: Comments concerning the scope of this analysis must be received by September 10, 2009. The draft environmental impact statement is expected January 2010 and the final environmental impact statement is expected summer 2010.

ADDRESSES: Send written comments to Jodi Leingang, Naches Ranger Station, Okanogan-Wenatchee National Forest, 10237 Highway 12, Naches, WA 98942. Comments can also be sent via e-mail to okawen_forestwide_invasives_eis@fs.fed.us or via facsimile to (509) 653-2638, Attention: Jodi Leingang.

Comments received in response to this solicitation, including names and addresses of those who comment, will become part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the respondent with standing to participate in subsequent administrative review or judicial review.

FOR FURTHER INFORMATION CONTACT: Jodi Leingang, Naches Ranger Station, 10237 Highway 12, Naches, WA 98942; 509-653-1450.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 pm, Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Wenatchee National Forest Land and Resource Management Plan (LRMP, 1990) requires that existing populations of invasive species (termed "noxious weeds") be contained, controlled or eradicated as the budget allows (page IV-89). The Okanogan National Forest Land and Resource Management Plan (LRMP, 1989) requires that noxious weeds be controlled to the extent

practical with a priority on treatment of new infestations (LRMP, page 4-45). The Pacific Northwest Region's Invasive Plant Program for Preventing and Managing Invasive Plants Record of Decision (PNW ROD, 2005), an amendment to the Wenatchee and Okanogan LRMPs, directs that invasive plant populations be prioritized for treatment and a long term strategy be developed for restoring/revegetating invasive plant sites (PNW ROD, page 20).

Invasive plants on the Forest are compromising the ability for the Forest Service to manage for healthy native ecosystems. Invasive plants create a host of environmental and other effects, most of which are harmful to native ecosystem processes, including: displacement of native plants; reduction in functionality of habitat and forage for wildlife and livestock; loss of threatened, endangered, and sensitive species; increased soil erosion and reduced water quality; alteration of physical and biological properties of soil, including reduced soil productivity; changes to the intensity and frequency of fires; high cost (dollars spent) of controlling invasive plants; and loss of recreational opportunities.

New and existing invasive plant populations on the Forest require analysis to implement new or more effective and cost-efficient treatments, including the Regional EIS updated list of herbicides. The most recent inventory shows that 15,246 acres are infested on the Forest. There are likely additional infestations that are not yet discovered, and these, as well as known sites, will continue to expand and spread every year without effective treatment. Without action, invasive plant populations will become increasingly difficult and costly to control and will further degrade native ecosystems.

The purpose of this action is to provide a rapid and more comprehensive, up to date approach to control and eradicate invasive plants on the Forest. The purpose of controlling or eradicating weed populations is to maintain or improve the diversity, function and sustainability of native plant communities, and other resources that depend on them. Specifically, there is a need to: (1) contain and reduce the extent of invasive plants at existing inventoried sites, and (2) quickly detect and rapidly respond to new and changing invasive plant populations.

Proposed Action

The Okanogan-Wenatchee National Forest Supervisor proposes to treat currently existing invasive species on 15,246 acres across the Okanogan-

Wenatchee National Forest, including approximately 1,712 acres on the Chelan Ranger District, 1,968 acres on the Cle Elum Ranger District, 2,346 acres on the Entiat Ranger District, 799 acres on the Methow Valley Ranger District, 3,299 acres on the Naches Ranger District, 4,399 acres on the Tonasket Ranger District, and 723 acres on the Wenatchee River Ranger District. Infestations that occur on 216 acres within congressionally designated Wilderness areas would also be treated. The proposed invasive species treatments would begin in 2010 and span the next 15 years. Under the proposed action those treatment methods and herbicides analyzed in the *Pacific Northwest Region Invasive Plant Program: Preventing and Managing Invasive Plants, Final Environmental Impact Statement (FEIS)* (USDA 2005) would be used, along with one additional herbicide. Invasive plants would be treated using one or a combination of manual (e.g. hand-pulling, digging with hand tools, clipping), mechanical (e.g. mowing, weed whacking, road brushing, root tilling, steaming, infrared), cultural (e.g. competitive seeding/planting, mulching, adding soil amendments/fertilizer), biological, and chemical methods (e.g. spot spraying, wicking, and limited broadcast application). Proposed herbicide mixtures would include one or more of the following active ingredients: chlorosulfuron, clopyralid, glyphosate, imazapic, imazapyr, metsulfuron methyl, picloram, sethoxydim, sulfometuron methyl, and triclopyr. In addition to the herbicides analyzed in the 2005 Invasive Plant FEIS, the proposed action would include application of aminopyralid. Herbicide treatments would be part of the initial prescription for currently identified sites on 15,246 acres. On many sites, the use of herbicides would be expected to decline in subsequent entries with manual, mechanical, biological and cultural methods becoming the common control measure over time. Therefore, within the 15,246 acres identified for chemical treatment; other treatments could also occur including; 450 acres of manual treatment, 350 acres of mechanical treatment, 1,750 acres of cultural treatment, and 3,500 acres of biological treatment. In other cases, although herbicide use would continue as the preferred treatment method through time, the amount of herbicide applied would greatly diminish as the infestation is brought nearer to eradication. Infested acres would be treated with an initial prescription, and

retreated in subsequent years, until control objectives are met. Site-specific treatment prescriptions would be developed based on the ability to eradicate, control, contain, suppress or tolerate an infestation. Selection of treatment methods and prioritization of sites would follow amended LRMP direction, and take into account the biology of the particular invasive species, its proximity to water and other sensitive resources (values at risk), and the size of the infestation.

The Proposed Action would also allow for treatment of infestations that are not currently inventoried through an early detection/rapid response (EDRR) strategy and annual implementation planning. To these ends, this EIS will include analysis associated with the treatment of currently documented infestations (sites) as well as areas where invasive species are not currently present but are most likely to spread and establish over time. The EIS will include analysis of approximately 16,448 additional acres of treatment associated with EDRR. Ongoing inventories would continually locate and confirm infestation locations. Treatment recommendations for presently uninventoried infestations would be similar to that described for known infestations, in that, herbicides would be part of the initial prescription; with manual, mechanical, biological and cultural methods becoming the common control measure over time. Treatment prescriptions for these presently undocumented sites would be strict enough to ensure that adverse effects are minimized to remain within the scope of effects analyzed in this EIS, and still be flexible enough to adapt to changing conditions over time (*i.e.* adaptive management).

The total number of acres of invasive species treatment that would be approved in this document and decision for known and EDRR is 31,694 acres; 15,246 acres of presently known infestation and 16,448 acres under the early detection rapid response strategy. The number of acres treated in any given year would not exceed this total. However, provided the recent history of funding available to accomplish this work, it is very unlikely that we would treat the total in any given year. Monitoring would evaluate the effectiveness of past treatments and direct adaptive management needs over time.

A connected action of the Proposed Action is the restoration of treatment sites with desirable vegetation to prevent re-infestation. The restoration objectives may be passive (allowing native plants to fill in a site) or active

(any combination of seeding, mulching, or planting). Some sites will require active re-vegetation to achieve the desired future condition.

In 2002, the Okanogan-Wenatchee National Forest adopted an invasive weeds prevention strategy which includes best management practices for the prevention of weed spread and introduction. These practices would continue to be an important part of the Forest's invasive species management strategy under the proposed action described above.

This project does not include herbicide application directly to water, use of any pesticides other than herbicides, treatment of aquatic invasive plants (floating and submerged), or treatment of native vegetation.

Possible Alternatives

The No Action alternative will serve as a baseline for comparison of alternatives. Under the No Action alternative, the Okanogan-Wenatchee National Forest would continue to treat invasive plant species as authorized under existing National Environmental Policy Act (NEPA) documents including; current noxious weed, dry forest restoration, and other site-specific projects. Additional action alternatives may be developed to respond to significant issues, if any.

Responsible Official

The responsible official for this project is the Okanogan-Wenatchee National Forest Supervisor Rebecca Lockett Heath.

Nature of the Decision To Be Made

The Okanogan-Wenatchee National Forest Supervisor will decide whether or not invasive species will be treated on the Forest, and if so, what mitigation measures and monitoring requirements will be required for implementation.

Preliminary Issues

Several analysis efforts related to the treatment of invasive species on National Forests in Washington and Oregon (Region 6) have been completed or are currently on-going at this time. Preliminary issues identified during the scoping process associated with these efforts have included: Human health/public and worker exposure to herbicides, effects of herbicide on native and non-target vegetation including threatened, endangered and special status plants, and the effects of herbicide on wildlife including threatened, endangered and special status animals and aquatic organisms, including special status fish.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. To assist the Forest Service in identifying and considering issues and concerns about the proposed action, public comment opportunities will continue to be provided throughout the EIS process. In addition to taking written comments, the Forest Service will hold a series of public meetings across the Forest during the late summer/early fall of 2009 to ensure that those who are interested have every opportunity to provide additional information or comments and to identify any issues or concerns they may have relative to the proposed action.

It is important that reviewers provide their comments at such times and in such a way that they are useful to the Agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. The submission of timely and specific comments can affect a reviewer's ability to participate in subsequent administrative review or judicial review.

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, respondents who submit anonymous comments will not be granted standing to appeal the subsequent decision under 36 CFR Part 215 or judicial review. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied; the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Dated: August 7, 2009.

Stuart Woolley,

Acting Forest Supervisor.

[FR Doc. E9-19451 Filed 8-12-09; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Arizona Counties Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Eastern Arizona Counties Resource Advisory Committee will meet in Show Low, Arizona. The purpose of the meeting is to review organizational processes, operating guidelines, and legal requirements of Resource Advisory Committee members in accordance with Public Law 110-343 (the Secure Rural Schools and Community Self Determination Act).

DATES: The meeting will be held August 24, 2009 starting at 1 p.m.

ADDRESSES: The meeting will be held in the conference room at the Holiday Inn Express, 151 West Deuce of Clubs, Show Low, Arizona 85901. Send written comments to Robert Dyson, Eastern Arizona Counties Resource Advisory Committee, c/o Forest Service, USDA, P.O. Box 640, Springerville, Arizona 85938 or electronically to rdyson@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Robert Dyson, Public Affairs Officer, Apache-Sitgreaves National Forests, (928)333-4301.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. This is an administrative and organizational meeting only and no project proposals will be reviewed. Committee discussion is limited to Forest Service staff and Committee members. However, persons who wish to bring Public Law 110-343 related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Opportunity for public input will be provided.

Dated: August 6, 2009.

Chris Knopp,

Forest Supervisor, Apache-Sitgreaves National Forests.

[FR Doc. E9-19287 Filed 8-12-09; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

International Trade Administration

[A-475-059]

Pressure Sensitive Plastic Tape From Italy: Final Results of Expedited Sunset Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On May 1, 2009, the Department of Commerce (the Department) initiated a sunset review of the antidumping duty finding on pressure sensitive plastic tape (PSP Tape) from Italy pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). The Department conducted an expedited (120-day) sunset review of this finding. As a result of this sunset review, the Department finds that revocation of the antidumping duty finding would be likely to lead to continuation or recurrence of dumping. The dumping margins are identified in the *Final Results of Review* section of this notice.

DATES: Effective Date: August 13, 2009.

FOR FURTHER INFORMATION CONTACT:

Terre Keaton Stefanova or Brandon Farlander, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-1280 or (202) 482-0182, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2009, the Department published the notice of initiation of the sunset review of the antidumping duty finding on PSP Tape from Italy pursuant to section 751(c) of the Act. See *Initiation of Five-Year Sunset Review*, 74 FR 20286 (May 1, 2009). The Department received a Notice of Intent to Participate on behalf of 3M Company (3M), a domestic producer of PSP Tape, within the deadline specified in 19 CFR 351.218(d)(1)(i). 3M claimed interested party status, under section 771(9)(C) of the Act, as a producer of a domestic like product in the United States. We received a complete substantive response from 3M within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). The Department did not receive substantive responses from respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of this finding.

Scope of Review

The products covered in this review are shipments of PSP Tape measuring over one and three-eighths inches in width and not exceeding four millimeters in thickness. The above described PSP Tape is classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 3919.90.20 and 3919.90.50. The HTS subheadings are provided for convenience and for customs purposes. The written description remains dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the "Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Antidumping Duty Finding on Pressure Sensitive Plastic Tape from Italy" (Decision Memo), which is hereby adopted by this notice. The issues discussed in the Decision Memo include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the finding were to be revoked. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, room 1117 of the main Commerce building.

In addition, a complete version of the Decision Memo can be accessed directly on the Web at <http://ia.ita.doc.gov/frn/index.html>. The paper copy and electronic version of the Decision Memo are identical in content.

Final Results of Review

The Department determines that revocation of the antidumping duty finding on PSP Tape from Italy would be likely to lead to continuation or recurrence of dumping at the following weighted-average percentage margins:

Manufacturers/exporters/producers	Weighted-average margin (percent)
Comet SARA, S.p.A	10
Tyco Adhesives Italia S.p.A ¹	10
All Others	10

¹ Tyco Adhesives Italia S.p.A is the successor-in-interest to Manuli Tapes S.p.A.

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or

conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

The Department is issuing and publishing the results and notice in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: August 7, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. E9-19430 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-950]

Wire Decking from the People's Republic of China: Notice of Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 13, 2009.

FOR FURTHER INFORMATION CONTACT:

Robert Copyak, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone 202-482-2209.

SUPPLEMENTARY INFORMATION:

Background

On July 2, 2009, the Department of Commerce (the Department) initiated the countervailing duty investigation of wire decking from the People's Republic of China. *See Wire Decking From the People's Republic of China: Initiation of Countervailing Duty Investigation*, 74 FR 31700 (July 2, 2009).

Postponement of Due Date for Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which the Department initiated the investigation. However, the Department may postpone making the preliminary determination until no later than 130 days after the date on which the administering authority initiated the investigation if, pursuant to section 703(c)(1)(B) of the Act, the Department concludes that the parties concerned in

the investigation are cooperating and determines that the investigation is extraordinarily complicated and that "additional time is necessary to make the preliminary determination."

The Department is currently investigating a number of complex alleged subsidy programs, including various loan programs, grants, income tax incentives, and the provision of goods and services for less than adequate remuneration. Due to the number and complexity of the alleged subsidy programs being investigated, we find that this investigation is extraordinarily complicated and that additional time is necessary to make the preliminary determination. Therefore, in accordance with section 703(c)(1)(B) of the Act, we are fully extending the due date for the preliminary determination to no later than 130 days after the day on which the investigation was initiated. The deadline for completion of the preliminary determination is now November 2, 2009.

This notice is issued and published pursuant to section 703(c)(2) of the Act.

Dated: August 7, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. E9-19429 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Deadline Extension for Applications for Seat on the Monterey Bay National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Deadline Extension Notice and request for applications.

SUMMARY: The ONMS is extending the deadline for applications for the following vacant seat on the Monterey Bay National Marine Sanctuary Advisory Council: Education. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen

should expect to serve until February 2011.

DATES: Applications are due by September 11, 2009.

ADDRESSES: Application kits may be obtained from 299 Foam Street, Monterey, CA 93940. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT:

Nicole Capps, 299 Foam Street, Monterey, CA 93940, (831) 647-4206, nicole.capps@noaa.gov.

SUPPLEMENTARY INFORMATION: On July 20, 2009, ONMS published a request for application to fill a vacancy on the MBNMS Advisory Council (74 FR 35160). The original deadline for submitting applications was August 21, 2009. ONMS is extending that deadline until September 11, 2009.

The MBNMS Advisory Council was established in March 1994 to assure continued public participation in the management of the Sanctuary. Since its establishment, the Advisory Council has played a vital role in decisions affecting the Sanctuary along the central California coast.

The Advisory Council's twenty voting members represent a variety of local user groups, as well as the general public, plus seven local, State and Federal governmental jurisdictions. In addition, the respective managers or superintendents for the four California National Marine Sanctuaries (Channel Islands National Marine Sanctuary, Cordell Bank National Marine Sanctuary, Gulf of the Farallones National Marine Sanctuary and the Monterey Bay National Marine Sanctuary) and the Elkhorn Slough National Estuarine Research Reserve sit as non-voting members.

Four working groups support the Advisory Council: The Research Activity Panel ("RTP") chaired by the Research Representative, the Sanctuary Education Panel ("SEP") chaired by the Education Representative, the Conservation Working Group ("CWG") chaired by the Conservation Representative, and the Business and Tourism Activity Panel ("BTAP") chaired by the Business/Industry Representative, each dealing with matters concerning research, education, conservation and human use. The working groups are composed of experts from the appropriate fields of interest and meet monthly, or bi-monthly, serving as invaluable advisors to the Advisory Council and the Sanctuary Superintendent.

The Advisory Council represents the coordination link between the Sanctuary and the State and Federal

management agencies, user groups, researchers, educators, policy makers, and other various groups that help to focus efforts and attention on the central California coastal and marine ecosystems.

The Advisory Council functions in an advisory capacity to the Sanctuary Superintendent and is instrumental in helping develop policies, program goals, and identify education, outreach, research, long-term monitoring, resource protection, and revenue enhancement priorities. The Advisory Council works in concert with the Sanctuary Superintendent by keeping him or her informed about issues of concern throughout the Sanctuary, offering recommendations on specific issues, and aiding the Superintendent in achieving the goals of the Sanctuary program within the context of California's marine programs and policies.

Authority: 16 U.S.C. Sections 1431, *et seq.*
(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: August 4, 2009.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. E9-19288 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-NK-M

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting; Postponed

The Materials Technical Advisory Committee scheduled for on August 13, 2009, 10 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues, NW., Washington, DC has been postponed. The new meeting date is forthcoming.

For more information, call Yvette Springer at (202) 482-2813.

Dated: August 10, 2009.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. E9-19436 Filed 8-12-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XQ94

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Committee in September, 2009 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, September 1, 2009 at 9 a.m. and Wednesday, September 2, 2009 at 9 a.m.

ADDRESSES: This meeting will be held at the Hotel Providence, 139 Mathewson Street, Providence, RI 02903; telephone: (401) 861-8000; fax: (401) 861-8002.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: The committee will clarify any outstanding issues related to alternatives under consideration in Amendment 15. Specifically, the committee will review recommendations from the PDT related to updated fishing power adjustment alternatives for stacking and leasing alternatives, recommendations from the SSC related to setting ABC control rule, and other outstanding issues. The committee will also review some preliminary impact analyses of measures under consideration. The committee will begin developing measures for Framework 21. Specifically, the committee will review input from the PDT about projections for fishing year 2010 and possible fishery specifications. Other measures under discussion are possible consideration of a new scallop access area closure in the Great South Channel with high scallop recruitment, minor modifications to the observer set-aside program, and compliance with the recent turtle biological opinion.

Although non-emergency issues not contained in this agenda may come

before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions 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 Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

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

Dated: August 7, 2009.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. E9-19377 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

Marine Protected Areas Federal Advisory Committee; Public Meeting

AGENCY: National Ocean Service, NOAA, Department of Commerce.

ACTION: Notice of open meeting

SUMMARY: Notice is hereby given of a meeting of the Marine Protected Areas Federal Advisory Committee (Committee) in Anchorage, Alaska.

DATES: The meeting will be held Wednesday, September 9, 2009, from 9 a.m. to 5:30 p.m., Thursday, September 10, from 8:30 a.m. to 5 p.m., and Friday, September 11, from 8:30 a.m. to 4:30 p.m. These times and the agenda topics described below are subject to change. Refer to the Web page listed below for the most up-to-date meeting agenda.

ADDRESSES: The meeting will be held at the Hilton Anchorage, 500 West Third Avenue, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Lauren Wenzel, Designated Federal Officer, MPA FAC, National Marine Protected Areas Center, 1305 East West Highway, Silver Spring, Maryland 20910. (Phone: 301-713-3100 x136. Fax: 301-713-3110); e-mail: lauren.wenzel@noaa.gov; or visit the

National MPA Center Web site at <http://www.mpa.gov>.

SUPPLEMENTARY INFORMATION: The Committee, composed of external, knowledgeable representatives of stakeholder groups, was established by the Department of Commerce (DOC) to provide advice to the Secretaries of Commerce and the Interior on implementation of section 4 of Executive Order 13158 on MPAs. The meeting will be open to public participation from 4:30 p.m. to 5:30 p.m. on Wednesday, September 9, 2009, and from 8:35 a.m. to 9:30 a.m. on Friday, September 11, 2009. In general, each individual or group will be limited to a total time of five (5) minutes. If members of the public wish to submit written statements, they should be submitted to the Designated Federal Official by September 4, 2009.

Matters To Be Considered: The Committee meeting will include two expert panel presentations, one on how the national system can contribute to ecological resilience in the face of climate change, and one, including invited management agencies and stakeholders, on marine protected areas in Alaska. The Scientific and Technical Subcommittee and the Review and Evaluation Subcommittee will meet to finalize recommendations, and will report back to the full MPA FAC for deliberations and action. The meeting also will include elections of a new MPA FAC Chair and Vice Chair. The agenda is subject to change. The latest version will be posted at <http://www.mpa.gov>.

Dated: August 3, 2009.

David M. Kennedy,

Director, Office of Ocean and Coastal Resource Management.

[FR Doc. E9-19286 Filed 8-12-09; 8:45 am]

BILLING CODE M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Estuarine Research Reserve System

AGENCY: Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of Public Comment Period for the Revised Management Plan for the Jacques Cousteau National Estuarine Research Reserve.

SUMMARY: Notice is hereby given that the Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce is announcing a thirty day public comment period on the Jacques Cousteau National Estuarine Research Reserve Management Plan Revision.

The Jacques Cousteau National Estuarine Research Reserve consists of public lands within the Mullica River-Great Bay watershed of New Jersey and managed by a variety of local, state, and federal agencies. The site was designated as the Jacques Cousteau National Estuarine Research Reserve in 1998 pursuant to Section 315 of the Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1461. The reserve has been operating in partnership with The Institute of Marine and Coastal Sciences of Rutgers, the State University of New Jersey under a management plan approved in 1997. Pursuant to 15 CFR 921.33(c), a state must revise their management plan every five years. The submission of this plan fulfills this requirement and sets a course for successful implementation of the goals and objectives of the reserve. A boundary expansion and land conservation initiative, new facilities, and updated programmatic objectives are notable revisions to the 1997 approved management plan.

The revised management plan outlines the administrative structure; the research, coastal training, education and outreach, and stewardship goals of the reserve; and the plans for future land acquisition and facility development to support reserve operations. This management plan describes how the reserve will focus on three key coastal management issues: Nutrient inputs into coastal waters; human alteration of habitat and water quality; and effects of climate change on coastal and estuarine systems.

Since 1997, the reserve has completed a site profile that characterizes the reserve; they have also expanded the coastal training, research and monitoring, stewardship and education programs significantly. A new administrative building, the Jacques Cousteau Coastal Center, and a new interpretive exhibit, "Life on the Edge" at the Tuckerton Seaport, have been built to support the growth of reserve programs.

With the approval of this management plan, the Jacques Cousteau National Estuarine Research Reserve will expand their total acreage from 114,665 acres to 114,873 acres. This change is

attributable to the acquisition of four parcels within the Mullica River watershed through a partnership with New Jersey Conservation Foundation and the continued implementation of the Mullica River Conservation Initiative. The acquisition of Bear Creek Preserve (100 acres), Hanselman Preserve (57 acres), Rudolph Property (31 acres), and Lee Property (20 acres) provides additional buffer areas (mixed pitch pine-scrub oak upland, Atlantic white cedar forest) for key land and water areas (salt marsh flats, tidal wetlands).

FOR FURTHER INFORMATION CONTACT:

Michael Migliori at (301) 563-1126 or Laurie McGilvray at (301) 563-1158 of NOAA's National Ocean Service, Estuarine Reserves Division, 1305 East-West Highway, N/ORM5, 10th floor, Silver Spring, MD 20910. For copies of the Jacques Cousteau Management Plan revision, visit <http://www.jcnerr.org/>.

Dated: August 3, 2009.

David M. Kennedy,

Director, Office of Ocean and Coastal Resource Management, National Oceanic and Atmospheric Administration.

[FR Doc. E9-19284 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-08-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XQ83

Taking and Importing of Marine Mammals

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

ACTION: Notice; annual affirmative finding renewals.

SUMMARY: The Assistant Administrator for Fisheries, NMFS (Assistant Administrator), has renewed the affirmative findings for the Government of Ecuador, the Government of El Salvador, the Government of Mexico and the Government of Spain under the Marine Mammal Protection Act (MMPA). These affirmative findings will allow yellowfin tuna harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Ecuadorian-flag, El Salvadorian-flag, Mexican-flag or Spanish-flag purse seine vessels or purse seine vessels operating under Ecuadorian, El Salvadorian, Mexican, or Spanish jurisdiction to be imported into the United States. These

affirmative findings were based on review of documentary evidence submitted separately by the Governments of Ecuador, El Salvador, Mexico, and Spain and obtained from the Inter-American Tropical Tuna Commission (IATTC) and the U.S. Department of State.

DATES: The affirmative finding renewals are effective from April 1, 2009, through March 31, 2010.

FOR FURTHER INFORMATION CONTACT:

Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213; phone 562-980-4000; fax 562-980-4018.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.*, allows the entry into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator for Fisheries (Assistant Administrator) will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, and the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request an affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determine whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted separately by the Government of Ecuador, the Government of El

Salvador, the Government of Mexico, and the Government of Spain, as well as evidence obtained from the IATTC and the Department of State and has determined that Ecuador, El Salvador, Mexico and Spain have each met the MMPA's requirements to receive annual affirmative finding renewals.

After consultation with the Department of State, the Assistant Administrator issued annual affirmative finding renewals to the Governments of Ecuador, El Salvador, Mexico, and Spain, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Ecuadorian-flag, El Salvadorian-flag, Mexican-flag or Spanish-flag purse seine vessels or purse seine vessels operating under the jurisdiction of these nations. These annual renewals of affirmative findings for Ecuador, El Salvador, Mexico and Spain will remain valid through March 31, 2010.

Dated: August 7, 2009.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E9-19470 Filed 8-12-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

RIN 0710-ZA04

Proposed Suspension and Modification of Nationwide Permit 21

AGENCY: United States Army Corps of Engineers, Department of Defense,

ACTION: Notice; extension of comment period.

SUMMARY: In the July 15, 2009, issue of the **Federal Register** (74 FR 34311) the U.S. Army Corps of Engineers published a proposal to take two actions concerning Nationwide Permit 21, which authorizes discharges of dredged or fill material into waters of the United States for surface coal mining activities. The two proposed actions are to suspend NWP 21 to prohibit its use to authorize surface coal mining activities in the Appalachian region of Kentucky, Ohio, Pennsylvania, Tennessee, Virginia, and West Virginia, and then to modify NWP 21 to make that prohibition permanent until NWP 21 expires on March 18, 2012. The July 15, 2009, notice stated that public comments and any requests for a public hearing must be received by August 14,

2009. We have received several requests to extend the comment period. We are extending the comment period to September 14, 2009.

DATES: Comments must be received by September 14, 2009.

ADDRESSES: You may submit comments, identified by docket number COE-2009-0032, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: U.S. Army Corps of Engineers, Attn: CECW-CO (Attn: Ms. Desiree Hann), 441 G Street, NW., Washington, DC 20314-1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

We will not accept e-mailed or faxed comments. We will post all comments on <http://www.regulations.gov> under docket number COE-2009-0032.

FOR FURTHER INFORMATION CONTACT: Ms. Desiree Hann or Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC. Ms. Hann can be reached at 202-761-4560 and Mr. Olson can be reached at 202-761-4922.

SUPPLEMENTARY INFORMATION: In the July 15, 2009, issue of the **Federal Register** (74 FR 34311) the U.S. Army Corps of Engineers published a proposal to take two actions concerning Nationwide Permit 21, which authorizes discharges of dredged or fill material into waters of the United States for surface coal mining activities.

First, the Corps proposes to modify NWP 21 to prohibit its use to authorize discharges of dredged or fill material into waters of the United States for surface coal mining activities in the Appalachian region of the following states: Kentucky, Ohio, Pennsylvania, Tennessee, Virginia, and West Virginia until it expires on March 18, 2012. The proposed modification would enhance environmental protection of aquatic resources by requiring surface coal mining projects in the affected region to obtain individual permit coverage under the Clean Water Act, which includes increased public and agency involvement in the permit review process, including an opportunity for public comment on individual projects.

Second, the Corps is proposing to suspend NWP 21 to provide an interim means of requiring individual permit reviews in Appalachia, while proposing to undertake the longer-term measure of modifying NWP 21 to prohibit its use to authorize discharges of dredged or fill material into waters of the United States

associated with surface coal mining activities in the Appalachian region of these six States. The Corps is also proposing to suspend NWP 21 to provide immediate environmental protection while it evaluates the comments received in response to the proposal to modify NWP 21.

The application of NWP 21 to surface coal mining activities in the rest of the United States would not be affected by this proposed modification or the proposed suspension.

Several entities have requested an extension of the comment period for the proposed rule. We have determined that a 30-day extension of the comment period for this proposed rule is warranted. Therefore, the comment period for these proposed actions is extended until September 14, 2009.

Dated: August 10, 2009. Approved By:

Jonathan A. Davis,

Deputy Chief, Operations, Directorate of Civil Works.

[FR Doc. E9-19446 Filed 8-12-09; 8:45 am]

BILLING CODE 3710-92-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8945-5]

Cross-Media Electronic Reporting Rule State Authorized Program Revision/Modification Approvals: State of Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval, under regulations for Cross-Media Electronic Reporting, of the State of Washington's request to revise/modify programs to allow electronic reporting for certain of their EPA-authorized programs under title 40 of the CFR.

DATES: EPA's approval is effective on August 13, 2009.

FOR FURTHER INFORMATION CONTACT: Evi Huffer, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 566-1697, huffer.evi@epa.gov, or David Schwarz, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 566-1704, schwarz.david@epa.gov.

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media

Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR, requires that State, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and get EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, in § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the State, tribe or local government has sufficient legal authority to implement the electronic reporting components of its authorized programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On October 10, 2008, the State of Washington Department of Ecology (WAECY) submitted an application for its enterprise-wide electronic document receiving system for revision or modification of multiple EPA-authorized programs under title 40 CFR. EPA reviewed WAECY's request to revise/modify their EPA-authorized programs and, based on this review, EPA determined the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Washington's request for revision/modification to certain of their authorized programs is being published in the **Federal Register**.

Specifically, EPA has approved WAECY's request for revisions/modifications to the following of their authorized programs to allow electronic reporting under 40 CFR parts 51, 60-63, 70, 122-124, 144-147, and 280:

- Part 52—Approval and Promulgation of Implementation Plans;

- Part 61—National Emission Standards For Hazardous Air Pollutants;
- Part 62—Approval and Promulgation of State Plans for Designated Facilities and Pollutants;
- Part 63—National Emission Standards For Hazardous Air Pollutants For Source Categories;
- Part 70—State Operating Permit Programs;
- Part 123—State Program Requirements (National Pollutant Discharge Elimination System Permit Program);
- Part 147—State, Tribal, and EPA-administered Underground Injection Control Programs; and
- Part 282—Approved Underground Storage Tank Programs.

WAE CY was notified of EPA's determination to approve its application with respect to the authorized programs listed above in a letter dated August 6, 2009.

Dated: August 6, 2009.

Lisa Schlosser,

Director, Office of Information Collection.

[FR Doc. E9-19463 Filed 8-12-09; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8945-4]

Notice of a Regional Waiver of Section 1605 (Buy American Requirement) of the American Recovery and Reinvestment Act of 2009 (ARRA) to the City of Ocean Shores (the City), Washington for the Purchase of Resin Beads (Miex® DOC Resin) Manufactured Outside of the United States Under the Section 1605 Waiver Authority Based on the Conclusion That Iron, Steel, and the Relevant Manufactured Goods Are Not Produced in the United States in Sufficient and Reasonably Available Quantities and of a Satisfactory Quality

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Acting Regional Administrator of EPA Region 10, is hereby granting a waiver of the Buy America requirements of ARRA Section 1605 under the authority of Section 1605(b)(2) [manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality] to the City for the purchase of resin beads (MIEX® DOC Resin) supplied by Orica Ltd, in Victoria, Australia and manufactured in Australia. The

applicant indicates that MIEX® DOC Resin is necessary to the MIEX® process, a treatment process evaluated in pilot studies and selected for implementation. While the majority of other equipment is manufactured in the U.S., the MIEX® DOC Resin is only manufactured in Australia. It is patented and no alternative exists which can be used with the MIEX® process. The Acting Regional Administrator is making this determination based on the review and recommendations of the Drinking Water Unit. The City has provided sufficient documentation to support their request.

DATES: *Effective Date:* July 24, 2009.

FOR FURTHER INFORMATION CONTACT: Rick Green, DWSRF Coordinator, Drinking Water Unit (DWU), Office of Water & Watersheds (OWW), (206) 553-8504, U.S. EPA Region 10 (OWW-136), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.

SUPPLEMENTARY INFORMATION:

In accordance with ARRA Section 1605(c), the EPA hereby provides notice that it is granting a project waiver of the requirements of Section 1605(b)(2) of Public Law 111-5, Buy American requirements, to the City for the acquisition of resin beads (MIEX® DOC Resin) supplied by Orica Ltd, in Victoria, Australia and manufactured in Australia. The applicant indicates that MIEX® DOC Resin is necessary to the MIEX® process, a treatment process evaluated in pilot studies at the City and selected for use. While the majority of other equipment is manufactured in the U.S., the MIEX® DOC Resin is only manufactured in Australia. It is patented and no alternative exists which can be used with the MIEX® process. Section 1605 of the ARRA requires that none of the appropriated funds may be used for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project is produced in the United States unless a waiver is provided to the recipient by EPA. A waiver may be provided if EPA determines that (1) applying these requirements would be inconsistent with public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) inclusion of iron, steel, and the relevant manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent.

The construction project being undertaken by the City is treatment of

water from a shallow aquifer, which contains problematic levels of iron, manganese, hydrogen sulfide, ammonia, organic nitrogen, and organic carbon. Based on the results of pilot studies, the City chose to use a combination of greensand filtration and the MIEX® process to treat this water supply. The community chose this treatment process over the alternatives of ultrafiltration or nanofiltration because the capital costs are significantly lower, the electrical consumption is significantly less, and there is much less water wasted during the treatment process.

The City's submission clearly articulates entirely reasonable reasons for choosing the type of technology that it chose for this project and has provided sufficient documentation that the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantity and of a satisfactory quality to meet its technical specifications.

The April 28, 2009 EPA HQ Memorandum, Implementation of Buy American provisions of Public Law 111-5, the "American Recovery and Reinvestment Act of 2009", defines "reasonably available quantity" as the quantity of iron, steel, or relevant manufactured good is available or will be available at the time needed and place needed, and in the proper form or specification as specified in the project plans and design. The City has incorporated specific technical design features for the proposed project based on pilot studies which demonstrated that the combination of greensand filtration and MIEX treatment is the best alternative.

The City has provided information to the EPA representing that there are currently no resin beads manufactured in the United States that have the exact same product specifications in place. The City has also provided certification from its supplier representing that there are no beads of comparable quality available from a domestic manufacturer to meet its exact specifications.

Based on additional research by EPA's consulting contractor (Cadmus), and to the best of the Region's knowledge at this time, there does not appear to be other resin beads available to meet the City's specifications.

Furthermore, the purpose of the ARRA provisions was to stimulate economic recovery by funding current infrastructure construction, not to delay projects that are already shovel ready by requiring entities, like the City, to revise their design and potentially choose a more costly and less efficient project. The imposition of ARRA Buy American requirements on such projects eligible

for DWSRF assistance would result in unreasonable delay and thus displace the “shovel ready” status for this project. To further delay construction is in direct conflict with the most fundamental economic purposes of ARRA; to create or retain jobs.

The Drinking Water Unit (DWU) has reviewed this waiver request and has determined that the supporting documentation provided by the City is sufficient to meet the following criteria listed under Section 1605(b) and in the April 28, 2009, Implementation of Buy American provisions of Public Law 111–5, the “American Recovery and Reinvestment Act of 2009” Memorandum: Iron, steel, and the manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality.

The basis for this project waiver is the authorization provided in Section 1605(b)(2), due to the lack of production of this product in the United States in sufficient and reasonably available quantities and of a satisfactory quality in order to meet the City’s design specifications.

The March 31, 2009 Delegation of Authority Memorandum provided Regional Administrators with the authority to issue exceptions to Section 1605 of ARRA within the geographic boundaries of their respective regions and with respect to requests by individual grant recipients.

Having established both a proper basis to specify the particular good required for this project, and that this manufactured good was not available from a producer in the United States, the City is hereby granted a waiver from the Buy American requirements of Section 1605(a) of Public Law 111–5 for the purchase of resin beads (MIEX® DOC Resin) supplied by Orica Ltd, in Victoria, Australia and manufactured in Australia as specified in the City’s request of June 26, 2009. This supplementary information constitutes the detailed written justification required by Section 1605(c) for waivers based on a finding under subsection (b).

Authority: Public Law 111–5, section 1605.

Issued on: July 28, 2009.

Michelle Pirzadeh,

Acting Regional Administrator, EPA, Region 10.

[FR Doc. E9–19465 Filed 8–12–09; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that at 9:03 a.m. on Tuesday, August 11, 2009, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation’s resolution activities.

In calling the meeting, the Board determined, on motion of Director Thomas J. Curry (Appointive), seconded by Vice Chairman Martin J. Gruenberg, concurred in by Ms. Julie L. Williams, acting in the place and stead of Director John C. Dugan (Comptroller of the Currency), Director John E. Bowman (Acting Director, Office of Thrift Supervision), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days’ notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the “Government in the Sunshine Act” (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, NW., Washington, DC.

Dated: August 11, 2009.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. E9–19492 Filed 8–12–09; 8:45 am]

BILLING CODE P

GOVERNMENT ACCOUNTABILITY OFFICE

System of Personnel Records

AGENCY: Government Accountability Office.

ACTION: Notice of Establishment of Human Capital Management System of Records.

SUMMARY: The Government Accountability Office (GAO) proposes to establish a new system of personnel records under its privacy regulations, Privacy Procedures for Personnel Records. This Human Capital Management System of Records encompasses GAO payroll- and

personnel-related information maintained by GAO and exchanged with the U.S. Department of Agriculture’s National Finance Center (USDA/NFC) and the U.S. Department of the Treasury’s HR Connect program (Treasury/HR Connect). To support its human capital management activities, GAO has entered into interagency agreements with these two Federal Executive Branch agencies as shared service providers. USDA/NFC provides payroll and personnel information processing (Department of Agriculture, Systems of Record Notice OP–1), and Treasury/HR Connect operates a human capital management support system (Department of Treasury .001—Treasury Payroll and Personnel System). The policies and procedures described in this notice are intended to ensure that personal information contained in GAO’s personnel records is protected as provided by GAO’s privacy regulation.

DATES: Comments may be submitted on or before September 14, 2009.

ADDRESSES: Comments should be sent to: Government Accountability Office, Privacy Office, Room 1127, 441 G St., NW., Washington, DC 20548, or by e-mail to privacy@gao.gov. Please include reference to “Comment: Human Capital Management System of Records” at the top of a comment letter or in the subject line of an e-mail.

FOR FURTHER INFORMATION CONTACT: For information about GAO human capital information management, contact the Chief Human Capital Officer, Government Accountability Office, Room 1157, 441 G St., NW., Washington, DC 20548; e-mail, HCOhelp@gao.gov. For information about GAO privacy protections, contact the Chief Agency Privacy Officer, Government Accountability Office, Room 1127, 441 G St., NW., Washington, DC 20548; e-mail, privacy@gao.gov.

SUPPLEMENTARY INFORMATION:

Background

A. GAO. GAO is an independent, nonpartisan Legislative Branch agency that examines a wide range of government activities and provides analyses, recommendations, and other assistance to help Congress make sound oversight, policy, and funding decisions. As a Legislative Branch agency, GAO is not subject to the privacy and information security laws applicable to Executive Branch agencies, such as the Privacy Act of 1974 (Privacy Act), Federal Information Security Management Act of 2002 (FISMA), the E-Government Act of 2002 (E-Government Act), and Office of

Management and Budget (OMB) and National Institute of Standards and Technology (NIST) guidance issued under those laws. Nonetheless, it is GAO's policy to conduct its activities in a manner consistent with the spirit of those laws and guidance generally applicable to Executive Branch agencies, and related best practices.

Notwithstanding the similarities with privacy and information security laws, regulations, or policies applicable to Executive Branch agencies, GAO's application of, or compliance with, those laws, regulations, or policies shall not be interpreted as controlling legal authorities over GAO. The GAO regulation, 4 CFR Part 83, Privacy Procedures for Personnel Records, provides the basis for this notice.

B. GAO Human Capital Management. The GAO Human Capital Management System of Records, managed by GAO's Human Capital Office (HCO), is comprised of information supporting GAO human capital activities, primarily relating to pay, benefits, performance, recruitment, and personnel actions. This information is maintained in paper and electronic formats, including in the GAO Competency Based Performance System (CBPS), which tracks employee performance reviews; My Locator, which compiles contact information of GAO employees and contractors; and WebTA, which records time and attendance for GAO employees.

GAO Human Capital Management information is also maintained and managed in systems of records operated by two Federal human capital shared service providers: the U.S. Department of Agriculture (USDA), and the U.S. Department of the Treasury (Treasury), and contractors supporting these agencies. In order to streamline its human capital processes, reduce costs, and improve efficiencies, GAO has entered into agreements for the provision of human capital management services with these agencies.

The USDA's National Finance Center (NFC) provides payroll processing and related services. The Treasury HR Connect program operates an automated human resources system to support human capital management activities in Treasury and other Federal agencies through cross-servicing agreements. Implementation of GAO's agreements with USDA/NFC and Treasury/HR Connect will be phased in over 18 months. Full implementation is scheduled for January 2011.

Authorized GAO employees access human capital information maintained in GAO systems and in systems maintained by GAO's shared service providers and their contractors. All

information is securely transmitted to and from GAO and its shared service providers and their contractors as necessary to support agreed upon human capital management activities (e.g., employment application processing, recruiting, hiring, pay, promotions, employee awards processing, and compiling reports).

For a description of the privacy protections provided by USDA/NFC and Treasury/HR Connect, as required by law of Executive Branch agencies, see the following: Treasury/HR Connect Privacy Act System of Records Notice, <http://www.ustreas.gov/foia/privacy/treas001.html>; Treasury/HR Connect Privacy Impact Assessment (PIA), <http://www.treas.gov/pia/HRCPIA05-01-2008v10Final.pdf>; NFC Privacy Act System of Records Notice (Personnel and Payroll System for USDA/NFC Employees USDA/NFC/OP-1), <http://www.ocio.usda.gov/OP%20-%201.txt>; and NFC PIA, http://www.usda.gov/documents/NFC_Mainframe_GSS_Redacted_PIA.doc. Privacy protections for GAO information maintained by contractors of those agencies are provided under contracts between the agencies and their contractors. The text of GAO's human capital management system of records is set forth below.

SYSTEM NAME:

Government Accountability Office, Human Capital Management System of Records.

SYSTEM LOCATION:

Information maintained in this system of records is located at GAO headquarters in Washington, DC, and GAO field offices. GAO human capital information exchanged with Federal shared service providers (i.e., USDA/NFC and Treasury/HR Connect) is maintained in those agencies' systems of records. GAO human capital information maintained by contractors of those shared service providers is maintained at information processing facilities under the control of those contractors.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records contains information on current GAO employees, former GAO employees, and applicants for GAO employment.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records contains GAO human capital information, which comprises both biographic and employment information. Biographic information includes identifying information (e.g., name, social security number, date of birth, gender, race, and

national origin), education, and disabilities. Employment information includes compensation (e.g., salary, date of salary increases, pay plan, pay basis, sick and annual leave balances), benefits (e.g., pension, Thrift Savings Plan, health insurance, life insurance, Medicare and Federal Employees Compensation Act benefits), employment actions (e.g., promotions, demotions, removals), performance appraisals (e.g., individual ratings), veterans preference, military service, work schedule (e.g., telework and alternate work schedule), awards, dates of probationary periods, type of position appointment, and changes in position (e.g. position identification number, occupational series, organization location, and accounting classification codes), payroll data such as earnings and deductions (e.g., Federal, State, and local taxes), time and attendance data, and training courses attended. Both biographic and employment information may be maintained in electronic and paper format.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

4 CFR Part 83; System of Personnel Records.

PURPOSE:

The purpose of this system of records is to maintain records relating to current and former GAO employees and applicants for GAO employment as are relevant and necessary to efficiently and effectively conduct authorized GAO human capital management activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

All or a portion of personal information maintained in this system of records may only be disclosed as permitted under 4 CFR Part 83, http://www.access.gpo.gov/nara/cfr/waisidx_09/4cfr83_09.html. Specifically, such information shall not be disclosed to any person or entity without the written consent of the individual to whom the information pertains, except as permitted under § 83.4 and § 83.5. As permitted under § 83.4(a) and § 83.19, personal information in this system of records may be disclosed to those GAO employees and contractors who have a need for the record in the performance of their official duties. All or a portion of the records in this system of records may be disclosed as a routine use pursuant to § 83.4(c) in support of GAO's human capital management activities, as follows:

(a) To Federal shared service providers and their contractors as

reasonably necessary to provide agreed upon services to support GAO human capital management activities;

(b) To Federal, State, local, territorial, Tribal, or foreign law enforcement authorities or other appropriate entities where a record, either alone or in conjunction with other information, indicates a violation, or potential violation, of law or regulation, and where such entities are responsible for investigating or prosecuting such violation or enforcing or implementing such law or regulation;

(c) To Federal, State, local, or international agencies in connection with an individual's hiring, employment, related benefits, suitability, or security investigation, or security clearance; or in connection with the letting of a contract, or the issuance of a grant or other benefit to the extent that GAO determines the information is relevant and necessary to an agency or organization's decision;

(d) To Federal agencies to verify or determine the citizenship or immigration status of any individual seeking employment with GAO or as required by law;

(e) To agencies, entities, and persons when: (1) GAO suspects or has confirmed that the security or confidentiality of information in this system of records has been compromised; (2) GAO has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by GAO or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with GAO's efforts to respond to a suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(f) To an agency, organization, or individual for the purposes of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function; and

(g) To a public or professional licensing, certification, or accreditation organization to confirm the claimed credentials of a GAO applicant or employee, or when information indicates, either by itself or in combination with other information, a violation or potential violation of professional standards, or reflects on the moral, educational, or professional qualifications of an individual who

either is seeking to become or is already licensed, certified, or accredited.

RETRIEVABILITY:

Information maintained in the system may be retrieved only by employees of GAO who have a need for the information in the performance of their official duties.

SAFEGUARDS:

Information maintained in the system is safeguarded under 4 CFR 83.7(i), and GAO information systems security policies and procedures. Strict controls are imposed to minimize the risk of compromising the information maintained in this system of records and any of its supporting information systems. Furthermore, GAO human capital information maintained by GAO's Federal shared service providers and their contractors are subject to privacy and security laws applicable to executive branch agencies (*e.g.*, the Privacy Act, FISMA, the E-Government Act), and related regulations, standards, and guidance.

RETENTION AND DISPOSAL:

All GAO human capital information will be retained in accordance with the following schedule:

(a) Time and attendance records are destroyed 7 years after the end of the fiscal year in which they are created.

(b) Individual employee payroll records are destroyed 7 years after the end of the fiscal year in which they are created.

(c) An individual's Official Personnel Folder (OPF) is retained for 65 years after separation.

Compelling legal or policy purposes (*e.g.*, ongoing or potential litigation) may require retention of certain records beyond the retention periods identified above.

SYSTEM MANAGER AND ADDRESS:

The GAO official responsible for this system of records is the Chief Human Capital Officer (CHCO), Human Capital Office, U.S. Government Accountability Office, Room 1157, 441 G St., NW., Washington, DC, 20548.

NOTIFICATION PROCEDURE:

As provided under 4 CFR 83.12-18 and Appendix I to Part 83—Memorandum of Understanding, GAO employees, former employees, or applicants to GAO interested in knowing whether this system of records contains information about them, how to obtain access to such information, or how to contest any element of such information may submit a request in writing to the Chief Privacy Officer, U.S. Government Accountability Office,

Room 1127, 441 G St., NW., Washington, DC 20548, or by e-mail to privacy@gao.gov.

RECORD ACCESS PROCEDURES:

See "Notification Procedure" above.

CONTESTING RECORD PROCEDURE:

See "Notification Procedure" above.

RECORD SOURCE CATEGORIES:

Information in this system of records originates from individuals whose personal information is maintained in this system of records, agency records, financial institutions, employee and professional organizations, previous employers, consumer reporting agencies, debt collection agencies, courts, and other government agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Certain records contained in this system of records are exempt from access, amendment, and other procedural requirements pursuant to 4 CFR 83.21.

Catherine Teti,

Chief Agency Privacy Officer, Government Accountability Office.

[FR Doc. E9-19445 Filed 8-12-09; 8:45 am]

BILLING CODE 1610-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Advanced Education Nursing Traineeship (AENT) and Nurse Anesthetist Traineeship (NAT) (OMB No. 0915-0305): Revision

The Health Resources and Services Administration (HRSA) provides training grants to educational institutions to increase the numbers of advanced education nurses through the Advanced Education Nursing Traineeship (AENT) program and the Nurse Anesthetist Traineeship (NAT) program.

HRSA developed the AENT and NAT tables for the application guidances and

the Nurse Traineeship Database for the two nursing traineeship programs. The AENT and NAT tables are used annually by grant applicants that are applying for AENT and NAT funding. The funds appropriated for the AENT and NAT programs are distributed among eligible institutions based on a formula. Award amounts are based on enrollment and graduate data reported on the tables and two funding factors (Statutory Funding Preference and Statutory Special Consideration).

The AENT and NAT tables include information on program participants such as the number of enrollees, projected data on enrollees and graduates for the following academic year, number of trainees supported, number of graduates, number of graduates supported and the types of programs they are enrolling into and/or from which they are graduating. AENT and NAT applicants will have a single

access point to submit their grant applications including the tables. Applications are submitted in two phases: Grants.gov (Phase 1) and the HRSA Electronic Handbooks (Phase 2). These tables will be available electronically through the HRSA Electronic Handbooks (Phase 2) for applicants to submit their AENT and/or NAT grant application(s). The tables are also used in the Nurse Traineeship Database which is used by Division of Nursing staff and not the applicants.

Data from the tables will be used in the award determination and validation process. Additionally, the data will be used to ensure programmatic compliance, report to Congress and policymakers on the program accomplishments, and formulate and justify future budgets for these activities submitted to OMB and Congress.

The burden estimate for this project is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
AENT	500	1	500	1.5	750
NAT	100	1	100	1	100
Total	600		600		850

E-mail comments to paperwork@hrsa.gov or mail to the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 5, 2009.

Alexandra Huttinger,
Director, Division of Policy Review and Coordination.

[FR Doc. E9-19393 Filed 8-12-09; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to

OMB for review, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program [NEW]

Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also

generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

Enrollment/Registration

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA requires entities to submit administrative information (e.g., shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and State/local government representatives. The purpose of this registration information

is to determine eligibility for the 340B program. This information is received and verified according to 340B requirements and entered into the 340B database. Accurate records are critical to implementation of the 340B legislation especially to prevent diversion and duplicate discounts. To maintain accurate records, the OPA requests

entities to submit modifications to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is minimal.

Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy

arrangements, covered entities that elect to utilize a contract pharmacy are required to submit to OPA a self-certification form similar to the registration form that they have signed an agreement with the contract pharmacy.

The Estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
DSH & Children's Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Disproportionate Share Hospitals	70	1	70	.25	17.5
340B Program Registrations & Certifications for Children's Hospitals	80	1	80	.25	20
Certifications to Enroll DSH & Children's Hospitals Out-patient facilities to 340B Program	180	1	180	.083	14.94
DSH & Children's Hospitals' Annual Recertification	937	1	937	.5	468.5
Registration for Entities Other Than Hospitals & Recertifications					
340B Registration Form (Family Planning, STD, TB, and others)	170	1	170	.083	14.11
Family Planning Annual Recertification	85	47	3995	.083	331.59
STD & TB Annual Recertification	111	11	1221	.083	101.34
Other Entity Annual Recertification for entities other than DSHs, FP, STD or TB entities	400	10	4000	.083	332
Submission of Administrative Changes for any entity	460	1	460	.083	38.18
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	2000	1	2000	.083	166
Total	* 4493		13,313		1504.16

* The total number of respondents may be overestimated since we are unable to avoid duplication of respondents who submit information to the OPA over the course of participation in the 340B Drug Pricing Program, via the initial registration process to any updates/modifications and enrolling contract pharmacies, if applicable, to the recertification process.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 5, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-19381 Filed 8-12-09; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels N, O and P), RFA-DP09-101SUPP09, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Dates:

9 a.m.-5 p.m., August 5, 2009 (closed).

9 a.m.-5 p.m., August 6, 2009 (closed).

9 a.m.-5 p.m., August 7, 2009 (closed).

Place: Westin Hotel, 3377 Peachtree Road, NE., Atlanta, GA, 30326, Telephone (678) 500-3100.

Status: The meeting will be closed to the public in accordance with provisions set

forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of the application received in response to "Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels N, O and P), RFA-DP09-101SUPP09, initial review."

Contact Person for More Information: Brenda Colley-Gilbert, Ph.D., Director, Extramural Research Program Office, CCH, 47770 Buford Highway, MS K-92, Atlanta, GA 30341, Telephone (770) 488-8390.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9-19293 Filed 8-12-09; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIAAA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Alcohol Abuse and Alcoholism, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAAA.

Date: September 23–24, 2009.

Open: September 23, 2009, 8:15 a.m. to 8:30 a.m.

Agenda: Program reports and presentations.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Closed: September 23, 2009, 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate the Laboratory of Membrane Biochemistry and Biophysics (LMBB).

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Closed: September 24, 2009, 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate the Laboratory of Molecular Signaling and Metabolic Control.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Trish Scullion, Chief of Administrative Branch, National Institute of Health, National Institute on Alcohol Abuse, and Alcoholism, 5635 Fishers Lane, Room 3061, Rockville, MD 20852. 301–443–6076. (Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants;

93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: August 6, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–19425 Filed 8–12–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group. Anterior Eye Disease Study Section.

Date: September 21–22, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Washington DC, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Jerry L. Taylor, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301–435–1175, taylorje@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group. Neurobiology of Motivated Behavior Study Section.

Date: September 30–October 1, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, NW., Washington, DC 20037.

Contact Person: Edwin C. Clayton, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5095C, MSC 7844, Bethesda, MD 20892, (301) 402–1304, claytone@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience

Integrated Review Group. Auditory System Study Section.

Date: September 30–October 1, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco, 501 Geary Street, San Francisco, CA 94102.

Contact Person: Lynn E. Luethke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 435–1018, luethkel@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group.

Pregnancy and Neonatology Study Section.

Date: October 1–2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Harbor Court Baltimore, 550 Light Street, Baltimore, MD 21202.

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, knechtm@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group. Neurobiology of Learning and Memory Study Section.

Date: October 1–2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Points by Sheraton Washington DC Downtown, 1201 K Street, NW., Washington, DC 20005.

Contact Person: Bernard F. Driscoll, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892. (301) 435–1242. driscolb@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group. Lung Injury, Repair, and Remodeling Study Section.

Date: October 1–2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ghenima Dirami, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4112, MSC 7814, Bethesda, MD 20892. 301–594–1321. diramig@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel. Small Business.

Date: October 1–2, 2009.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Bill Bunnag, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892. (301) 435-1177. bunnagb@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group. Myocardial Ischemia and Metabolism Study Section.

Date: October 1–2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Joseph Thomas Peterson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892. 301-443-8130. petersonjt@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group. Acute Neural Injury and Epilepsy Study Section.

Date: October 1–2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Washington DC, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Seetha Bhagavan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892. (301) 435-1121. bhagavas@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies. Community-Level Health Promotion Study Section.

Date: October 1–2, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street, NW., Washington, DC 20037.

Contact Person: William N. Elwood, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3162, MSC 7770, Bethesda, MD 20892. 301/435-1503. elwoodwi@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies. Biomedical Computing and Health Informatics Study Section.

Date: October 2, 2009.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Bill Bunnag, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5124, MSC 7854, Bethesda, MD 20892. (301) 435-1177. bunnagb@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 6, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–19447 Filed 8–12–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Rescission of February 4, 2004, Order and Subsequent Amendments Prohibiting the Importation of Birds and Bird Products From Specified Countries

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final Notice.

SUMMARY: On January 21, 2009, CDC published a notice in the **Federal Register** (74 FR 3608) announcing its intent to rescind its February 4, 2004 order and subsequent amendments prohibiting the importation of birds and bird products from specified countries based on the threat that imports from such countries increases the risk that highly pathogenic avian influenza (HPAI) may be introduced into the United States. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has implemented and continues to enforce regulations to prohibit or restrict the importation of birds, poultry, and unprocessed birds and poultry products from regions that have reported the presence of highly pathogenic avian influenza H5N1 in poultry. While USDA/APHIS actions are based primarily on protecting the U.S. commercial poultry industry from the introduction of highly pathogenic avian influenza H5N1, these actions have the added benefit of mitigating the risk of human exposure to the virus. Because the USDA/APHIS import restrictions adequately address risks to human health, HHS/CDC is announcing, in this Notice, its decision to lift its embargo against imports of birds and unprocessed bird products from those same countries. All of the bird embargoes that are currently in force under USDA regulations remain in effect. HHS/CDC will work closely with USDA/APHIS to monitor the international situation regarding HPAI H5N1 outbreaks and if human health risks are not adequately contained by USDA regulatory actions, CDC will take

action to mitigate any human health risks associated with these outbreaks.

DATE: The decision is effective September 14, 2009.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Mullan, Division of Global Migration and Quarantine, National Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION:

Background

Since late 2003, highly pathogenic avian influenza (HPAI) has become established as a veterinary and human health threat throughout the world. As of April 1, 2009 HPAI has been confirmed by the World Organization for Animal Health (OIE) in birds from over 60 countries in Asia, Europe, and Africa. In addition, as of March 30, 2009, 413 human cases, including 256 deaths, have been confirmed by the World Health Organization (WHO). Birds imported into the United States from countries with HPAI could pose a risk for human infection or spread of virus to U.S. birds.

USDA Actions

To protect the U.S. commercial poultry industry, USDA/APHIS has taken specific actions to reduce the threat of importing birds or products with HPAI.

- USDA's authority for these actions is found at 9 CFR Parts 93, 94, and 95.

- USDA/APHIS issued an interim final rule on February 4, 2004, and a final rule on July 20, 2005, providing restrictions on the importation of birds and unprocessed bird products from countries confirmed to have HPAI in commercial birds.

- To date, USDA has placed import restrictions on 46 countries.

- Import restrictions allow US-origin pet birds and performing birds to return to the United States following a 30-day quarantine at a USDA facility. Importations of processed bird products that have been rendered noninfectious are also allowed provided such products are accompanied by a USDA Veterinary Services (VS) permit and a government certification confirming that the products were treated according to USDA requirements.

- Bird products that are potentially infectious may be imported for science and education purposes under a USDA/APHIS permit process, provided that the product can be safely transported.

CDC Actions

On February 4, 2004, HHS/CDC issued an order to immediately ban the import of all birds (Class: Aves) from specified countries, subject to limited exemptions for returning pet birds of US origin and certain processed bird-derived products. HHS/CDC took this action because birds from these countries can potentially infect humans with HPAI. Countries affected by the February 4, 2004, order included Cambodia, Indonesia, Japan, Laos, People's Republic of China (including Hong Kong Special Administrative Region [SAR]), South Korea, Thailand, and Vietnam. This order was further amended on March 10, 2004, to lift the embargo of birds and bird products from the Hong Kong SAR because of the documented control of the outbreak there and the absence of HPAI cases in Hong Kong's domestic bird populations. Following the documentation of HPAI in commercial birds in additional countries, HHS/CDC amended the February 4, 2004, order to add these countries to its embargo: Malaysia on September 28, 2004; Kazakhstan, Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; Israel on March 20, 2006; Afghanistan on March 21, 2006; Jordan on March 29, 2006; Burkina Faso on April 10, 2006; Pakistan on April 10, 2006; Gaza, the West Bank, and Ivory Coast (Côte d'Ivoire) on April 28, 2006; Sudan on May 16, 2006; Djibouti on June 2, 2006; and Kuwait on February 28, 2007.

HHS/CDC has experienced practical and operational issues since the implementation of these orders. The orders

- Duplicate the USDA/APHIS rule and thus do not provide any additional protection of the public's health;
- Cause confusion at ports of entry regarding which agency has primary authority to respond;
- Give the appearance of a lack of coordinated action by the U.S. government, and
- May interfere with the importation of products for laboratory evaluation, epidemiologic assessment, and vaccine distribution and research.

Thus, on January 21, 2009, CDC published a notice with a 30-day comment period in the **Federal Register** (74 FR 3608) in which it announced its intention to rescind the February 4, 2004, order and all subsequent orders

prohibiting the importation of birds and bird products from specified countries.

Public Comments Received and CDC Responses

CDC received three comments from the public in response to its January 21, 2009 Notice. Two commenters opposed CDC's proposal to rescind its bird embargo and one commenter commended CDC on its recognition that USDA's ban also protects human health.

Public Comment #1: The first comment opposing the plan for CDC to rescind its bird embargo cited three concerns, as follows:

1. The USDA and CDC prohibitions have been part of a well-coordinated federal response to the avian influenza threat, and there is no need to change these practices.
2. The USDA does not have the mandate to protect human health from the introduction of pathogens into the United States, and CDC does.
3. Rescinding the CDC prohibitions might have the undesirable effect of reducing the public's understanding of human health concerns, including avian influenza, associated with the importation of birds and bird products into the United States.

CDC Response: While the USDA/APHIS rule is based primarily on protecting the U.S. commercial poultry industry from introduction of HPAI H5N1, it has the added benefit of mitigating the risk of human exposure to the virus. Through contacts with international veterinary authorities and trade relationships with countries of concern, USDA/APHIS is able to quickly assess import risk and subsequently implement importation restrictions on affected countries. By working in close collaboration with USDA/APHIS, CDC is confident that their actions before issuing new bird import orders are sufficient to protect public health.

As the nation's lead agency for human health, HHS/CDC will ensure mitigation of the human health risks from HPAI and other animal influenza viruses that pose a risk to human health while also demonstrating a coordinated and efficient federal approach to managing risks from imported birds and unprocessed bird products. HHS/CDC will also take action if future USDA/APHIS restrictions do not adequately address the public health risk from HPAI or other influenza viruses in animals.

HHS/CDC will take the following steps to ensure the human health threat of HPAI H5N1 continues to be prevented:

1. To enforce USDA's importation embargo, CDC staff at the 20 U.S. Quarantine Stations will continue working closely with other federal agencies at ports of entry, such as USDA, the Department of Homeland Security (DHS), and the U.S. Fish and Wildlife Service (FWS) of the Department of the Interior (DoI).

2. CDC staff will closely follow the international situation regarding HPAI outbreaks and spread through review of information from its internal surveillance systems, World Health Organization Influenza Collaborating Centers, CDC's USDA liaison officer, the United Nations Food and Agriculture Organization, and the World Organization for Animal Health.

3. CDC staff will continue to monitor the World Organizations for Animal Health (OIE) and USDA/APHIS actions toward countries in which HPAI has been established in commercial birds to ascertain that they are consistent and make an assessment if actions taken mitigate the human health risk to the United States. If the review process identifies human health risks that are not adequately contained by USDA/APHIS actions, HHS/CDC will implement additional importation restrictions for birds and unprocessed bird products. For example, if human cases of HPAI were reported in a country with no official confirmation of avian cases (that would normally trigger a USDA ban), HHS/CDC could implement restrictions on an emergency basis.

4. CDC staff will post a link to all USDA/APHIS restrictions on its Web site (<http://www.cdc.gov/flu/avian/outbreaks/embargo.htm>).

5. CDC and USDA will continue to collaborate on guidelines and protocols to ensure a timely and coordinated response to an HPAI outbreak should it occur in the United States. In 2005–2006 the agencies worked together with other federal agencies on the USDA Playbook for Avian Influenza, a protocol that defines each agency's roles and responsibilities in response to H5N1 in the United States.

6. CDC staff will closely monitor human cases of HPAI and human infections with other novel influenza strains in other countries. If the review process identifies clearly that risks to human health could be further mitigated by an importation ban on birds and bird products coming from a particular country, HHS/CDC will implement additional importation restrictions for birds and unprocessed bird products. For example, if human illnesses and/or deaths from infection with a novel strain of influenza also shown to be

circulating in birds were reported in a country with no official confirmation of avian cases (that would normally trigger a USDA ban), HHS/CDC could implement restrictions on an emergency basis.

Public Comment #2: The second comment was not specific for HPAI, but addressed general concerns about potentially zoonotic diseases associated with wild birds. The commenter urged CDC to reconsider rescinding this order with respect to live birds and to review the disease risks created by these bird imports to protect people from dangerous infectious diseases.

CDC Response: The current embargo on birds and bird products from countries that have had HPAI identified in poultry is very specific and does not cover all potentially zoonotic diseases from imported wild birds. Therefore, rescinding the current order would have neither an adverse nor a positive affect on the zoonotic risks of importing wild birds.

Public Comment #3: The third comment was in support of CDC's rescission of its bird embargo.

CDC Response: As stated above, CDC will continue to work closely with USDA and other human and animal health partners to monitor the situation with HPAI in both birds and people to protect both animal and human health in the United States.

In summary, HHS/CDC believes that the actions taken to date by USDA/APHIS adequately mitigate the human health risks of HPAI associated with birds and unprocessed bird products imported from the countries of concern. HHS/CDC plans to mitigate any future human health risks that are not adequately addressed by USDA/APHIS regulations, thus ensuring a strong coordinated federal response. Therefore, the HHS/CDC order of February 4, 2004, and its subsequent amendments are no longer needed.

Action

Therefore, effective September 14, 2009, HHS/CDC is rescinding its February 4, 2004, order and all amendments from the following dates: March 10, 2004; September 28, 2004; December 29, 2005; February 8, 2006; February 22, 2006; February 27, 2006; March 2, 2006; March 15, 2006; March 20, 2006; March 21, 2006; March 29, 2006; April 10, 2006; April 28, 2006; May 16, 2006; June 2, 2006; and February 28, 2007.

Dated: August 5, 2009.

James Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E9-19453 Filed 8-12-09; 8:45 am]

BILLING CODE P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will meet Wednesday, August 19, 2009. The meeting will be held in the Caucus Room of the Cannon House Office Building, Independence Avenue, and 1st Street, SE., Washington, DC at 9 a.m. The ACHP was established by the National Historic Preservation Act of 1966 (16 U.S.C. 470 *et seq.*) to advise the President and Congress on national historic preservation policy and to comment upon Federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for inclusion in the National Register of Historic Places. The ACHP's members are the Architect of the Capitol; the Secretaries of the Interior, Agriculture, Defense, Housing and Urban Development, Commerce, Education, Veterans Affairs, and Transportation; the Administrator of the General Services Administration; the Chairman of the National Trust for Historic Preservation; the President of the National Conference of State Historic Preservation Officers; a Governor; a Mayor; a Native American; and eight non-Federal members appointed by the President.

The agenda for the meeting includes the following:

Call to Order—9 a.m.:

I. Chairman's Welcome.

II. Preserve America and Chairman's Award Presentation.

III. Native American Activities.

A. Native American Advisory Group.

B. Native American Program Report.

IV. Engaging Youth in Historic Preservation.

V. Preserve America Program Implementation.

VI. Department of Interior's Treasured Landscapes Initiative.

VII. Preservation Initiatives Committee.
A. Administration Urban Policy Initiative.

B. Legislative Update.

VIII. Federal Agency Programs Committee.

A. Recovery Act Update.

B. Trans Alaska Pipeline Exemption.

C. Section 106 Case Updates.

IX. Communications, Education, and Outreach Committee.

A. Service Learning Initiative.

X. Chairman's Report.

A. ACHP Alumni Foundation.

B. Transition.

C. FY 2011 Budget.

XI. Executive Director's Report.

A. Staff Changes and Recruitment.

XII. New Business.

XIII. Adjourn.

Note: The meetings of the ACHP are open to the public.

If you need special accommodations due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Room 803, Washington, DC, 202-606-8503, at least seven (7) days prior to the meeting.

FOR FURTHER INFORMATION CONTACT:

Additional information concerning the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., #803, Washington, DC 20004.

Dated: August 6, 2009.

John Fowler,

Executive Director.

[FR Doc. E9-19282 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-K6-M

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Protest

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Revision of an existing information collection: 1651-0017.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Protest (Form 19). This is a proposed revision and extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to

obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 16227) on April 9, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before September 14, 2009.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104-13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's/component's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Abstract: Protest (Form 19) is used by an importer, filer, or any party at interest to petition CBP, or protest any action made by the port director on or against any imported merchandise. The burden hours were adjusted for this information collection due to revised estimates by CBP which included increasing the estimated time per response from 30 minutes to 60 minutes. No substantive revisions were made to Form 19.

Current Actions: This submission is being made to extend the expiration date with a change to the burden hours.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 3,750.

Estimated Number of Annual Responses per Respondent: 12.

Estimated Number of Total Annual Responses: 45,000.

Estimated Time per Respondent: 60 minutes.

Estimated Total Annual Burden Hours: 45,000.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: August 7, 2009.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E9-19438 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0680]

Certificate of Alternative Compliance for the Offshore Supply Vessel CALLAIS NAVIGATOR

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel CALLAIS NAVIGATOR as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on July 14, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0680 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight,

Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel CALLAIS NAVIGATOR will be used for offshore supply operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 20' 8⁵/₈". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck, where it would interfere with loading and unloading operations. The offset from centerline of the RAM/NUC lights may be 3'. Offsetting the RAM/NUC lights 2 meters from the centerline as required by Annex I paragraph 3(c) and Annex I, section 84.05(c) would place them in an exposed position beyond the width of the aft end of the pilothouse.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, section 84.05(a) of the Inland Rules Act, as well as the offset of the RAM/NUC lights to deviate from the requirements of Annex I, paragraph 3(c) of 72 COLREGS and Annex I, section 84.05(c) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander, Eighth Coast Guard District.

[FR Doc. E9-19403 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0681]

Certificate of Alternative Compliance for the Offshore Supply Vessel HOS SWEET WATER

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel HOS SWEET WATER as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on July 6, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0681 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel HOS SWEET WATER will be used for offshore supply operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 21'11". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, by Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19402 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0704]

Certificate of Alternative Compliance for the Oceanographic Research Vessel FAIRFIELD CHALLENGER

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the oceanographic research vessel FAIRFIELD CHALLENGER as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on June 2, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0704 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The oceanographic research vessel FAIRFIELD CHALLENGER will be used for oceanographic operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 50'¾". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location that would interfere with crane operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19401 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0705]

Certificate of Alternative Compliance for the Offshore Supply Vessel BJ BLUE DOLPHIN

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel BJ BLUE DOLPHIN as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on May 18, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0705 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel BJ BLUE DOLPHIN will be used for offshore supply operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 21'10". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I,

paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19400 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0706]

Certificate of Alternative Compliance for the Offshore Supply Vessel PAO DE ACUCAR

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel PAO DE ACUCAR as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on May 18, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0706 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V.

Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel PAO DE ACUCAR will be used for offshore supply operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 21' 10". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck, where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19399 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0654]

Certificate of Alternative Compliance for the Offshore Supply Vessel HOS SILVER ARROW

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel HOS SILVER ARROW as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on July 2, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday,

except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0654 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel HOS SILVER ARROW will be used for offshore supply operations. The Certificate of Alternative Compliance allows for the horizontal distance between the forward and aft masthead lights to be 21' 11". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck, where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19398 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0580]

Certificate of Alternative Compliance for the Lift Boat CAITLIN

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the lift boat CAITLIN as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternate Compliance was issued on June 22, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0580 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The lift boat CAITLIN will be used for oil exploration. The horizontal distance between the stem of the vessel and masthead light is permitted to be 108'. Placing the masthead light at the horizontal distance from the stem of the vessel as required by Annex I, paragraph 3(d) of the 72 COLREGS, and Annex I, Section 84.05(d) of the Inland Rules Act, would result in a masthead light location that would interfere with crane operations. In addition, the sidelights may be located on the outermost edges of the top of the pilothouse, 7' 6" from the centerline. Placing the sidelights in the locations required by Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act would expose the sidelights to probable damage from the working machinery around the forward legs of the vessel.

The Certificate of Alternative Compliance allows for the horizontal separation of the masthead light from the stem of the vessel to deviate from the requirements of Annex I, paragraph 3(d) of 72 COLREGS, and Annex I, Section 84.05(d) of the Inland Rules Act. In addition, this Certificate of Alternative Compliance allows for the placement of the sidelights to deviate from requirements set forth in Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19397 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0581]

Certificate of Alternative Compliance for the Lift Boat PAUL

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the lift boat PAUL as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternate Compliance was issued on June 12, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0581 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The lift boat PAUL will be used for oil exploration. The Certificate of Alternative Compliance allows for the horizontal distance between the stem of the vessel and masthead light to be 108'. Placing the masthead light at the horizontal distance from the stem of the vessel as required by Annex I, paragraph 3(d) of the 72 COLREGS, and Annex I, Section 84.05(d) of the Inland Rules Act, would result in a masthead light location that would interfere with crane operations. In addition, the sidelights

may be located on the outermost edges of the top of the pilothouse, 7' 6" from the centerline. Placing the sidelights in the locations required by Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act would expose the sidelights to probable damage from the working machinery around the forward legs of the vessel.

The Certificate of Alternative Compliance allows for the horizontal separation of the masthead light from the stem of the vessel to deviate from the requirements of Annex I, paragraph 3(d) of 72 COLREGS, and Annex I, Section 84.05(d) of the Inland Rules Act. In addition, this Certificate of Alternative Compliance allows for the placement of the side lights to deviate from requirements set forth in Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: July 27, 2009.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander Eighth Coast Guard District.

[FR Doc. E9-19394 Filed 8-12-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Oiltest, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Oiltest, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Oiltest, Inc., 100 Grove Road, Paulsboro, NJ 08066, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested.

Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Oiltest, Inc., as commercial gauger and laboratory became effective on June 9, 2009. The next triennial inspection date will be scheduled for June 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19382 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 151 James Drive West, St. Rose, LA 70087, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed

to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on April 21, 2009. The next triennial inspection date will be scheduled for April 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19384 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Intertek USA, Inc., 4951A East Adamo Drive, Suite 130, Tampa, FL 33605, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060.

The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on June 03, 2009. The next triennial inspection date will be scheduled for June 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19385 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 2947 Duttons Mill Road, Suite A-1, Aston, PA 19014, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to

cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on June 11, 2009. The next triennial inspection date will be scheduled for June 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19387 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 235 Marginal St. Suite 3, Chelsea, MA 02150, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and

accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on April 09, 2009. The next triennial inspection date will be scheduled for April 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19391 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 710 Loop 197 North, Texas City, TX 77590, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on March 24, 2009. The next triennial inspection date will be scheduled for March 2012.

FOR FURTHER INFORMATION CONTACT: Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19386 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Marine Technical Surveyors, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Marine Technical Surveyors, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Marine Technical Surveyors, Inc., 2382 Highway 1 South, Donaldsonville, LA 70346, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The approval of Marine Technical Surveyors, Inc., as commercial gauger became effective on March 19, 2009. The next triennial inspection date will be scheduled for March 2012.

FOR FURTHER INFORMATION CONTACT:

Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19383 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY**U.S. Customs and Border Protection****Approval of Intertek USA, Inc., as a Commercial Gauger**

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Intertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Intertek USA, Inc., 354 Fairbanks Street, Valdez, AK 99686, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The approval of Intertek USA, Inc., as commercial gauger became effective on May 28, 2009. The next triennial inspection date will be scheduled for May 2012.

FOR FURTHER INFORMATION CONTACT:

Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19389 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY**U.S. Customs and Border Protection****Approval of Intertek USA, Inc., as a Commercial Gauger**

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Intertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Intertek USA, Inc., 91-110 Hanua Street #204, Kapolei, HI 96707, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The approval of Intertek USA, Inc., as commercial gauger became effective on May 20, 2009. The next triennial inspection date will be scheduled for May 2012.

FOR FURTHER INFORMATION CONTACT:

Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19390 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY**U.S. Customs and Border Protection****Approval of Petrospect, Inc., as a Commercial Gauger**

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Petrospect, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Petrospect, Inc., 499 N. Nimitz Pier 21, Honolulu, HI 96817, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquires regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The approval of Petrospect, Inc., as commercial gauger became effective on May 21, 2009. The next triennial inspection date will be scheduled for May 2012.

FOR FURTHER INFORMATION CONTACT:

Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: August 4, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-19388 Filed 8-12-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****[Docket No. USCG–2009–0693]****Maritime Labour Convention, 2006; Informational Meeting****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of informational meeting.

SUMMARY: The Coast Guard and the Maritime Administration will host an informational meeting to discuss the content of the Maritime Labour Convention, 2006 (MLC, 2006). The purpose of this meeting is to provide the industry with an overview of the MLC, 2006, and to help clarify areas that may require additional interpretation. This meeting is strictly informational and it is not meant to discuss the merits of ratification of the MLC, 2006. The meeting will be on Monday, August 24, 2009, and open to the public.

DATES: The public meeting will be on Monday, August 24, 2009, from 9 a.m. to 11:50 a.m., at the Department of Transportation, Conference Center, Rooms 8–9–10, 1200 New Jersey Avenue, SE., Washington, DC 20590, telephone 202–366–4000. Please note this meeting may close early if all business is finished.

ADDRESSES: This notice is available on the Internet at www.regulations.gov under the docket number USCG–2009–0693. The MLC, 2006, is available on the Internet at http://www.ilo.org/global/What_we_do/InternationalLabourStandards/MaritimeLabourConvention/lang-en/index.htm.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice contact Mr. Anthony D. Morris, U.S. Coast Guard Headquarters, CG–5221, Room 1210, 2100 Second Street SW., Stop 7126, Washington, DC 20593–7126; telephone 202–372–1408, fax 202–372–1926, or e-mail at Anthony.D.Morris@uscg.mil.

SUPPLEMENTARY INFORMATION:**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Anthony D. Morris at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice as soon as possible.

Background and Purpose: The MLC, 2006, was adopted by the International Labour Conference of the International

Labour Organization (ILO) in February 2006. It sets out seafarers' rights to decent conditions of work and helps to create conditions of fair competition for shipowners. The MLC, 2006, has been designed to become the "fourth pillar" of the international regulatory regime for quality shipping complementing the key conventions of the International Maritime Organization (IMO), such as the International Convention for the Safety of Life at Sea, 1974, as amended (SOLAS), the International Convention on Standards of Training, Certification and Watchkeeping, 1978, as amended (STCW), and the International Convention for the Prevention of Pollution from Ships, 73/78 (MARPOL). The MLC, 2006, contains a comprehensive set of global standards, based on those that are already found in 68 maritime labour instruments adopted by the ILO since 1920.

Meeting Agenda: The purpose of this meeting is to provide the industry with an overview of the MLC, 2006, and to help clarify areas that may require additional interpretation. This meeting is strictly informational and it is not meant to discuss the merits of ratification of the MLC, 2006. The tentative agenda of the meeting is:

- Introduction to the MLC, 2006;
- Seafarer's perspective;
- Shipowner's perspective;
- Overview of the MLC, 2006;
- United States Process for ratification.

Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. At the meeting facilitator's discretion, members of the public may make presentations and ask questions in response to information provided at the meeting. The meeting will not be recorded and the Coast Guard and the Maritime Administration do not intend to provide response to presentations. However, a summary of the information presented by the Coast Guard and the Maritime Administration will be made available after the meeting on the Internet at <http://homeport.uscg.mil>.

A government-issued photo identification (for example, a driver's license) will be required for entrance at the meeting location. We encourage individuals planning on attending to arrive early in order to allow sufficient time before the meeting to clear security.

This notice is issued under authority of 5 U.S.C. 552.

Dated: August 7, 2009.

J.G. Lantz,*Director of Commercial, Regulations and Standards.*

[FR Doc. E9–19395 Filed 8–12–09; 8:45 am]

BILLING CODE 4910–15–P**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****Notice of Proposed Information Collection for 1029–0098****AGENCY:** Office of Surface Mining Reclamation and Enforcement.**ACTION:** Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval to continue the collection of information under 30 CFR Part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned clearance number 1029–0098.

DATES: Comments on the proposed information collection activity must be received by October 13, 2009, to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request, or to comment on the information collection activity, contact John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW., Room 202–SIB, Washington, DC 20240. You may contact Mr. Trelease or submit comments electronically at jtrelease@osmre.gov.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that OSM will be submitting to OMB for renewed approval. This collection is contained in 30 CFR Part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations.

OSM will request a 3-year term of approval for this information collection activity.

Comments are invited On: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title: 30 CFR Part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations.

OMB Control Number: 1029-0098.

Summary: This part establishes the minimum procedures and standards for designating Federal lands unsuitable for certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decisionmaking process to approve or disapprove a request.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: People who may be adversely affected by surface mining on Federal lands.

Total Annual Responses: 1.

Total Annual Burden Hours: 1,000 hours.

Dated: August 7, 2009.

John R. Craynon,

Chief, Division of Regulatory Support.

[FR Doc. E9-19426 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-MB-2009-N169] [91200-1231-9BPP-L2]

Proposed Information Collection; OMB Control Number 1018-0121; Depredation Orders for Double-Crested Cormorants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on December 31, 2009. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by October 13, 2009.

ADDRESSES: Send your comments on the IC to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); or hope_grey@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey by mail or e-mail (see ADDRESSES) or by telephone at (703) 358-2482.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection is associated with regulations

implementing the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 et seq.). Under the MBTA, it is unlawful to take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, migratory birds or their parts, nests, or eggs, except as authorized by regulations implementing the MBTA.

The regulations at 50 CFR 21.47 (Aquaculture Depredation Order) authorize aquaculture producers in 13 States to take double-crested cormorants when the birds are found committing or about to commit depredations on commercial freshwater aquaculture stocks. The regulations at 50 CFR 21.48 (Public Resource Depredation Order) authorize State fish and wildlife agencies, the U.S. Department of Agriculture (APHIS-Wildlife Services), and federally recognized tribes in 24 States to take double-crested cormorants to prevent depredations on the public resources of fish, wildlife, plants, and their habitats.

Both 50 CFR 21.47 and 21.48 impose reporting and recordkeeping requirements on those operating under the depredation orders. We use the information collected to:

(1) Help assess the impact of the depredation orders on double-crested cormorant populations.

(2) Protect nontarget migratory birds or other species.

(3) Ensure that agencies and individuals are conforming to the terms, conditions, and purpose of the orders.

(4) Help gauge the effectiveness of the orders at mitigating cormorant-related damages.

II. Data

OMB Control Number: 1018-0121.

Title: Depredation Orders for Double-Crested Cormorants, 50 CFR 21.47 and 21.48.

Service Form Number(s): None.

Type of Request: Extension of a currently approved collection.

Affected Public: Aquaculture producers, States, and tribes.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually for reports; ongoing for recordkeeping.

Activity	Number of annual respondents	Number of annual responses	Completion time per response	Annual burden hours
Report take of migratory bird species other than double-crested cormorants (21.47(d)(7); 21.48(d)(7)).	1	1	1 hour	1
Report take of species protected under Endangered Species Act (21.47(d)(8); 21.48(d)(8)).	1	1	1 hour	1
Written notice of intent to conduct control activities (21.48(d)(9)).	12	12	3 hours	36
Report of control activities (21.48(d)(10) and (11))	12	12	20 hours	240
Report effects of management activities (21.48(d)(12))	9	9	100 hours	900

Activity	Number of annual respondents	Number of annual responses	Completion time per response	Annual burden hours
Recordkeeping (21.47(d)(9))	500	500	7 hours	3,500
Totals	535	535		4,678

III. Request for Comments

We invite comments concerning this IC on:

(1) Whether or not the collection of information is necessary, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information;

(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.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 6, 2009

Hope Grey,

*Information Collection Clearance Officer,
Fish and Wildlife Service.*

FR Doc. E9-19405 Filed 8-12-09; 8:45 am

BILLING CODE 4310-55-S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R9-LE-2009-N168] [99011-1224-0000-9B]

Proposed Information Collection; OMB Control Number 1018-0012; Declaration for Importation or Exportation of Fish or Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service, Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC)

described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on January 31, 2010. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by October 13, 2009.

ADDRESSES: Send your comments on the IC to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222-ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); or hope_grey@fws.gov (e-mail).

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey by mail or e-mail (see ADDRESSES) or by telephone at (703) 358-2482.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Endangered Species Act (16 U.S.C. 1531 et seq.) makes it unlawful to import or export fish, wildlife, or plants without filing a declaration or report deemed necessary for enforcing the Act or upholding the Convention on International Trade in Endangered Species (CITES) (see 16 U.S.C. 1538(e)). With a few exceptions, businesses or individuals importing into or exporting from the United States any fish, wildlife, or wildlife product must complete and submit to the Service an FWS Form 3-177 (Declaration for Importation or Exportation of Fish or Wildlife). This form as well as FWS Form 3-177a (Continuation Sheet) and instructions for completion are available for electronic submission at <https://edecs.fws.gov>. These forms are also available in hard copy at <http://www.fws.gov/forms/>.

The information that we collect is unique to each wildlife shipment and enables us to:

- Accurately inspect the contents of the shipment;
- Enforce any regulations that pertain to the fish, wildlife, or wildlife products contained in the shipment; and

- Maintain records of the importation and exportation of these commodities.

Additionally, we use information from FWS Forms 3-177 and 3-177A to compile an annual report that we provide to the CITES Secretariat in Geneva, Switzerland. This annual report on the number and types of imports and exports of fish, wildlife, and wildlife products is one of our treaty obligations under CITES. The report does not contain any personally identifying information.

We also use the information obtained from FWS Form 3-177 as an enforcement tool and management aid to monitor the international wildlife market and detect trends and changes in the commercial trade of fish, wildlife, and wildlife products. Our Division of Scientific Authority and Division of Management Authority use this information to assess the need for additional protection for native species.

The information we collect is part of a system of records covered by the Privacy Act (5 U.S.C. 552(a)).

Businesses or individuals must file FWS Forms 3-177 and 3-177a with us at the time and port where they request clearance of the import or export of wildlife or wildlife products. Our regulations allow for certain species of wildlife to be imported or exported between the United States and Canada or Mexico at U.S. Customs and Border Protection ports, even though our wildlife inspectors may not be present. In these instances, importers and exporters may file the forms with U.S. Customs and Border Protection. We collect the following information:

- (1) Name of the importer or exporter and broker.
- (2) Scientific and common name of the fish or wildlife.
- (3) Permit numbers (if permits are required).
- (4) Description, quantity, and value of the fish or wildlife.
- (5) Natural country of origin of the fish or wildlife.

In addition, certain information, such as the airway bill or bill of lading number, the location of the fish or wildlife for inspection, and the number of cartons containing fish or wildlife, assists our wildlife inspectors if a physical examination of the shipment is necessary.

II. Data

OMB Control Number: 1018-0012.

Title: Declaration for Importation or Exportation of Fish or Wildlife.

Service Form Number(s): 3-177 and 3-177a.

Type of Request: Extension of a currently approved collection.
Affected Public: Businesses or individuals that import or export fish, wildlife, or wildlife products; scientific institutions that import or export fish or wildlife scientific specimens;

government agencies that import or export fish or wildlife specimens for various purposes.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of annual respondents	Number of annual responses	Completion time per response	Annual burden hours
3-177 - Hard Copy Submission	4,200	37,000	15 minutes	9,250
3-177 -Electronic Submission	16,500	145,000	10 minutes	24,167
Totals	20,700	182,000		33,417

III. Request for Comments

We invite comments concerning this IC on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 6, 2009

Hope Grey,

Information Collection Clearance Officer,
Fish and Wildlife Service.

FR Doc. E9-19404 Filed 8-12-09; 8:45 am

BILLING CODE 4310-55-S

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS-R7-R-2009-N0105; 70133-1265-0000-S3]

Koyukuk/Nowitna National Wildlife Refuges, Galena, AK

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of the revised comprehensive conservation plan and finding of no significant impact for environmental assessment.

SUMMARY: We, the Fish and Wildlife Service (Service, USFWS), announce the availability of our revised comprehensive conservation plan (CCP) and finding of no significant impact (FONSI) for the Koyukuk, Northern Unit Innoko, and Nowitna National Wildlife Refuges (Refuges). In this revised CCP, we describe how we will manage the Refuges for the next 15 years.

ADDRESSES: You may view or obtain copies of the revised CCP and FONSI by any of the following methods. You may request a paper copy, a summary, or a CD-ROM containing both.

Agency Web Site: Download a copy of the documents at <http://alaska.fws.gov/nwr/planning/plans.htm>.

E-mail: fw7_KoyukukNowitna_planning@fws.gov. Please include "Revised CCP" in the subject line of the message.

Mail: Mikel R. Haase, Natural Resource Planner, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, MS-231, Anchorage, AK 99503-6199, or Refuge Manager, Koyukuk/Nowitna NWRs, P.O. Box 287, Galena, AK 99741.

In-Person Viewing or Pickup: Call (907) 786-3357 to make an appointment during regular business hours at the USFWS Regional Office, 1011 E. Tudor Road, Anchorage AK 99053, or call (907) 656-1231 to make an appointment during business hours at the Koyukuk/Nowitna Refuges' office in Galena, AK.

FOR FURTHER INFORMATION CONTACT: Mikel Haase, (907) 786-3402 (phone); (907) 786-3965 (fax); or fw7_KoyukukNowitna_planning@fws.gov (e-mail).

SUPPLEMENTARY INFORMATION:

With this notice, we finalize the revised CCP for Koyukuk, Northern Unit Innoko, and Nowitna National Wildlife Refuges. We started this process through a notice of intent in the **Federal Register** (72 FR 57343; October 9, 2007). We

made available our draft CCP and Environmental Assessment (EA) and requested comments in a notice of availability in the **Federal Register** (73 FR 58259; October 6, 2008). The draft CCP and EA evaluated two alternatives for managing the Refuges for the next 15 years.

Established in 1980 by the Alaska National Interest Lands Conservation Act (ANILCA: 16 U.S.C. 410hh *et seq.*, 43 U.S.C. 1602 *et seq.*), Koyukuk, Northern Unit Innoko, and Nowitna Refuges encompass approximately 6 million acres under Service jurisdiction. The purposes for which the Refuges were established include: (i) To conserve fish and wildlife populations and habitats in their natural diversity; (ii) to fulfill international treaty obligations of the United States with respect to fish and wildlife and their habitats; (iii) to provide the opportunity for continued subsistence use by local residents; and (iv) to ensure water quality and necessary water quantity within the Refuge. The Draft CCP and EA for the Refuges was developed consistent with Section 304(g) of ANILCA and the Refuge Administration Act as amended by the Refuge Improvement Act (16 U.S.C. 668dd *et seq.*).

CCPs were originally prepared for the Refuges in 1987. The revised plan includes management direction updated by changes to policy since completion of the 1987 plans. It also includes a vision statement, goals, and objectives for management of the Refuge. Management of the Refuges would generally continue to follow management direction described in the 1987 CCPs and records of decisions as modified by subsequent program-specific plans (*e.g.*, fisheries, cultural resources, and fire management plans). As required by ANILCA, areas of the Refuges were designated in the 1987 CCPs according to their respective resources. Under the original CCPs and the revised CCP, 91 percent of the Refuge is Minimal management, 7

percent is designated Wilderness, and 2 percent is Wild River management. The revised plan would continue to protect and maintain existing wildlife values, natural diversity, and ecological diversity of the Refuge. Human disturbances to fish and wildlife habitats and populations would be minimal. Private and commercial uses of the Refuges would not change, and public uses employing existing access methods would continue to be allowed. Opportunities to pursue traditional subsistence activities, and recreational hunting, fishing, and other wildlife-dependent activities, would be maintained. Opportunities to pursue research would be maintained.

We selected Alternative B, the preferred alternative, because it provides a realistic balance between public use of the Refuges and the conservation needs of the Refuges. Alternative B best accomplishes the Refuges' purposes, best helps achieve the missions of the National Wildlife Refuge System and the Service, and best meets the vision and goals identified in the plan. It provides long-term protection of fish and wildlife populations and their habitats while allowing for appropriate levels of fish and wildlife-dependent recreation, interpretation and environmental education, subsistence, and other public uses. Objectives identified in the plan address the effects of climate change on the Refuges now and in the future.

We are furnishing this notice to advise other agencies and the public of the availability of the final CCP and FONSI. Based on the review and evaluation of the information contained in the draft CCP and EA, we have determined that implementation of the final CCP does not constitute a major Federal action that would significantly affect the quality of the human environment within the meaning of Section 102(2)(c) of the National Environmental Policy Act (NEPA). Therefore, an Environmental Impact Statement will not be prepared. Future site-specific proposals discussed in the final CCP requiring additional NEPA compliance will be addressed in separate planning efforts with full public involvement.

Dated: August 7, 2009.

Gary Edwards,

Acting Regional Director, U.S. Fish and Wildlife Service, Anchorage, Alaska.

[FR Doc. E9-19444 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTB07900 09 L10100000.PH0000
LXAMANMS0000]

Notice of Public Meeting, Western Montana Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM), the Western Montana Resource Advisory Council will meet as indicated below.

DATES: The Western Montana RAC will meet Sept. 3, 2009 at 9 a.m. The public comment period for the meeting will begin at 11:30 a.m. and the meeting is expected to adjourn at approximately 3 p.m.

ADDRESSES: The meeting will be held at the Dillon Field Office, 1005 Selway Drive, Dillon, Montana.

FOR FURTHER INFORMATION CONTACT: David Abrams, Western Montana Resource Advisory Council Coordinator, Butte Field Office, 106 North Parkmont, Butte, Montana 59701, telephone 406-533-7617.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in western Montana. At the September meeting, topics we plan to discuss include: Abandoned Mines Reclamation, trapping on public lands, Economic Stimulus Package Project Updates, public access issues, travel management implementation, and a review of Forest Service fee proposals.

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, or other

reasonable accommodations, should contact the BLM as provided below.

Renee Johnson,

Assistant Field Manager, Renewable Resources.

[FR Doc. E9-19441 Filed 8-12-09; 8:45 am]

BILLING CODE 4310--\$-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLID100000-L10200000-PH0000]

Notice of Public Meeting, Idaho Falls District Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Idaho Falls District Resource Advisory Council (RAC) Sub-Committee, will meet as indicated below.

DATES: The RAC Sub-Committee will be having a meeting on September 21, 2009 from 1 p.m. to 4:30 p.m. at the Pocatello Field Office, 4350 Cliffs Drive, Pocatello, Idaho 83204. All meetings are open to the public.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in the BLM Idaho Falls District (IFD), which covers eastern Idaho.

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided below.

FOR FURTHER INFORMATION CONTACT: Joanna Wilson, RAC Coordinator, Idaho Falls District, 1405 Hollipark Dr., Idaho Falls, ID 83401. Telephone: (208) 524-7550. E-mail: Joanna_Wilson@blm.gov.

Dated: August 4, 2009.

Joanna Wilson,

RAC Coordinator, Public Affairs Specialist.

[FR Doc. E9-19439 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-GG-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT924000 L12200000.PM0000]

Proposed Supplementary Rules for Camping on Undeveloped Public Lands in Montana, North Dakota, and South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) is proposing supplementary rules regarding time limits for camping and the storage of property on undeveloped public lands managed by the BLM in Montana, North Dakota, and South Dakota. These proposed supplementary rules consolidate existing rules for camping on undeveloped BLM-administered public lands throughout Montana, North Dakota, and South Dakota. These proposed supplementary rules will supersede prior published rules.

DATES: You should submit your comments by September 14, 2009. In developing final rules, BLM will not accept written comments postmarked or received in person or by electronic mail after this deadline.

ADDRESSES: You may mail or deliver comments on the proposed supplementary rules to Christina Miller, Outdoor Recreation Planner, Bureau of Land Management, Montana State Office, 5001 Southgate Drive, Billings, Montana 59101-4669. You may also comment by e-mail at the following address: MT_Billings_SO@blm.gov.

FOR FURTHER INFORMATION CONTACT: Christina Miller, Outdoor Recreation Planner, BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101-4669, (406) 896-5038.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

Written comments on the proposed supplementary rules should be specific, be confined to issues pertinent to the proposed supplementary rules, and explain the reason for any recommended change. Where possible, comments should reference the specific section or paragraph of the proposal which the comment is addressing. The BLM is not obligated to consider or

include in the administrative record for the supplemental rule, comments that the BLM receives after the close of the comment period (see **DATES**), unless they are postmarked or electronically dated before the deadline, or comments delivered to an address other than the address listed above (See **ADDRESSES**).

The BLM will make your comments, including your name and address, available for public review at the Montana State Office address listed in “**ADDRESSES**” above during regular business hours (8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays). Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Clarity of the Proposed Supplementary Rules

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these proposed supplementary rules easier to understand, including answers to questions such as the following:

- (1) Are the requirements in the proposed supplementary rules clearly stated?
- (2) Do the proposed supplementary rules contain technical language or jargon that interferes with its clarity?
- (3) Does the format of the proposed supplementary rules (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity?
- (4) Would the proposed supplementary rules be easier to understand if they were divided into more (but shorter) sections?

(5) Is the description of the proposed supplementary rules in the “**SUPPLEMENTARY INFORMATION**” section of this preamble helpful in understanding these proposed supplementary rules? How could this description be more helpful in making the proposed supplementary rules easier to understand?

Please send any comments you have on the clarity of the proposed supplementary rules to the address specified in the “**ADDRESSES**” section.

II. Discussion of the Proposed Supplementary Rules

These proposed supplementary rules would apply to undeveloped public lands administered by the BLM within the States of Montana, North Dakota, and South Dakota. They would supersede all existing camping stay limits and occupancy on undeveloped public land administered by the BLM in Montana, North Dakota, and South Dakota published previously. These proposed supplementary rules would allow camping at a particular location for 16 days, either cumulatively or consecutively, during any 30-day interval. Any camp relocation within that 30-day period would not be allowed within a one-half mile radius from the original site. These supplemental rules are consistent with existing recreation sections and management plans in each district office. These rules are not contradictory to campsite selections stated in the Montana, North Dakota and South Dakota June 2003 Record of Decision and Environmental Impact Statement for Off-Highway Vehicles. This notice does not affect more restrictive camping limits that may already be in place for certain areas. Future exceptions to the 16-day camping limit for any field office will be considered and analyzed through their respective land use plan revisions.

These proposed supplementary rules would not apply to locations that contain structures or capital improvements (such as boat launch sites, picnic areas, and interpretive centers) and that are used primarily by the public for recreational purposes. Examples of such locations include developed campgrounds, designated recreation areas, and special recreation management areas. The BLM regulates the use and occupancy at such developed locations in accordance with 43 CFR 8365.1-2. In addition, site-specific rules for these locations remain in effect and are posted at each site.

These proposed supplementary rules would supersede rules previously published at 72 FR 19958 (April 20, 2007). The rules in the 2007 notice required camps to be moved a minimum of 5 miles every 14 days. These proposed supplementary rules would allow camping at a particular location for 16 days, either cumulatively or consecutively, during any 30-day interval. The placing or leaving of unattended motor vehicles, trailers, or other personal property for the purpose of reserving a camping site is considered camping for the purpose of these

supplementary rules. Thus, overnight occupation is not necessarily the only criterion for determining whether or not the 16-day limit has been met.

Once campers have met the 16-day limit, they would be prohibited from camping at the original location for at least 30 days, and any camp relocation within that 30-day period would not be allowed within a one-half mile radius from the original site. These changes are being proposed to better allow the public to remain in the general area in which they wish to recreate while still achieving the BLM's goal of protecting public lands and natural resources by prohibiting long-term camps in a single location.

III. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These proposed supplementary rules are not a significant regulatory action and are not subject to review by Office of Management and Budget under E.O. 12866. These proposed supplementary rules will not have an effect of \$100 million or more on the economy. These proposed supplementary rules will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. These proposed supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. These proposed supplementary rules do not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the right or obligations of their recipients; nor do these proposed supplementary rules raise novel legal or policy issues. They establish limits for public recreational use of undeveloped public lands in Montana, North Dakota, and South Dakota to protect public lands and natural resources.

National Environmental Policy Act

The BLM prepared an environmental impact statement (EIS) as part of the development of the resource management plan (RMP) for each district office. During that National Environmental Policy Act (NEPA) process, many proposed decisions were fully analyzed, including the substance of these supplementary rules. The pertinent analysis can be found in Chapter 4, Alternatives, of the RMP for each district office. These supplementary rules provide for enforcement of plan decisions.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended, 5 U.S.C. 601–612, to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These supplementary rules do not pertain specifically to commercial or governmental entities of any size, but to public recreational use of specific public lands. Therefore, the BLM has determined under the RFA that these proposed supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These proposed supplementary rules do not constitute a “major rule” as defined at 5 U.S.C. 804(2). Again, these proposed supplementary rules merely establish limits for recreational use of certain public lands. These proposed supplementary rules have no effect on business—commercial or industrial—use of the public lands.

Unfunded Mandates Reform Act

These proposed supplementary rules do not impose an unfunded mandate on State, local or tribal governments, or the private sector of more than \$100 million per year; nor do these proposed supplementary rules have a significant or unique effect on State, local, or tribal governments, or the private sector. These proposed supplementary rules do not require anything of State, local, or tribal governments. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

These proposed supplementary rules do not represent a government action capable of interfering with constitutionally protected property rights. These proposed supplementary rules do not address property rights in any form and do not cause the impairment of anybody's property rights. Therefore, the Department of the Interior has determined that these proposed supplementary rules would not cause a taking of private property or require further discussion of takings

implications under this Executive Order.

Executive Order 13132, Federalism

These proposed supplementary rules do 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. These supplementary rules will have little or no effect on State or local government. Therefore, in accordance with E.O. 13132, the BLM has determined that these proposed supplementary rules do not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under E.O. 12988, the BLM has determined that these proposed supplementary rules would not unduly burden the judicial system and that they meet the requirements of sections 3(a) and 3(b)(2) of the Executive Order.

Paperwork Reduction Act

These proposed supplementary rules do not directly provide for any information collection that the Office of Management and Budget must approve under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Any information collection that may result from Federal criminal investigations or prosecutions conducted in enforcing these proposed supplementary rules is exempt from the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3518(c)(1).

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments In accordance with Executive Order 13175, the BLM has found that these supplementary rules do not include policies that have tribal implications. These supplementary rules provide for enforcement of decisions adopted in the Record of decision and thoroughly analyzed in the EIS prepared for the resource management plans (RMP) of each district office. During preparation of the EIS, government-to-government consultation was conducted with the tribal governments with interests in the affected area. None of these tribal governments expressed concerns regarding the decisions these supplementary rules are designed to enforce. Therefore, in accordance with Executive Order 13175, the BLM has found that these supplementary rules do not include policies that have tribal implications.

Supplementary Rules for Undeveloped BLM-Administered Lands in the States of Montana, North Dakota, and South Dakota

Definitions

Camping: The erecting of a tent or shelter of natural or synthetic material, preparing a sleeping bag or other bedding material for use, parking of a motor vehicle, motor home, or trailer, or mooring of a vessel for the apparent purpose of overnight occupancy. The placing or leaving of unattended motor vehicles, trailers, or other personal property for the purpose of reserving a camping site is considered camping for the purpose of these supplementary rules.

You must follow these rules:

These supplementary rules apply, except as specifically exempted, to all camping on undeveloped public lands managed by the Montana State Office of the Bureau of Land Management within the states of Montana, South Dakota, and North Dakota. These supplementary rules are in effect on a year-round basis and will remain in effect until modified by the BLM.

1. You must not camp longer than 16 consecutive days at any one location.

2. No person or group may camp within a single location on public lands more than 16 days within any period of 30 consecutive days. The 16-day limit may be reached either by compiling individual visits during a 30-day interval, or by occupying a location continuously for 16 days during a 30-day interval. A 16-day interval begins when a person initially camps or leaves vehicles or property at a site on public lands.

3. After 16 days of camping in a single location, you must not camp at that location until at least 30 days have passed, and any camp relocation within that 30-day period shall not be within a one-half mile radius from the original site. Under special circumstances and upon request, the BLM may issue a written permit for extension of the 16-day limit.

4. You must not leave any personal property or refuse after vacating the campsite. This includes any property left for the purposes of use by another camper or occupant.

5. The time such property is left unattended at a site will be counted towards the 16-day camping limit. (Unattended property is still subject to the time limits found in 43 CFR 8365.1–2(b)).

6. The following persons are exempt from these supplementary rules: Any Federal, State, or local officer or employee in the scope of their duties;

members of any organized rescue or fire-fighting force in performance of an official duty; and any person whose activities are authorized in writing by the Bureau of Land Management.

Penalties

The rules we are proposing here provide for penalties that may depend on the location where a violation occurs. The primary statutory authority for proposing these supplementary rules is the Federal Land Policy and Management Act (FLPMA). Section 310 of FLPMA (43 U.S.C. 1740) authorizes us to issue rules and regulations to carry out the purposes of FLPMA and other laws applicable to the public lands. Under section 303(a) of the Federal Land Policy and Management Act, 43 U.S.C. 1733(a), and 43 CFR 8360.0–7, any person who violates any of these supplementary rules on any public lands may be tried before a United States Magistrate and fined no more than \$1,000 or imprisoned for no more than 12 months, or both. Also, such violations may be subject to the enhanced fines provided for by 18 U.S.C. 3571. Under the Taylor Grazing Act, any person who violates any of these supplementary rules on public lands within grazing districts (see 43 U.S.C. 315a), or on public lands subject to a grazing lease (see 43 U.S.C. 315m), may be tried before a United States Magistrate and fined no more than \$500.00. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Any person who violates any of these supplementary rules on public lands managed in accordance with the Sikes Act may be tried before a United States Magistrate and fined no more than \$500 or imprisoned for no more than 6 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Montana, North Dakota, or South Dakota law.

Gene R. Terland,

Montana/Dakotas State Director, Bureau of Land Management.

[FR Doc. E9–19412 Filed 8–12–09; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–D04–1430–ES; WYW–167587]

Notice of Realty Action: Recreation and Public Purposes Act Classification of Public Lands in Sweetwater County, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification for lease and/or conveyance to the Sweetwater County Fire District #1 under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended, 20 acres of public land in Sweetwater County, Wyoming. The Sweetwater County Fire District #1 proposes to use the land for a training facility and fire station.

DATES: Interested parties may submit written comments until September 28, 2009.

ADDRESSES: Mail written comments to the Field Manager, Bureau of Land Management, Rock Springs Field Office, 280 Highway 191 North, Rock Springs, Wyoming 82901.

FOR FURTHER INFORMATION CONTACT: Carol Montgomery, Realty Specialist, Bureau of Land Management, Rock Springs Field Office, at (307) 352–0344.

SUPPLEMENTARY INFORMATION: The following described public land in Sweetwater County, Wyoming, has been examined and found suitable for classification for lease and/or conveyance under the provisions of the R&PP Act, as amended, (43 U.S.C. 869 *et seq.*):

Sixth Principal Meridian

T. 19 N., R. 105 W.,
Sec. 4, S½NW¼SE¼.

The area described contains 20 acres, more or less, in Sweetwater County.

In accordance with the R&PP Act, the Sweetwater County Fire District #1 has filed an R&PP application and plan of development in which it proposes to develop the above described land to construct a proposed training facility and fire station for the purpose of meeting the fire protection needs for the community of Rock Springs. The proposed project will include a parking lot, training tower, and fire station. Additional detailed information pertaining to this application, plan of development, and site plan is in case file WYW167587, located in the Bureau of Land Management (BLM) Rock

Springs Field Office at the above address. The land is not needed for any Federal purpose. Lease and/or conveyance is consistent with the BLM Green River Resource Management Plan dated August 8, 1997, and would be in the public interest. The Sweetwater County Fire District #1 has not applied for more than the 640-acre limitation for non-recreation public uses in a year and has submitted an application in compliance with the regulations at 43 CFR 2741.4(b). The patent or lease, if issued, will be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior, and will contain the following terms, conditions, and reservations:

1. Provisions of the R&PP Act, including, by not limited to, the terms required by 43 CFR 2741.9.

2. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

3. All minerals, together with the right to prospect for, mine, and remove the minerals under applicable laws and regulations established by the Secretary of the Interior shall be reserved to the United States.

4. Lease and/or patent of the lands shall be subject to all valid existing rights of record documented on the official public land records at the time of lease/patent issuance.

5. Any other reservations that the authorized officer deems appropriate.

6. An appropriate indemnification clause protecting the United States from claims arising out of the lease/patentee's use, occupancy, or operations on the property.

Upon publication of this notice in the **Federal Register**, the lands will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease and/or conveyance under the R&PP Act.

Classification Comments: Interested parties may submit comments involving the suitability of the land for a fire facility. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision or any other factor not

directly related to the suitability of the land for a fire facility.

Confidentiality of Comments: Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Only written comments submitted by postal service or overnight mail to the Field Manager—BLM Rock Springs Field Office will be considered properly filed. Electronic mail, facsimile or telephone comments will not be considered.

Any adverse comments will be reviewed by the BLM State Director, who may sustain, vacate or modify this realty action. In the absence of any adverse comments, the classification of the land described in this notice will become effective October 13, 2009.

Authority: 43 CFR 2740.

Lance Porter,

Field Manager.

[FR Doc. E9-19417 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-22-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC02200-L14300000-EQ0000; MTM-74913]

Notice of Realty Action; Proposed Amendment to Noncompetitive Land Use Lease; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action and request for public comment.

SUMMARY: On March 6, 2009, the Bureau of Land Management (BLM) received a proposal from Spring Creek Coal Company to amend their existing land use lease, MTM-74913. The BLM is hereby notifying any interested parties of the proposal to amend land use lease MTM-74913 and is accepting comments on the proposed land use lease amendment.

DATES: Interested parties may submit comments on or before September 28, 2009.

ADDRESSES: Written comments should be sent to the Field Manager, Miles City Field Office, Bureau of Land Management, 111 Garryowen Road,

Miles City, Montana 59301. Comments received in electronic form, such as e-mail or facsimile, will not be considered.

FOR FURTHER INFORMATION CONTACT:

Information regarding the proposed land use lease amendment and proposed land use may be reviewed at the BLM Miles City Field Office address listed in **ADDRESSES** above during regular business hours, 7:45 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays. For this and additional information contact Pam Wall, BLM Miles City Field Office, Miles City, Montana 59301, telephone 406-233-2846.

SUPPLEMENTARY INFORMATION: The following described land, associated with the proposed amendment, has been examined and identified as suitable for leasing under section 302 of the Federal Land Policy and Management Act (43 U.S.C. 1732) at not less than fair market value:

Principal Meridian, Montana

T. 8 S., R. 39 E.,

Sec. 35, NE $\frac{1}{4}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NE $\frac{1}{4}$,
E $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ W $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$,
NW $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$,
NE $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$,
E $\frac{1}{2}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$, and
NE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$.

T. 9 S., R. 40 E.,

Sec. 6, lot 5.

The area described contains 197.12 acres, more or less, in Big Horn County.

The BLM is hereby notifying any interested parties of the proposal to amend land use lease MTM-74913 and is accepting comments on the proposed land use lease amendment.

Spring Creek Coal Company's existing land use lease MTM-74913, which was issued under the authority of section 302 of the Federal Land Policy and Management Act (43 U.S.C. 1732), may be amended to authorize the surface use of 197.12 acres of public land for coal mine layback, a flood control structure, topsoil and overburden stockpiles, and transportation and utility line corridors in order to facilitate the full recovery of coal reserves from their adjoining Federal Coal Lease MTM-94378, Montana State Coal Lease C-1088-05, and for Spring Creek's pending Coal Lease Modification MTM-069782. The layback is a critical component in coal strip mine recovery which consists of a series of benches cut into the mine highwall to stabilize the wall as mining progresses into an area. The lands adjacent to a coal lease need to be disturbed during normal mining operations to completely and safely remove the coal within the lease boundary. The flood control structure

consists of a reservoir sized at approximately 159 acre feet, to contain a 100-year, 24-hour flood event associated with the Pearson Creek drainage. This reservoir is needed to prevent saturation and potential failure of the highwall and/or flooding into the pit which would not only slow or stop coal production but expose mine personnel to a health and safety hazard. The topsoil stripped from the coal leases would be stockpiled on the subject lands to be used in reclamation after mining. The overburden removed from the pit would also be stockpiled on the subject lands to be used in post-mining topography construction. An electric line and distribution station would be located within the use area to keep it safely away from the pit and grading activity and buffered by the access/haul roads which will be used in the mining process and to service the stockpiles.

The proposed land use lease amendment consists of 160 acres in the E $\frac{1}{2}$ of section 35, T. 8 S., R. 39 E., and 37.12 acres in lot 5 of section 6, T. 9 S., R. 40 E. The total disturbed area in section 35 is estimated to be 108.90 acres with the remaining 51.10 acres receiving a 10 percent usage. The total disturbed area in section 6 is estimated to be 21.20 acres with the remaining 15.92 acres receiving a 10 percent usage.

The subject land could be offered noncompetitively to Spring Creek Coal Company as an amendment to their existing Land Use Lease MTM-74913 for stockpiling of topsoil and overburden, construction of a haul road, and for drainage control, for their current coal mining operation. The proposed land use lease amendment, which would be authorized under the authority of section 302 of the Federal Land Policy and Management Act (43 U.S.C. 1732) and pursuant to regulations found at 43 CFR 2920, would provide authorized surface use only of the public land and would be subject to the terms and conditions of the existing lease. No mineral use would be authorized under this land use lease amendment, however Spring Creek Coal Company has applied for a modification of coal lease MTM-069782 which is being processed concurrently (under regulations found at 43 CFR 3432) with the land use lease amendment.

The application will be accepted for this land use lease amendment at the address listed above at the end of the 45 day comment period for this notice. The application will be subject to reimbursement of costs in accordance with the provisions of 43 CFR 2920.6. The land would be leased at fair market value as determined by appraisal and as provided for at 43 CFR 2920.8. The

application must include a reference to this notice and a complete description of the proposed project. An environmental analysis will be completed addressing this proposed land use lease amendment, along with the proposed coal lease modification, after publication of this notice and comment period. A National Environmental Policy Act analysis will be completed prior to any decision by the BLM to approve the proposed application for a land use lease amendment and coal lease modification.

Public Comment Procedures: Please submit your comments on issues related to the proposed action, in writing, according to the **ADDRESSES** section above. Comments on the proposed action should be specific, should be confined to issues pertinent to the proposed action, and should explain the reason for any recommended change. Where possible, your comments should reference the specific section or paragraph of the proposal that you are addressing. The BLM may not necessarily consider or include in the Administrative Record comments that the BLM receives after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the BLM Miles City Field Office address listed in **ADDRESSES** above during regular business hours, 7:45 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays. Before including your address, phone number, e-mail address, or other personal identifying information in your comments, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Any adverse comments will be evaluated by the BLM Montana State Director, who may sustain, vacate or modify this realty action. In the absence of timely filed objections, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2920.4(c).

M. Elaine Raper,

Field Office Manager.

[FR Doc. E9-19415 Filed 8-12-09; 8:45 am]

BILLING CODE 4310-DN-P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-660]

Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on a Settlement Agreement and Withdrawal of the Complaint; Request for Briefing on Bonding and the Public Interest; In the Matter of Certain Active Comfort Footwear

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 12) of the presiding administrative law judge ("ALJ") granting motions for termination of the investigation; based on a settlement agreement and withdrawal of the complaint. The Commission has also requested briefing on remedy, bonding, and the public interest in connection with issuing a default limited exclusion order.

FOR FURTHER INFORMATION CONTACT:

Mark B. Rees, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202-205-3116. Copies of the ID and all other nonconfidential 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. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 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) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 25, 2008, based on the complaint of Masai Marketing & Trading AG of Romanshorn, Switzerland and Masai USA Corp. of Haley, Idaho ("Complainants"). 73 FR 73884 (Nov. 25, 2008). The complaint, as supplemented, 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 active comfort footwear that infringes certain claims of U.S. Patent No. 6,341,432. Complainants named as respondents RYN Korea Co., Ltd. of Seoul, Korea (RYN); Main d/b/a *WalkingShoesPlus.com* of Los Angeles, California ("WalkingShoesPlus"); and Feet First Inc. of Boca Raton, Florida ("Feet First"). The Tannery of Cambridge, Massachusetts and A Better Way to Health of West Melbourne, Florida were subsequently added as respondents in the investigation by an unreviewed ID. 74 FR 11378 (Mar. 17, 2009).

On May 21, 2009, the Commission determined not to review an ID (Order No. 6) finding WalkingShoesPlus and Feet First in default for failure to respond to the complaint and notice of investigation.

On July 13, 2009, the ALJ issued the subject ID (Order 12), terminating the investigation based on a settlement agreement as to RYN and withdrawal of the complaint as to the remaining respondents. No party petitioned for review of the subject ID.

The Commission has determined not to review the ID.

Section 337(g)(1), 19 U.S.C. 1337(g)(1) and Commission Rule 210.16(c), 19 U.S.C. 210.16(c) authorize the Commission to order relief against respondents found in default unless, after consideration of the public interest, it finds that such relief should not issue. Complainants did not file a declaration stating that they were seeking a general exclusion order as provided in Commission Rule 210.16(c).

In conjunction with the final disposition of this investigation, therefore, the Commission may: (1) Issue an order that could result in the exclusion of articles manufactured or imported by the defaulting respondents; and/or (2) issue a cease and desist order that could result in the defaulting respondents 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 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 for consumption, they should so indicate and provide information establishing that activities involving other types of entry either are 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. 2843 (Dec. 1994) (Comm'n Op.).

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 orders 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 U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. See Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). 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: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of the public interest, and bonding. Complainants and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the HTSUS numbers under which the accused products are imported and the date on which the patent at issue expires. Main written submissions must be filed no later than close of business on August 24, 2009. Reply submissions must be filed no later than the close of business on August 31, 2009. No further submissions on any of 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 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 210.6. 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 section 210.16 and 210.42-46 of the Commission's Rules of Practice and Procedure (19 CFR 210.16; 210.42-46).

By order of the Commission.

Issued: August 5, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9-19413 Filed 8-12-09; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-649]

Notice of Commission Determination Not To Review an Initial Determination Granting Complainant's Motion To Terminate the Investigation; Termination of Investigation; In the Matter of Certain Semiconductor Chips With Minimized Chip Package Size and Products Containing Same (IV)

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 25) of the presiding administrative law judge ("ALJ") granting complainant Tessera, Inc.'s motion to terminate the investigation.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202-205-3152. Copies of the ID and all other nonconfidential 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. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 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) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: On May 28, 2008, the Commission instituted an investigation under section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, based on a complaint filed by Tesser, Inc. of San Jose, California ("Tesser"), alleging a violation of section 337 in the importation, sale for importation, and sale within the United States after importation of certain semiconductor chips with minimized chip package size and products containing same that infringe certain claims of U.S. Patents Nos. 5,852,326; 6,433,419; and 5,679,977. 73 FR 30628 (May 28, 2008). The complaint named numerous entities as respondents. Subsequently, the complaint and Notice of Investigation were amended to add U.S. Patent No. 5,663,106, and the target date for completion of this investigation was extended.

On March 12, 2009, complainant Tesser moved to terminate the investigation based on withdrawal of the complaint. On July 17, 2009, the ALJ issued Order No. 25 granting the motion. No petitions for review were filed. The Commission has determined not to review the ID.

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 section 210.42(h) of the Commission's Rules of Practice and Procedure (19 CFR 210.42(h)).

By order of the Commission.

Issued: August 7, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9-19411 Filed 8-12-09; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

Investigation No. AA1921-167 (Third Review); Pressure Sensitive Plastic Tape From Italy

AGENCY: International Trade Commission.

ACTION: Notice of Commission determination to conduct a full five-year review concerning the antidumping finding on pressure sensitive plastic tape from Italy.

SUMMARY: The Commission hereby gives notice that it will proceed with a full review pursuant to section 751(c)(5) of

the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) to determine whether revocation of the antidumping duty finding on pressure sensitive plastic tape from Italy would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the review will be established and announced at a later date. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: *Effective Date:* August 4, 2009.

FOR FURTHER INFORMATION CONTACT:

Edward Petronzio (202-205-3176), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: On August 4, 2009, the Commission determined that it should proceed to a full review in the subject five-year review pursuant to section 751(c)(5) of the Act. The Commission found that the domestic interested party group response to its notice of institution (74 FR 20340, May 1, 2009) was adequate but that the respondent interested group response was inadequate. The Commission also found that other circumstances warranted conducting a full review.¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

¹ Commissioners Irving A. Williamson and Dean A. Pinkert dissenting.

Issued: August 7, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9-19410 Filed 8-12-09; 8:45 am]

BILLING CODE 7020-06-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-345]

Shifts in U.S. Merchandise Trade 2008

AGENCY: United States International Trade Commission.

ACTION: Availability on Commission's Web site of 2009 report on shifts in merchandise trade during 2008; opportunity to submit written comments relating to the 2009 report and possible content of the 2010 report.

SUMMARY: The 2009 report can now be accessed and downloaded from the Commission's Web site at http://www.usitc.gov/research_and_analysis/trade_shifts.htm. The format used by the Commission since 2004 includes links to Commission research and other resources including data, as well as links to other organizations with related information. User feedback on the revised format is encouraged by providing access to the ITC online Reader Satisfaction Survey (http://reportweb.usitc.gov/reader_survey/readersurvey.html). A CD-ROM version of the 2008 report may be requested by contacting the Office of the Secretary at 202-205-2000 or by fax at 202-205-2104. Readers of the report may also provide comments by downloading the survey form and business reply mailer for this publication from the Commission's Web site.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC 20436. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

FOR FURTHER INFORMATION CONTACT:

Project leader, Jeremy Wise, Office of Industries (202-205-3190 or jeremy.wise@usitc.gov) or deputy project leader Brendan Lynch (202-205-3313 or brendan.lynch@usitc.gov). For information on the legal aspects, please contact William Gearhart, Office of General Counsel (202-205-3091 or

william.gearhart@usitc.gov). The media should contact Margaret O'Laughlin, Public Affairs Officer (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 on 202-205-2648.

Background: The Commission has prepared and published annual reports on U.S. trade shifts in selected industries/commodity areas under investigation No. 332-345 since 1993. Beginning in 2004, the Commission converted the report to an exclusively web-based format (with added focus on sectoral issues) that can be accessed electronically. The initial notice of institution of this investigation was published in the **Federal Register** of September 8, 1993 (58 FR 47287). The Commission expanded the scope of this investigation to cover services trade in a separate report, which it announced in a notice published in the **Federal Register** of December 28, 1994 (59 FR 66974). The merchandise trade report has been published in the current series under investigation No. 332-345 annually since September 1993.

This year's Web-based format identifies the key trends affecting principal foreign markets and 10 major U.S. sectors.

By order of the Commission.

Issued: August 6, 2009.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9-19378 Filed 8-12-09; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-09-024]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 21, 2009 at 2 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, *Telephone:* (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agenda for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 701-TA-467 and 731-TA-1164-1165 (Preliminary) (Narrow Woven Ribbons with Woven Selvedge from China and Taiwan)—briefing and vote. (The Commission is currently scheduled to transmit its determinations

to the Secretary of Commerce on or before August 24, 2009; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before August 31, 2009.)

5. *Outstanding action jackets:* none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier announcement of this meeting was not possible.

Issued: August 11, 2009.

By order of the Commission.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E9-19554 Filed 8-11-09; 4:15 pm]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act and Resource Conservation and Recovery Act

Under 28 CFR 50.7, notice is hereby given that on August 7, 2009, a proposed Consent Decree ("Consent Decree") in the matter of *United States v. Bradford Industries*, Civil Action No. 1:09-cv-09-11333, was lodged with the United States District Court for the District of Massachusetts.

In the complaint in this matter, the United States sought injunctive relief and civil penalties against Bradford Industries, Inc. ("Bradford") for claims arising under the Clean Air Act and the Resource Conservation and Recovery Act, in connection with the operation of the Bradford's operation of its facility located at 75 Rogers Street in Lowell, MA. Under the Consent Decree, Bradford will hire an independent auditor to conduct two environmental compliance audits, and pay a civil penalty of \$75,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Bradford Industries, Inc.*, D.J. Ref. No. 90-5-2-1-09314.

The Consent Decree may be examined at the Office of the United States Attorney, 1 Courthouse Way, John Joseph Moakley Courthouse, and at U.S.

EPA Region I, Robert F. Kennedy Federal Building, Boston, Massachusetts 02203-2211. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent-Decrees.html*. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*) fax number (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$8.00 (25 cents per page reproduction cost) payable to the U.S. Treasury, or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E9-19421 Filed 8-12-09; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Membership of the Senior Executive Service Standing Performance Review Boards

AGENCY: Department of Justice.

ACTION: Notice of Department of Justice's standing members of the Senior Executive Service Performance Review Boards.

SUMMARY: Pursuant to the requirements of 5 U.S.C. 4314(c)(4), the Department of Justice announces the membership of its 2009 Senior Executive Service (SES) Standing Performance Review Boards (PRBs). The purpose of a PRB is to provide fair and impartial review of SES performance appraisals, bonus recommendations and pay adjustments. The PRBs will make recommendations regarding the final performance ratings to be assigned, SES bonuses and/or pay adjustments to be awarded.

FOR FURTHER INFORMATION CONTACT: Rod Markham, Director, Human Resources, Justice Management Division, Department of Justice, Washington, DC 20530; (202) 514-4350.

Lee J. Lofthus,

Assistant Attorney General for Administration.

Name	Position title
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RICHARDSON, MARGARET	COUNSELOR TO THE ATTORNEY GENERAL FOR EXECUTIVE BRANCH RELATIONS.
BIES, JOHN E	COUNSELOR TO THE ATTORNEY GENERAL.
GARLAND, JAMES	DEPUTY CHIEF OF STAFF AND COUNSELOR.
OLSEN, MATTHEW G	EXECUTIVE DIRECTOR.
JEFFRESS, DOROTHY, AMES	COUNSELOR TO THE ATTORNEY GENERAL.
Office of the Deputy Attorney General—DAG	
MACBRIDE, NEIL H	ASSOCIATE DEPUTY ATTORNEY GENERAL.
LIBIN, NANCY	CHIEF PRIVACY AND CIVIL LIBERTIES OFFICER.
DELERY, STUART F	CHIEF OF STAFF AND COUNSELOR.
RUEMLER, KATHYREN H	PRINCIPAL ASSOCIATE DEPUTY ATTORNEY GENERAL.
MARGOLIS, DAVID	ASSOCIATE DEPUTY ATTORNEY GENERAL.
SCHOOLS, SCOTT N	ASSOCIATE DEPUTY ATTORNEY GENERAL.
VERRILLI, DONALD B	ASSOCIATE DEPUTY ATTORNEY GENERAL.
BURROWS, CHARLOTTE	ASSOCIATE DEPUTY ATTORNEY GENERAL.
Office of the Associate Attorney General—OASG	
GUERRA, JOSEPH R	PRINCIPAL DEPUTY ASSOCIATE ATTORNEY GENERAL.
MASON, KAROL V	DEPUTY ASSOCIATE ATTORNEY GENERAL.
GREENFELD, HELAINE ANN	DEPUTY ASSOCIATE ATTORNEY GENERAL.
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DREEBEN, MICHAEL R	DEPUTY SOLICITOR GENERAL.
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Antitrust Division—ATR	
SOVEN, JOSHUA H	CHIEF LITIGATION I SECTION.
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DAVIS, NEZIDA S	CHIEF, ATLANTA FIELD OFFICE.
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HAMMOND, SCOTT D	DEPUTY ASSISTANT ATTORNEY GENERAL.
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POTTER, ROBERT A	CHIEF, LEGAL POLICY SECTION.
FAMILANT, NORMAN	CHIEF, ECONOMIC LITIGATION SECTION.
HEYER, KENNETH	DIRECTOR OF ECONOMICS.
BOAST, MARY H	DEPUTY ASSISTANT ATTORNEY GENERAL.
PETRIZZI, MARIBETH	CHIEF, LITIGATION II SECTION.
KING, THOMAS D	EXECUTIVE OFFICER.
GOODMAN, NANCY M	CHIEF, TELECOMMUNICATIONS AND MEDIA SECTION.
PHELAN, LISA M	CHIEF, NATIONAL CRIMINAL ENFORCEMENT SECTION.
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Bureau of Alcohol, Tobacco, Firearms, and Explosives—ATF	
CHAIT, MARK R	DEPUTY ASSISTANT DIRECTOR, FIELD OPERATIONS—CENTRAL.
Bureau of Alcohol, Tobacco, Firearms, and Explosives—ATF	
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STUCKO, AUDREY M	DEPUTY ASSISTANT DIRECTOR, ENFORCEMENT PROGRAM AND SERVICES.
GODDARD, VALERIE J	DEPUTY ASSISTANT DIRECTOR, TRAINING AND PROFESSIONAL DEVELOPMENT.
LOGAN, MARK	ASSISTANT DIRECTOR, TRAINING AND PROFESSIONAL DEVELOPMENT.

Name	Position title
CRENSHAW, KELVIN N	ASSISTANT DIRECTOR, OFFICE OF PROFESSIONAL RESPONSIBILITY AND SECURITY OPERATIONS.
MICHALIC, VIVIAN B	DEPUTY ASSISTANT DIRECTOR, MANAGEMENT.
STINNETT, MELANIE S	ASSISTANT DIRECTOR, MANAGEMENT AND CHIEF FINANCIAL OFFICER.
BELL, WILLIAM L	DEPUTY ASSISTANT DIRECTOR, SCIENCE AND TECHNOLOGY.
ETHRIDGE, MICHAEL W	DIRECTOR, LABORATORY SERVICES.
FICARETTA, TERESA G	DEPUTY CHIEF COUNSEL.
LOOS, ELEANER R	ASSOCIATE CHIEF COUNSEL, ADMINISTRATION AND ETHICS.
MCMAHON JR, WILLIAM G	DEPUTY ASSISTANT DIRECTOR, FIELD OPERATIONS—WEST.
TORRES, JOHN A	SPECIAL AGENT IN CHARGE, LOS ANGELES.
DOMENECH, EDGAR A	SPECIAL AGENT IN CHARGE, WASHINGTON D.C.
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RUBENSTEIN, STEPHEN R	CHIEF COUNSEL.
MASSEY, KENNETH	DEPUTY ASSISTANT DIRECTOR, OFFICE OF PROFESSIONAL RESPONSIBILITY AND SECURITY OPERATIONS.
ZAMMILLO SR, JAMES A	DEPUTY ASSISTANT DIRECTOR, INDUSTRY OPERATIONS.
CAVANAUGH, JAMES M	SPECIAL AGENT IN CHARGE, NASHVILLE.
FORD, WILFRED L	ASSISTANT DIRECTOR, OFFICE OF PUBLIC AND GOVERNMENTAL AFFAIRS.
MARTIN, STEPHEN K	DEPUTY ASSISTANT DIRECTOR, OFFICE OF STRATEGIC INTELLIGENCE AND INFORMATION.
MCDERMOND, JAMES E	ASSISTANT DIRECTOR, OFFICE OF STRATEGIC INTELLIGENCE AND INFORMATION.
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ANDERSON, GLENN N	SPECIAL AGENT IN CHARGE, BOSTON.
TRAVER, ANDREW L	SPECIAL AGENT IN CHARGE, CHICAGO.
BOXLER, MICHAEL B	SPECIAL AGENT IN CHARGE, KANSAS CITY.
POTTER, MARK W	SPECIAL AGENT IN CHARGE, PHILADELPHIA.
NEWELL, WILLIAM D	SPECIAL AGENT IN CHARGE, PHOENIX.
HERKINS, STEPHEN C	SPECIAL AGENT IN CHARGE, SAN FRANCISCO.
BARRERA, HUGO J	SPECIAL AGENT IN CHARGE, MIAMI.
GRAHAM, ZEBEDEE T	SPECIAL AGENT IN CHARGE, CHARLOTTE.
BRANDON, THOMAS E	SPECIAL AGENT IN CHARGE, DETROIT.
VIDO, PAUL J	SPECIAL AGENT IN CHARGE, LOUISVILLE.
O'BRIEN, VIRGINIA T	SPECIAL AGENT IN CHARGE, TAMPA.
ZAPOR, BERNARD J	SPECIAL AGENT IN CHARGE, ST PAUL.
HARPER, DAVID G	SPECIAL AGENT IN CHARGE, NEW ORLEANS.
SADOWSKI, CHRISTOPHER P	SPECIAL AGENT IN CHARGE, COLUMBUS.
STOOP, THERESA R	SPECIAL AGENT IN CHARGE, BALTIMORE.
HOOVER, WILLIAM J	ASSISTANT DIRECTOR, FIELD OPERATIONS.
CARTER, RONNIE A	SPECIAL AGENT IN CHARGE, DALLAS.
HORACE, MATTHEW W	SPECIAL AGENT IN CHARGE, NEWARK.
CHASE, RICHARD E	SPECIAL AGENT IN CHARGE, DENVER.
MELSON, KENNETH E	SENIOR POLICY ADVISOR.

Bureau of Prisons—BOP

LAPPIN, HARLEY G	DIRECTOR.
DALIUS, WILLIAM F. JR	ASSISTANT DIRECTOR FOR ADMINISTRATION.
CONLEY, JOYCE K	ASSISTANT DIRECTOR CORRECTIONAL PROGRAMS DIVISION.
KENNEY, KATHLEEN M	ASSISTANT DIRECTOR, OFFICE OF GENERAL COUNSEL.
DODRILL, D. SCOTT	REGIONAL DIRECTOR, NORTHEAST REGION.
HOLT, RAYMOND E	REGIONAL DIRECTOR, SOUTHEAST REGION.
NALLEY, MICHAEL K	REGIONAL DIRECTOR, NORTH CENTRAL REGION.
MCFADDEN, ROBERT E	REGIONAL DIRECTOR, WESTERN REGION.
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GRAYER, LOREN A	WARDEN, USP, ATLANTA, GA.
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THIGPEN SR, MORRIS L	DIRECTOR NATIONAL INSTITUTE OF CORRECTIONS.
REVELL, SARA M	WARDEN, FCC, BUTNER, NC.
EICHENLAUB, LOUIS C	WARDEN, FCI MARIANNA, FL.
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NUCLEAR REGULATORY COMMISSION

[NRC-2009-0353]

Draft Regulatory Guide: Issuance, Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Draft Regulatory Guide, DG-5029, "Pressure-Sensitive and Tamper-Indicating Device Seals for Material Control and Accounting Use."

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SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), entitled, "Pressure-Sensitive and Tamper-Indicating Device Seals for Material Control and Accounting Use," is temporarily identified by its task number, DG-5029, which should be mentioned in all related

correspondence. The NRC requires certain licensees to use tamper-indicating devices (TIDs) for material control and accounting (MC&A) and for physical security of special nuclear material (SNM). Title 10, part 70, "Domestic Licensing of Special Nuclear Material," of the *Code of Federal Regulations* (10 CFR part 70) requires, in part, that no person subject to the regulations in 10 CFR part 70 may receive title to, own, acquire, deliver, receive, possess, use, or transfer SNM, except as authorized in a license issued by the NRC.

This regulatory guide (RG) replaces the existing RG 5.10, "Selection and Use of Pressure-Sensitive Seals on Containers for Onsite Storage of Special Nuclear Material," issued July 1973 and the existing RG 5.15, "Tamper-Indicating Seals for the Protection and Control of Special Nuclear Material," issued March 1997, with a new title, "Pressure-Sensitive and Tamper-Indicating Device Seals for MC&A Use." RG 5.10 refers to a pressure-sensitive (PS) seal that is no longer in general use and may no longer be commercially available. RG 5.15 refers to tamper-indicating devices (TID) including PS seals. As a replacement, this guide describes a number of improved TIDs and PS seals developed in recent years primarily in response to commercial interests outside the nuclear industry.

II. Further Information

The NRC staff is soliciting comments on DG-5029. Comments may be accompanied by relevant information or supporting data and should mention DG-5029 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking and Directives Branch, Mail Stop: TWB-05-B01M, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. *Federal e-Rulemaking Portal:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2009-0353]. Address questions about NRC dockets to Carol Gallagher, 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

3. *Fax comments to:* Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 492-3446.

Requests for technical information about DG-5029 may be directed to the NRC contact, Steven Ward at (301) 492-3426 or e-mail to Steven.Ward@nrc.gov.

Comments would be most helpful if received by October 13, 2009. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in

guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG-5029 are available through the NRC's public Web site under Draft Regulatory Guides in the "Regulatory Guides" collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML091670070.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by e-mail to pdr.resource@nrc.gov.

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 6th day of August, 2009.

For the Nuclear Regulatory Commission.

John N. Ridgely,

Acting Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. E9-19458 Filed 8-12-09; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0352; Docket No. 40-9083]

Notice of License Application Request of U.S. Army Installation Command for Schofield Barracks, Oahu, HI, and Pohakuloa Training Area, Island of Hawaii, HI; and Notice of Opportunity for Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of license application and opportunity to request a hearing.

DATES: A request for a hearing must be filed by October 13, 2009.

FOR FURTHER INFORMATION CONTACT: John Hayes, Senior Project Manager, Materials Decommissioning Branch, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415-5928; fax number: (301) 415-5369; e-mail: John.Hayes@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

By letters dated November 6, 2008, and July 8, 2009, the U.S. Army Installation Command submitted a Source Material License application to the Nuclear Regulatory Commission (NRC), for the Schofield Barracks and Pohakuloa Training Area (PTA) sites in Oahu and the Island of Hawaii, Hawaii. This license application is for possession of depleted uranium (DU) due to the potential for residual DU to be at various Army Installations where testing of the M101 Spotting Round has occurred.

An NRC administrative review, documented in a letter to the U.S. Army Installation Command dated August 3, 2009, found the generic and site specific security and environmental radiation monitoring plans submitted by the applicant acceptable to begin a technical and environmental review. Before approving the license application, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended, and the NRC's regulations. These findings will be documented in a Safety Evaluation Report (SER) and a site-specific Environmental Review consistent with the provisions of 10 CFR Part 51.

II. Opportunity To Request a Hearing

The NRC hereby provides notice that this is a proceeding on an application for a source material license submitted by the U.S. Army Installation Command to possess depleted uranium at the Schofield Barracks and PTA sites in Oahu and the Island of Hawaii, Hawaii. Any person whose interest may be affected by this proceeding and who desires to participate as a party must file a request for a hearing and a specification of the contentions which the person seeks to have litigated in the hearing in accordance with the NRC E-Filing rule, which the NRC promulgated on August 28, 2007 (72 FR 49139). All documents filed in NRC adjudicatory proceedings, including documents filed by interested governmental entities participating under 10 CFR 2.315(c) and any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, must be filed in accordance with the E-Filing rule. The E-Filing rule requires participants to submit and serve all adjudicatory documents over the Internet or, in some cases, to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by e-mail at HEARING.DOCKET@NRC.GOV, or by calling (301) 415-1677, to request: (1) A digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory e-filing system

may seek assistance through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC Meta-System Help Desk, which is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays. The Meta-System Help Desk can be contacted by telephone at 1-866-672-7640 or by e-mail at MSHD.Resource@nrc.gov.

Participants who believe that they have a good cause for not submitting documents electronically must, in accordance with 10 CFR 2.302(g), file an exemption request with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii).

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include social security numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The formal requirements for documents contained in 10 CFR 2.304(c)-(e) must be met. If the NRC grants an electronic document exemption in accordance with 10 CFR 2.302(g)(3), then the requirements for paper documents, set forth in 10 CFR 2.304(b) must be met.

In accordance with 10 CFR 2.309(b), a request for a hearing must be filed by October 13, 2009.

In addition to meeting other applicable requirements of 10 CFR 2.309, a request for a hearing filed by a person other than an applicant must state:

1. The name, address, and telephone number of the requester;
2. The nature of the requester's right under the Act to be made a party to the proceeding;
3. The nature and extent of the requester's property, financial or other interest in the proceeding;
4. The possible effect of any decision or order that may be issued in the proceeding on the requester's interest; and
5. The circumstances establishing that the request for a hearing is timely in accordance with 10 CFR 2.309(b).

In accordance with 10 CFR 2.309(f)(1), a request for hearing or petition for leave to intervene must set forth with particularity the contentions sought to be raised. For each contention, the request or petition must:

1. Provide a specific statement of the issue of law or fact to be raised or controverted;
2. Provide a brief explanation of the basis for the contention;
3. Demonstrate that the issue raised in the contention is within the scope of the proceeding;
4. Demonstrate that the issue raised in the contention is material to the findings that the NRC must make to support the action that is involved in the proceeding;
5. Provide a concise statement of the alleged facts or expert opinions which support the requester's/petitioner's position on the issue and on which the requester/petitioner intends to rely to support its position on the issue; and
6. Provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. This information must include references to specific portions of the application that the requester/petitioner disputes and the supporting reasons for each dispute, or, if the requester/petitioner believes the application fails to contain information on a relevant matter as required by law, the identification of each failure and the

supporting reasons for the requester's/petitioner's belief.

In addition, in accordance with 10 CFR 2.309(f)(2), contentions must be based on documents or other information available at the time the petition is to be filed, such as the application or other supporting document filed by an applicant or licensee, or otherwise available to the petitioner. The requester/petitioner may amend those contentions or file new contentions if there are data or conclusions in the NRC documents that differ significantly from the data or conclusions in the applicant's documents. Otherwise, contentions may be amended or new contentions filed after the initial filing only with leave of the presiding officer.

Requesters/petitioners should, when possible, consult with each other in preparing contentions and combine similar subject matter concerns into a joint contention, for which one of the co-sponsoring requesters/petitioners is designated the lead representative. Further, in accordance with 10 CFR 2.309(f)(3), any requester/petitioner that wishes to adopt a contention proposed by another requester/petitioner must do so, in accordance with the E-Filing rule, within ten days of the date the contention is filed, and designate a representative who shall have the authority to act for the requester/petitioner.

In accordance with 10 CFR 2.309(g), a request for hearing and/or petition for leave to intervene may also address the selection of the hearing procedures, taking into account the provisions of 10 CFR 2.310.

III. Further Information

Documents related to this action, including the November 6, 2008, and July 8, 2009 application and the supporting documentation (*i.e.*, Environmental Radiation Plan and Security Plan), are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are: ML090070095, "US Department of Army Installations Application for Materials License;" ML091950280, "Memorandum on Security and Environmental Radiation Monitoring Plans;" and ML092150316, "Acknowledgement of Receipt of Generic and Site Specific Security and Environmental Radiation Monitoring

Plans.” If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@nrc.gov

These documents may also be viewed electronically on the public computers located at the NRC’s Public Document Room (PDR), O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland, this 5th day of August, 2009.

For the Nuclear Regulatory Commission.

Keith McConnell,

Deputy Director,

Decommissioning and Uranium Recovery, Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. E9-19449 Filed 8-12-09; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

In the Matter of V-Twin Holdings, Inc. (n/k/a Tobacco One, Inc.), Valley Media, Inc., Venturequest Group, Inc. (n/k/a Dex-Ray Resources, Inc.), Verex Laboratories, Inc., Vibro-Tech Industries, Inc., Video City, Inc., and Vidikron Technologies Group, Inc.; Order of Suspension of Trading

August 11, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of V-Twin Holdings, Inc. (n/k/a Tobacco One, Inc.) because it has not filed any periodic reports since the period ended March 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Valley Media, Inc. because it has not filed any periodic reports since the period ended September 29, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Venturequest Group, Inc. (n/k/a Dex-Ray Resources, Inc.), because it has not filed any periodic reports since the period ended September 30, 2001.

It appears to the Securities and Exchange Commission that there is a

lack of current and accurate information concerning the securities of Verex Laboratories, Inc. because it has not filed any periodic reports since the period ended March 31, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Vibro-Tech Industries, Inc. because it has not filed any periodic reports since it filed a Form 10-SB on January 5, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Video City, Inc. because it has not filed any periodic reports since the period ended July 31, 2003.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Vidikron Technologies Group, Inc. because it has not filed any periodic reports since the period ended March 31, 1999.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on August 11, 2009, through 11:59 p.m. EDT on August 24, 2009.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E9-19486 Filed 8-11-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60455; File No. SR-Phlx-2009-62]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Automatic Allocations of Options on Related Securities

August 6, 2009.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 ² thereunder, notice is hereby given that on July 31, 2009, NASDAQ OMX PHLX, Inc. (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission

(“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Phlx has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b-4(f)(6) under the Act,³ 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 proposes to amend Phlx Rule 506 (Allocation Application) regarding automatic allocation of options on related securities.

The text of the proposed rule change is available on the Exchange’s Web site at <http://nasdaqomxphlx.cchwallstreet.com/NASDAQOMXPHLX/Filings/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The amendments proposed to Phlx Rule 506 are based on and similar to Commentary .05 to AMEX Rule 27.⁴

The purpose of the proposed rule change is to amend Rule 506 to indicate

³ 17 CFR 240.19b-4(f)(6).

⁴ See Securities Exchange Act Release No. 45260 (January 9, 2002), 67 FR 2255 (January 16, 2002) (SR-AMEX-2001-19) (approval order regarding AMEX Rules 26 and 27). See also Securities Exchange Act Release No. 44972 (October 23, 2001), 66 FR 55031 (October 31, 2001) (SR-AMEX-2001-19) (notice of filing regarding, among other things, Commentary .05 to AMEX Rule 27). The American Stock Exchange LLC was purchased in 2008 by NYSE Euronext and is now known as NYSE Amex LLC (AMEX).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

that new options that are related to currently allocated options ("Related Options") shall be automatically allocated to the specialist unit that is already the current specialist in option(s) on the underlying security(ies) ("Current Specialist").⁵ If the Related Options are not automatically allocated, the Exchange may, nonetheless, allocate the Related Options to the Current Specialist if the Exchange determines that the trading characteristics of the Related Options to be allocated are similar to the options already allocated to the Current Specialist.⁶

The allocation and re-allocation process for classes of options to specialist units and individual specialists on the Exchange is found in Rules 500–599 (the "Allocation Rules"), which rules are administered by the exchange.⁷ The Allocation Rules also deal with, among other things: application for becoming and appointment of specialists; application for becoming and approval of Streaming Quote Traders ("SQTs")⁸ and Remote Streaming Quote Traders ("RSQTs")⁹ and assignment of options to them; and specialist, SQT, and RSQT performance evaluations. The Allocation Rules also indicate under what circumstances new allocations may not be made. Supplementary Material .01 to Rule 506, as an example, states that a specialist may not apply for a new allocation for a period of six months after an option allocation was taken away from the specialist in a disciplinary proceeding or an involuntary reallocation

proceeding ("Allocation Preclusion").¹⁰ The current Allocation Rules do not contain guidelines regarding allocation of Related Options.

This filing would amend Rule 506 to clarify that Related Options will be automatically allocated, under conditions set forth in new Supplementary Material .02, to the Current Specialist that is already allocated options overlying securities that are related to securities that the new options overlie.

In particular, Supplementary Material .02 in subsection (a) defines the term "Related Securities"¹¹ underlying options to mean, but not be limited to:

- Securities of a partially or wholly owned subsidiary;
- Securities that are convertible into the securities of the issuer;
- Warrants on securities of the issuer;
- Securities issued in connection with a name change;
- Securities issued in a reverse stock split;
- Contingent value rights;
- "Tracking" securities designed to track the performance of the underlying security or corporate affiliate thereof;
- Securities created in connection with the merger or acquisition of one or more companies;
- Securities created in connection with a "spin-off" transaction;
- Convertible on non-convertible senior securities; and
- Securities into which a listed security is convertible.

Where such Related Securities emanate from or are related to securities underlying options that are currently allocated to a specialist on the Exchange ("Currently Allocated Options").

Subsection (b) to Supplementary Material .02 goes on to state that while unallocated new Related Options shall be automatically allocated to the Current Specialist, no automatic allocation can occur if the Current Specialist is subject, pursuant to Supplementary Material .01, to an Allocation Preclusion because of a disciplinary proceeding or involuntary reallocation proceeding.¹² Where there is no automatic allocation the Exchange may decide to allocate Related Options to the Current Specialist that is already

trading allocated related options if the Exchange determines that the trading characteristics of the Related Options to be allocated are similar to the already allocated options.¹³

The following example illustrates how the proposed allocation process would work. In 2008, Wachovia Corporation (WB) was acquired by Wells Fargo & Company (WFC), with WFC being the surviving company (the "merger"). At the time of the merger, which was effective December 31, 2008, options on the surviving company WFC were already listed and being traded by one specialist (the "WFC Specialist") and options on WB were listed and being traded on the Exchange by another specialist (the "WB Specialist"). Under the current allocation structure, the WB Specialist would have to continue to act as a specialist vis a vis WB options for the purpose of trading the adjusted WB option series until all open interest traded out or expired. The WFC Specialist would, at the same time, trade the WFC options. Under the automatic allocation process proposed in this filing, in that WFC and WB would be Related Securities, WFC options would be Currently Allocated Options, the WFC Specialist would be the Current Specialist, and the adjusted WB options series would be new Related Options, by operation of Supplementary Material .02, the Related Options would be automatically allocated to the Current Specialist. As such, the WFC Specialist would assume specialist privileges in the WFC options and the adjusted WB option series, therefore becoming the specialist for all options related to the merger of WFC and WB.¹⁴

The Exchange believes that the automatic allocation of Related Options to Current Specialists as proposed herein should increase the efficiency and speed of the allocation of options that are logically related to each other, to the benefit of Exchange members and traders and the public.¹⁵

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act¹⁶ in general, and furthers the

⁵ Exchange specialists are allocated classes of options by the Exchange in relation to assisting in the maintenance, insofar as reasonably practicable, of a fair and orderly market in such options. See Rule 1020.

⁶ Related Options, Related Securities, and Current Specialist are defined in proposed Supplementary Material .02 to Rule 506.

⁷ See Rule 500. See also Securities Exchange Act Release No. 59924 (May 14, 2009), 74 FR 23759 (May 20, 2009) (SR-PHLX-2009-23).

⁸ An SQT is an Exchange Registered Options Trader ("ROT") who has received permission from the Exchange to generate and submit option quotations electronically in eligible options to which such SQT is assigned. An SQT may only submit such quotations while such SQT is physically present on the floor of the Exchange. See Rule 1014(b)(ii)(A). See also Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (approval order regarding enhancements to opening, linkage and routing, quoting, and order management processes in the Exchange's electronic options order entry, trading, and execution system PHLX XL II.) [sic]

⁹ An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in eligible options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. See Exchange Rule 1014(b)(ii)(B).

¹⁰ See Rule 960 *et seq.* for disciplinary procedures and Allocation Rules for reallocation procedures.

¹¹ For purposes of Supplementary Material .02, Related Securities does not mean Exchange Traded Funds.

¹² Although automatic allocation of New Options pursuant to Supplementary Material .02 will not require the Exchange to make an allocation determination as it would with regular option allocations, the Exchange will continue to perform other allocation-related duties such as, for example, written notification. See Rule 506.

¹³ An ETF (only) specialist will not be eligible to receive automatic allocations for the duration of the Allocation Preclusion applicable to him or her.

¹⁴ It is assumed, for purposes of this example, that the Current Specialist is not subject to an Allocation Preclusion as defined in Supplementary Material .01.

¹⁵ The Exchange has made conforming, technical changes to proposed Rule 506 to integrate the proposed language into its current rules and to correct a typographical error.

¹⁶ 15 U.S.C. 78f(b).

objectives of Section 6(b)(5) of the Act¹⁷ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by providing for automatic allocation to an Exchange specialist of options that are related to each other.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁸ and Rule 19b-4(f)(6) thereunder.¹⁹

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.

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-Phlx-2009-62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2009-62. 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR-Phlx-2009-62 and should be submitted on or before September 3, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-19374 Filed 8-12-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60454; File No. SR-CBOE-2009-054]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Marketing Fee Program

August 6, 2009.

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 31, 2009, the Chicago Board Options Exchange, Incorporated ("CBOE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. CBOE has designated this proposal as one establishing or changing a due, fee, or other charge applicable only to a member under Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b-4(f)(2) 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 parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to amend its Marketing Fee Program. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.org/Legal/>), at the Exchange's Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

¹⁷ 15 U.S.C. 78f(b)(5).

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file 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. Phlx has satisfied this requirement.

²⁰ 17 CFR 200.30-3(a)(12).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

Currently, CBOE's marketing fee is assessed only on transactions of Market-Makers, e-DPMs, and DPMs, resulting from (i) orders for less than 1,000 contracts from payment accepting firms, or (ii) customer orders for less than 1,000 contracts that have designated a "Preferred Market-Maker" under CBOE Rule 8.13. CBOE proposes to amend its marketing fee program such that the fee will be assessed on transactions of Market-Makers, e-DPMs, and DPMs resulting from *customer* orders for less than 1,000 contracts from payment accepting firms. CBOE believes that limiting the collection of the fee to transactions resulting from customer orders for less than 1,000 contracts from payment accepting firms is appropriate and will continue to allow its DPMs to compete for order flow.⁵

CBOE will continue to assess the fee on transactions resulting from customer orders for less than 1,000 contracts that have designated a "Preferred Market-Maker" under CBOE Rule 8.13. CBOE proposes to implement this change to the marketing fee program beginning on August 1, 2009.

Additionally, CBOE proposes to amend the marketing fee program to eliminate a limitation pertaining to the manner in which DPMs use the funds made available to them to attract order flow to CBOE. Currently, the funds made available to DPMs can only be used to attract orders in the option classes at the trading station where the fee is assessed. CBOE imposed this limitation at a time when CBOE Market-Makers' appointments consisted of those option classes located at a particular trading station. Market-Makers were required by rule to be physically present in the trading station in order to quote electronically into the classes at that station. As a result (and as discussed in CBOE's rule filing SR-CBOE-2004-58; Rel. No. 34-51429), Market-Makers effectively had a "one-station" appointment.

CBOE subsequently amended its rules to provide the same flexibility to its on-floor Market-Makers that its former Remote Market-Makers ("RMM") had. (CBOE eliminated its RMM program a couple years ago and all former RMMs were designated as Market-Makers with

the same trading privileges.) Today, as Rule 8.3(c)(i) makes clear, Market-Makers create customized class appointments, called "virtual trading crowd" appointments, which allow Market-Makers to quote electronically into various option classes irrespective of their geographic location on CBOE's trading floor. Additionally, as Rule 8.3(c)(ii) states, Market-Makers have an appointment to trade in open outcry in all Hybrid classes traded on CBOE, meaning that they are free to go from trading crowd to trading crowd to trade in open outcry in any Hybrid option class. Market-Makers are not required to be on the trading floor to submit electronic quotations into their appointed classes (*see* Rule 8.3(c)(v)) and also are permitted to enter orders electronically in non-appointed option classes (*see* Rule 8.7(b)(iii)B). Also, CBOE has established Off-Floor DPMs, and the option classes formerly located at one trading station can be relocated among various trading stations—even though the same DPM organization continues to function now as the Off-Floor DPM. As a result of all of these changes, this limitation has become unnecessary.

For an example of this proposed change, assume the same DPM operated at two different trading stations on CBOE's trading floor: Station 1 and Station 5. If \$10,000 was generated from the marketing fee in a given month from transactions in option classes located at Station 1 and \$15,000 from Station 5, under CBOE's proposed change a total of \$25,000 would be made available to the DPM for the month, and the DPM could use the funds to attract order flow in the option classes located at Stations 1 and 5. (This example assumes none of these funds were made available to Preferred Market-Makers.) CBOE believes that this is fair and reasonable in light of the manner in which Market-Makers function today on CBOE as described above.

Finally, CBOE proposes to delete reference in footnote 6 to two option classes it no longer trades: BXO and RUH.

CBOE is not amending its marketing fee program in any other respects.

(b) Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act⁶ in general, and furthers the objectives of Section 6(b)(4) of the Act⁷ in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and

other charges among persons using its facilities.

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 [sic] 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 rule change establishes or changes a due, fee, or other charge imposed by the Exchange, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁸ and subparagraph (f)(2) of Rule 19b-4⁹ thereunder. 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.

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-2009-054 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2009-054. This file number should be included on the subject line if e-mail is used. To help the

⁵ CBOE notes that in the past, its marketing fee was assessed on transactions resulting from customer orders. *See* Securities Exchange Act Rel. No. 34-50736 (11/24/04), 69 FR 69966 (12/1/04) (SR-CBOE-2004-68).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4).

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(2).

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 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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-2009-054 and should be submitted on or before September 3, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-19376 Filed 8-12-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60452; File No. SR-NYSEAmex-2009-54]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Implementing Its Schedule of Fees and Charges for Exchange Services

August 5, 2009.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder, ³ notice is hereby given that, on July 31, 2009, NYSE Amex LLC ("NYSE Amex" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and

III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act ⁴ and Rule 19b-4(f)(2) thereunder, ⁵ 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 proposes to amend its Schedule of Fees and Charges for Exchange Services ("Schedule") by waiving the Cancellation Fee until November 1, 2009. The Schedule is attached as Exhibit 5 to the 19b-4 form. A copy of this filing is available on the Exchange's Web site at <http://www.nyse.com>, at the Exchange's principal office and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to waive the Cancellation Fee until November 1, 2009. The Cancellation Fee was scheduled to take effect on August 1, 2009, however, the required development to Exchange billing systems has not been completed. Those system enhancements are scheduled to be implemented for the November billing cycle that begins on November 1, 2009.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act, in general, and Section 6(b)(4), in particular, in that it provides for the equitable allocation of dues, fees

and other charges among its members and other market participants that use the trading facilities of NYSE Amex Options. Under this proposal, all similarly situated members and other Exchange participants of NYSE Amex Options will be charged the same reasonable dues, fees and other charges.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) ⁶ of the Act and subparagraph (f)(2) of Rule 19b-4 ⁷ thereunder, because it establishes a due, fee, or other charge imposed by the NYSE Amex.

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.

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-NYSEAmex-2009-54 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary,

¹⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(3)(A).

⁵ 17 CFR 240.19b-4(f)(2).

⁶ 15 U.S.C. 78s(b)(3)(A).

⁷ 17 CFR 240.19b-4(f)(2).

Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEAmex-2009-54. 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEAmex-2009-54 and should be submitted on or before September 3, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-19375 Filed 8-12-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60456; File No. SR-Phlx-2009-63]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Extension of Sponsored Access Pilot Program

August 7, 2009.

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 29, 2009, NASDAQ OMX PHLX, Inc. (“Phlx” 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 Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to renew its sponsored access rule for a pilot period ending on October 29, 2009. The program expires on July 29, 2009.³ The text of the proposed rule change is available on the Exchange's Web site at <http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to attract additional business by renewing its sponsored access rule, which is similar to that of other exchanges. During the previous pilot program, no member organizations availed themselves of the program, but the Exchange seeks to make another attempt to institute the program, for a pilot period expiring October 29, 2009. The Exchange will evaluate whether to continue the sponsored access program or not.

A Sponsored Participant is a non-member of the Exchange, such as an institutional investor, that gains access to the Exchange and trades under a Sponsoring Member's execution and clearing identity pursuant to a sponsorship arrangement between such non-member and a member organization. Specifically, the Exchange proposes to permit Sponsored Participants to be sponsored by Sponsoring Member Organizations, and thereby access the Exchange, subject to certain requirements. These requirements are intended to confirm that the Sponsored Participant is required to and had procedures in place to comply with Exchange rules, and that the Sponsoring Member Organization takes responsibility for the Sponsored Participant's activity on the Exchange.

First, the Sponsored Participant and its Sponsoring Member Organization must have entered into and maintained an Access Agreement with the Exchange. The Sponsoring Member Organization must designate the Sponsored Participant by name in an addendum to the Access Agreement.

Second, there must be a Sponsored Participant Agreement between the Sponsoring Member Organization and the Sponsored Participant that contains the following sponsorship provisions, enumerated in full in Rule 1094(b)(ii):

(i) The orders of the Sponsored Participant are binding in all respects on the Sponsoring Member Organization;

(ii) The Sponsoring Member Organization is responsible for the actions of the Sponsored Participant;

(iii) In addition to the Sponsoring Member Organization being required to comply with the Exchange Certificate of Incorporation, By-laws, Rules and procedures of the Exchange, the Sponsored Participant shall do so as if such Sponsored Participant were an Exchange member organization;

(iv) The Sponsored Participant shall maintain, keep current and provide to the Sponsoring Member Organization a list of individuals authorized to obtain access to the Exchange on behalf of the Sponsored Participant;

(v) The Sponsored Participant shall familiarize its authorized individuals with all of the Sponsored Participant's obligations under this Rule and will assure that they receive appropriate training prior to any use or access to the Exchange;

(vi) The Sponsored Participant may not permit anyone other than authorized individuals to use or obtain access to the Exchange;⁴

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Release No. 59362 (February 5, 2009), 74 FR 6931 (February 11, 2009) (SR-Phlx-2009-10).

⁴ If the Exchange determines that an authorized individual has caused a Member Organization to

⁸ 17 CFR 200.30-3(a)(12).

(vii) The Sponsored Participant shall take reasonable security precautions to prevent unauthorized use or access to the Exchange, including unauthorized entry of information into the Exchange, and agrees that it is responsible for any and all orders, trades and other messages and instructions entered, transmitted or received under identifiers, passwords and security codes of authorized individuals, and for the trading and other consequences thereof;

(viii) The Sponsored Participant acknowledges its responsibility to establish adequate procedures and controls that permit it to effectively monitor its employees', agents' and Participants' use and access to the Exchange for compliance with the terms of this agreement;

(ix) The Sponsored Participant shall pay when due all amounts, if any, payable to Sponsoring Member Organization, the Exchange, or any other third parties that arise from the Sponsored Participant's access to and use of the Exchange. Such amounts include, but are not limited to applicable exchange and regulatory fees.

Third, the Sponsoring Member Organization must provide the Exchange with a Sponsored Participant Addendum to its Access Agreement acknowledging its responsibility for the orders, executions and actions of its Sponsored Participant at issue.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act⁶ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by helping market participants seeking access to a marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

violate the Exchange's Rules, the Exchange could direct the Member Organization to suspend or withdraw the person's status as an authorized individual.

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing 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 after the date of this filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and Rule 19b-4(f)(6) thereunder.⁸

A proposed rule change filed under 19b-4(f)(6) normally may not become operative prior to 30 days after the date of filing.⁹ However, Rule 19b-4(f)(6)(iii)¹⁰ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would allow the pilot program to continue uninterrupted. The Commission notes that the proposal is substantially similar to the rules of other national securities exchanges.¹¹ Accordingly, the Commission hereby grants the Exchange's request and designates the proposal operative upon filing.¹²

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

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(6).

⁹ 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied the five-day pre-filing notice requirement.

¹⁰ *Id.*

¹¹ See, e.g., International Securities Exchange, LLC Rule 706 and NYSE Arca, Inc. Rule 7.29.

¹² For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-Phlx-2009-63 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2009-63. 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, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2009-63 and should be submitted on or before September 3, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-19407 Filed 8-12-09; 8:45 am]

BILLING CODE 8010-01-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. USTR-2009-0022]

Implementation of the U.S.-EC Beef Hormones Memorandum of Understanding

AGENCY: Office of the United States Trade Representative.

ACTION: Notice, delay of action, and request for comments.

SUMMARY: On May 13, 2009, the United States and the European Communities ("EC") announced the signing of a Memorandum of Understanding (MOU) in the *Beef Hormones* dispute. Under the first phase of the agreement, the EC is obligated to open a new beef tariff-rate quota (TRQ) in the amount of 20,000 metric tons at zero rate of duty. The United States in turn is obligated not to increase additional duties above those in effect as of March 23, 2009. The EC opened the new beef TRQ on August 1, 2009. This notice undertakes the process necessary to implement U.S. obligations under the first phase of the MOU and to pursue additional market access under subsequent phases of the MOU.

DATES: *Effective Date:* A modified list of products subject to additional duties in connection with the *Beef Hormones* dispute (announced on January 15, 2009) had been scheduled to be effective with respect to products that are entered, or withdrawn from warehouse, for consumption on or after August 15, 2009. In order to meet U.S. obligations under the MOU, the United States Trade Representative ("Trade Representative") has now changed this effective date to September 19, 2009. Moreover, as explained below, the Trade Representative will take additional steps before that time in order to continue to implement U.S. obligations under the MOU.

FOR FURTHER INFORMATION CONTACT: Roger Wentzel, Director, Agricultural Affairs, (202) 395-6127 or David Weiner, Director for the European Union, (202) 395-4620 for questions concerning the *EC-Beef Hormones* dispute; or William Busis, Associate

General Counsel and Chair of the Section 301 Committee, (202) 395-3150, for questions concerning procedures under Section 301.

SUPPLEMENTARY INFORMATION:

A. Background

On January 15, 2009, the Trade Representative announced modifications ("January 15 modifications") to the action taken in July 1999 in connection with the World Trade Organization ("WTO") authorization of the United States in the *EC-Beef Hormones* dispute to suspend concessions and related obligations with respect to the European Communities ("EC"). See 74 FR 4265 (Jan. 23, 2009). The January 15 modifications initially had an effective date of March 23, 2009. The Trade Representative subsequently delayed the effective date of the additional duties imposed under the January 15 modifications to April 23, 2009; to May 9, 2009; and then to August 15, 2009. The effective date of the removal of duties under the January 15 modifications remained March 23, 2009. See 74 FR 11613 (March 18, 2009); 74 FR 12402 (March 24, 2009); 74 FR 19263 (April 28, 2009). As a result of removal of duties on March 23, 2009, a reduced list of products subject to additional duties (at a rate of 100 percent *ad valorem*) has been in place since that time. This reduced list is set out in the Annex to this notice. Under the first phase of the MOU, the United States maintains the right to impose these additional duties, and is obligated not to impose additional duties on any other products in connection with the *EC-Beef Hormones* WTO dispute.

The first phase of the MOU concludes on August 3, 2012. Under a possible second phase of the MOU, the EC would expand the beef TRQ to 45,000 metric tons, and the United States would suspend all of the additional duties imposed in connection with the *EC-Beef Hormones* WTO dispute.

For additional background concerning the *EC-Beef Hormones* WTO dispute; the January 15 modifications; and the prior delays in the effective date of the modifications, see 73 FR 66066 (Nov. 6, 2008); 74 FR 4265 (Jan. 23, 2009), 74 FR 11613 (March 18, 2009), 74 FR 12402 (March 24, 2009), 74 FR 19263 (April 28, 2009), and 74 FR 22626 (May 13, 2009). Further information on the May 13, 2009 U.S.-EC MOU may be found on USTR's Web site, <http://www.ustr.gov>.

B. Delay of Action

Pursuant to Section 305 of the Trade Act of 1974, the Trade Representative has determined that a further delay in implementation of the January 15

modifications would be desirable to obtain a satisfactory solution with respect to the EC's ban on U.S. beef. Accordingly, the Trade Representative has decided to delay the effective date of the additional duties imposed under the January 15 modifications from August 15, 2009 to September 19, 2009. The actions to be delayed are: (i) The imposition of increased duties on additional products, (ii) the application to products of additional EC member States of the increased duties on currently covered products, and (iii) the increase in the level of duties on one of the products that is being maintained on the product list. These are the same actions that were previously delayed until August 15, 2009.

The increased duties under the January 15 modifications are set out in Annex II of the notice published at 74 FR 12402 (March 24, 2009), as modified by the notice published at 74 FR 19263 (April 28, 2009). In order to delay the effective date of the increased duties until September 19, 2009, the Trade Representative has decided that the modifications to the Harmonized Tariff Schedule of the United States that are contained in Parts A and B of Annex II shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after September 19, 2009. As explained below, however, further steps are contemplated before that time. In addition, any merchandise covered under Part B of Annex II of the notice published at 74 FR 12402 that is admitted to a U.S. foreign-trade zone on or after September 19, 2009 must be admitted in "privileged foreign status" as defined in 19 CFR 146.41. Questions concerning customs matters may be directed to Renee Chovanec, International Coordination, Office of International Trade, U.S. Customs and Border Protection, (202) 863-6384.

C. Opportunity for Public Comments

Prior to September 19, 2009, the Trade Representative intends to take further steps under the Trade Act to implement U.S. obligations under the first phase of the MOU and to pursue additional market access under subsequent phases of the MOU. The Section 301 Committee seeks comments on these matters, including with regard to the imposition of 100 percent duties on the products currently subject to such duties throughout the remainder of the first phase of the MOU. (The list of products currently subject to 100 percent duties in connection with *EC-Beef Hormones* WTO dispute is set out in the Annex to this notice.) As noted above, the United States maintains the right to impose these additional duties

¹³ 17 CFR 200.30-3(a)(12).

during the first phase of the MOU, and under a possible second phase, the EC would expand the beef TRQ to 45,000 metric tons and the United States in turn would suspend all of the additional duties imposed in connection with the *EC-Beef Hormones* WTO dispute.

Any comments should be submitted by no later than September 12, 2009. To submit comments via <http://www.regulations.gov>, enter docket number USTR-2009-0022 on the home page and click "go". The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notice" under "Document Type" on the left side of the search-results page, and click on the link entitled "Send a Comment or Submission." (For further information on using the <http://www.regulations.gov> Web site, please consult the resources provided on the Web site by clicking on "How to Use This Site" on the left side of the home page.)

The <http://www.regulations.gov> site provides the option of providing comments by filling in a "General Comments" field, or by attaching a document. Given the detailed nature of the comments sought by the Section 301 Committee, all comments should be provided in an attached document. Submissions must state clearly the position taken and describe with specificity the supporting rationale and must be written in English. After

attaching the document, it is sufficient to type "See attached" in the "General Comments" field.

Interested persons may request a public hearing on these matters. Any request for a public hearing should be made by no later than August 20, 2009. In the event a hearing is to be held, USTR will issue a notice specifying the date of the hearing and the procedures for submitting written testimony.

Comments will be placed in the docket and open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15 or information determined by USTR to be confidential in accordance with 19 U.S.C. 2155(g)(2). Comments may be viewed on the <http://www.regulations.gov> Web site by entering docket number USTR-2009-0022 in the search field on the home page.

Persons wishing to submit business confidential information must certify in writing that such information is confidential in accordance with 15 CFR 2006.15(b), and such information must be clearly marked "BUSINESS CONFIDENTIAL" at the top and bottom of the cover page and each succeeding page. Any comment containing business confidential information must be accompanied by a non-confidential summary of the confidential information. The non-confidential summary will be placed in the docket

and open to public inspection. Comments containing business confidential information should not be submitted via the <http://www.regulations.gov> Web site. Instead, persons wishing to submit comments containing business confidential information should contact Sandy McKinzy at (202) 395-9483.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

- (1) Must clearly so designate the information or advice;
- (2) Must clearly mark the material as "SUBMITTED IN CONFIDENCE" at the top and bottom of the cover page and each succeeding page; and
- (3) Must provide a non-confidential summary of the information or advice.

The non-confidential summary will be placed in the docket and open to public inspection. Comments submitted in confidence should not be submitted via the <http://www.regulations.gov> Web site. Instead, persons wishing to submit such comments should contact Sandy McKinzy at (202) 395-9483.

William Busis,
Chair, Section 301 Committee.

BILLING CODE 3190-W9-P

ANNEX

EC-Beef Hormones - List of Products Currently Subject to Additional Duties

The products listed below are currently subject to 100 percent *ad valorem* duties in accordance with the WTO DSB authorization in the *EC-Beef Hormones* dispute. In all cases, the tariff nomenclatures in the HTS for the headings and subheadings listed below are definitive; the product descriptions in this list are for **information purposes only**.

Articles the product of Austria, Belgium, Denmark, Finland, France, the Federal Republic of Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, or Sweden:	
Meat of bovine animals, fresh or chilled (provided for in heading 0201):	
Articles of subheading 0201.10.05, 0201.10.10, 0201.20.02, 0201.20.04, 0201.20.06, 0201.20.10, 0201.20.30, 0201.20.50, 0201.30.02, 0201.30.04, 0201.30.06, 0201.30.10, 0201.30.30 or 0201.30.50	100%
Articles of subheading 0201.10.50, 0201.20.80 or 0201.30.80	100%
Meat of bovine animals, frozen (provided for in heading 0202):	
Articles of subheading 0202.10.05, 0202.10.10, 0202.20.02, 0202.20.04, 0202.20.06, 0202.20.10, 0202.20.30, 0202.20.50, 0202.30.02, 0202.30.04, 0202.30.06, 0202.30.10, 0202.30.30 or 0202.30.50	100%
Articles of subheading 0202.10.50, 0202.20.80 or 0202.30.80	100%
Meat of swine, fresh or chilled (provided for in subheading 0203.11, 0203.12 or 0203.19)	100%
Carcasses and half-carcasses of swine, frozen (provided for in subheading 0203.21) .	100%
Hams, shoulders and cuts thereof, with bone in, of swine, frozen (provided for in subheading 0203.22)	100%
Edible offal of bovine animals, fresh or chilled (provided for in subheading 0206.10)	100%
Edible offal of bovine animals, frozen (provided for in subheading 0206.21, 0206.22 or 0206.29)	100%
Roquefort cheese (provided for in subheading 0406.40.20 or 0406.40.40)	100%
Truffles, fresh or chilled (provided for in subheading 0709.59.10)	100%
Other prepared or preserved meat, meat offal or blood, of liver of any animal (provided for in subheading 1602.20)	100%

Articles the product of France:	
Hams, shoulders and cuts of meat of swine, with bone in, salted, in brine, dried or smoked (provided for in subheading 0210.11)	100%
Wool grease (other than crude wool grease) and fatty substances derived from wool grease (including lanolin) (provided for in subheading 1505.00.90)	100%
Chocolate and other food preparations containing cocoa, in blocks, slabs or bars, filled, weighing 2 kg or less each (provided for in subheading 1806.31)	100%
Lingonberry and raspberry jams (provided for in subheading 2007.99.05)	100%
Articles the product of Austria or France:	
Juice of any other single fruit, not elsewhere specified or included, not fortified with vitamins or minerals, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter (provided for in subheading 2009.80.60)	100%

[FR Doc. E9-19455 Filed 8-12-09; 8:45 am]

BILLING CODE 3190-W9-C

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC-2009-0009]

FEDERAL RESERVE SYSTEM

[Docket No. OP-1362]

FEDERAL DEPOSIT INSURANCE CORPORATION

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[Docket ID OTS-2009-0011]

NATIONAL CREDIT UNION ADMINISTRATION

Proposed Interagency Guidance—Funding and Liquidity Risk Management

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision, Treasury (OTS); and National Credit Union Administration (NCUA).

ACTION: Request for public comment; correction.

SUMMARY: This notice corrects the notice published on July 6, 2009 on the proposed guidance on funding and liquidity risk management. The Federal

Reserve is correcting the Affected Public and Estimated Burden sections of Part III (Paperwork Reduction Act) and the Office of the Comptroller of the Currency, Treasury; Board of Governors of the Federal Reserve System; Federal Deposit Insurance Corporation; Office of Thrift Supervision, Treasury; and National Credit Union Administration (the agencies) are correcting a footnote regarding the definition of “financial institution.”

DATES: Comments must be submitted on or before September 4, 2009.

FOR FURTHER INFORMATION CONTACT: James Embersit, Deputy Associate Director, Market and Liquidity Risk, 202-452-5249 or Mary Arnett, Supervisory Financial Analyst, Market and Liquidity Risk, 202-721-4534 or Brendan Burke, Supervisory Financial Analyst, Supervisory Policy and Guidance, 202-452-2987.

SUPPLEMENTARY INFORMATION: In the *Federal Register* issue of July 6, 2009 (74 FR 32035), the agencies, in conjunction with the Conference of State Bank Supervisors (CSBS), requested comment on the proposed guidance on funding and liquidity risk management (proposed Guidance). The proposed Guidance summarizes the principles of sound liquidity risk management that the agencies have issued in the past and, where appropriate, brings them into conformance with the “Principles for Sound Liquidity Risk Management and Supervision” issued by the Basel Committee on Banking Supervision (BCBS) in September 2008. While the BCBS liquidity principles primarily

focuses on large internationally active financial institutions, the proposed guidance emphasizes supervisory expectations for all domestic financial institutions including banks, thrifts and credit unions.

The Federal Reserve is correcting the Affected Public and Estimated Burden sections of Part III (Paperwork Reduction Act) to read:

Affected Public

FRB: Bank holding companies, state member banks, state-licensed branches and agencies of foreign banks (other than insured branches), and corporations organized or operating under sections 25 or 25A of the Federal Reserve Act (Agreement corporations and Edge corporations).

Estimate of Respondent Burden:

FRB: Number of respondents: 6,156 total (29 large (over \$100 billion in assets); 117 mid-size (\$10—\$100 billion); and 6,010 small (less than \$10 billion)).

Burden under Section 14: 720 hours per large respondent, 240 hours per mid-size respondent, and 80 hours per small respondent.

Burden under Section 20: 4 hours per month.

Total estimated annual burden: 825,248 hours.

In addition, the OCC, Board, FDIC, OTS, and NCUA are correcting footnote 4 (74 FR 32038) to read:

Unless otherwise indicated, this interagency guidance uses the term “financial institutions” or “institutions” to include banks, saving associations, credit unions, affiliated holding companies, state and federally chartered

U.S. branches and agencies of foreign banks, and Edge and agreement corporations. Federally insured credit unions (FICUs) do not have holding company affiliations and therefore references to holding companies contained within this guidance are not applicable to FICUs.

[THIS SIGNATURE PAGE PERTAINS TO THE NOTICE AND REQUEST FOR COMMENT TITLED, "PROPOSED INTERAGENCY GUIDELINES—FUNDING LIQUIDITY RISK MANAGEMENT."]

By order of the Board of Governors of the Federal Reserve System.

Robert deV. Frierson,

Deputy Secretary of the Board.

[THIS SIGNATURE PAGE PERTAINS TO THE NOTICE AND REQUEST FOR COMMENT TITLED, "PROPOSED INTERAGENCY GUIDELINES—FUNDING LIQUIDITY RISK MANAGEMENT."]

Dated: August 4, 2009.

John C. Dugan,

Comptroller of the Currency.

[THIS SIGNATURE PAGE PERTAINS TO THE NOTICE AND REQUEST FOR COMMENT TITLED, "PROPOSED INTERAGENCY GUIDELINES—FUNDING LIQUIDITY RISK MANAGEMENT."]

Dated at Washington, DC, the 3rd day of August, 2009.

By order of the Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[THIS SIGNATURE PAGE PERTAINS TO THE NOTICE AND REQUEST FOR COMMENT TITLED, "PROPOSED INTERAGENCY GUIDELINES—FUNDING LIQUIDITY RISK MANAGEMENT."]

Dated: August 7, 2009.

By the Office of Thrift Supervision.

John E. Bowman,

Acting Director.

[THIS SIGNATURE PAGE PERTAINS TO THE NOTICE AND REQUEST FOR COMMENT TITLED, "PROPOSED INTERAGENCY GUIDELINES—FUNDING LIQUIDITY RISK MANAGEMENT."]

Dated: August 3, 2009.

By the National Credit Union Administration Board.

Mary F. Rupp,

Secretary of the Board.

[FR Doc. E9-19406 Filed 8-12-09; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–New (0913)]

Proposed Information Collection (Applicant Background Survey): Comment Request

AGENCY: Human Resources and Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Human Resources and Administration (HRA), the Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each new collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to survey applicant for employment background information.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 13, 2009.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at <http://www.Regulations.gov> or to Thomas Middleton, Human Resources and Administration (06), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to thomas.middleton@va.gov. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Thomas Middleton at (202) 461-4036 or FAX (202) 501-2145.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, HRA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of its functions, including whether the information will have practical utility; (2) the accuracy of HRA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Applicant Background Survey, VA Form 0913.

OMB Control Number: 2900–New (0913).

Type of Review: New Collection.

Abstract: VA Form 0913 will be used to collect data needed for the planning and assessing affirmative employment program initiatives. The data will be used to report in an aggregated manner to the Equal Employment Opportunity Commission and to conduct aggregated adverse impact analysis to ensure VA's employment and selection decisions are fair and equitable.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,250 hours.

Estimated Average Burden Per Respondent: 5 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 15,000.

Dated: August 10, 2009.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9-19408 Filed 8-12-09; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

Geriatrics and Gerontology Advisory Committee;

Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92-463 (Federal Advisory Committee Act) that a meeting of the Geriatrics and Gerontology Advisory Committee will be held on September 10–11, 2009, in Room 630, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC. On September 10, the session will begin at 8:30 a.m. and end at 5 p.m. On September 11, the session will begin at 8 a.m. and end at 12 noon. This meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary of Veterans Affairs and the Under Secretary for Health on all matters pertaining to geriatrics and gerontology. The Committee assesses the capability of VA health care facilities and programs to meet the medical, psychological, and social needs of older Veterans and evaluates VA programs

designated as Geriatric Research, Education, and Clinical Centers.

The meeting will feature presentations and discussions on VA's geriatrics and extended care programs, aging research activities, update on the VA's geriatric workforce (to include training, recruitment and retention approaches), Veterans Health Administration (VHA) strategic planning activities in geriatrics and extended care, recent VHA efforts regarding dementia and program advances in palliative care, and performance and oversight of the VA Geriatric Research, Education, and Clinical Centers.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee not less than 10 days in advance of the meeting to Mrs. Marcia Holt-Delaney, Office of Geriatrics and Extended Care (114), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Individuals who wish to attend the meeting should contact Mrs. Holt-Delaney, Program Analyst, at (202) 461-6769.

Dated: August 11, 2009.

By Direction of the Secretary.

E. Philip Riggan,

Committee Management Officer.

[FR Doc. E9-19462 Filed 8-12-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Rural Health Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92-463 (Federal Advisory Committee Act) that the Veterans' Rural Health Advisory Committee will hold a meeting on September 2-3, 2009, in Capitol Room B at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC. The September 2 session will be from 8 a.m. to 4 p.m. and on September 3 the session will be from 8 a.m. to 11:30 a.m. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on health care issues affecting enrolled Veterans residing in rural areas. The Committee examines programs and policies that impact the provision of VA health care to enrolled Veterans residing

in rural areas, and discusses ways to improve and enhance VA services for these Veterans.

On September 2, the Committee will hear from VA officials such as the Director, Office of Rural Health, the Chief of Staff, a telehealth professional from the Office of Care Coordination, and a member of the Telehealth Outreach Clinic staff.

On September 3, the Committee will hear from VA officials such as the Chief Consultant on Telehealth from the Office of Care Coordination and a representative of the Office of General Counsel on the annual ethics review.

Interested parties should express in writing their desire to address the Committee not less than 10 days in advance of the meeting to Ms. Kara Hawthorne, Designated Federal Officer, 10A5, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, or by e-mail at rural.health.inquiry@va.gov.

Dated: August 10, 2009.

By Direction of the Secretary.

E. Philip Riggan,

Committee Management Officer.

[FR Doc. E9-19450 Filed 8-12-09; 8:45 am]

BILLING CODE 8320-01-P



Federal Register

**Thursday,
August 13, 2009**

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 312 and 316

**Charging for Investigational Drugs Under
and Investigational New Drug Application;
Expanded Access to Investigational Drugs
for Treatment Use; Final Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA-2006-N-0237] (formerly Docket No. 2006N-0061)

RIN 0910-AF13

Charging for Investigational Drugs Under an Investigational New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its investigational new drug application (IND) regulation concerning charging patients for investigational new drugs. This final rule revises the charging regulation to clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, to set forth criteria for charging for an investigational drug for the different types of expanded access for treatment use described in the agency's final rule on expanded access for treatment use of investigational drugs published elsewhere in this issue of the **Federal Register**, and to clarify what costs can be recovered for an investigational drug. This final rule will permit charging for a broader range of uses than was explicitly permitted previously.

DATES: This rule is effective October 13, 2009.

FOR FURTHER INFORMATION CONTACT:

For the Center for Drug Evaluation and Research: Colleen L. Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993-0002, 301-796-2270.

For the Center for Biologics Evaluation and Research: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

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- I. Alternatives
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I. Background

In the **Federal Register** of December 14, 2006 (71 FR 75168) (proposed rule), we proposed to amend our IND

regulation concerning charging patients for investigational new drugs (former § 312.7(d) (21 CFR 312.7(d))) and to add new § 312.8 (charging for investigational drugs). Under FDA's previous § 312.7(d), FDA could authorize charging for an investigational drug used in a clinical trial under an IND and for an investigational drug used in a treatment protocol or treatment IND:

- Former § 312.7(d)(1) provided that a sponsor that wished to charge for an investigational drug in a clinical trial needed to provide a full written explanation of why charging was necessary for the sponsor to undertake or continue the clinical trial, e.g., why distribution of the drug to test subjects should not be considered part of the normal cost of doing business.

- Former § 312.7(d)(2) described several conditions that needed to be met to charge for an investigational drug used under a treatment protocol or treatment IND.

- Former § 312.7(d)(3) provided that a sponsor could not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling of the investigational drug.

- Former § 312.7(d)(4) provided that FDA could withdraw authorization to charge if it determined that the conditions underlying the authorization were no longer being met.

In the preamble to the proposed rule, we identified three principal reasons for revising the previous charging regulation (the 1987 charging rule) (52 FR 19466, May 22, 1987).

First, the provisions of the 1987 charging rule concerning charging for investigational drugs in a clinical trial needed to be revised to take into account circumstances that were not anticipated when that original rule was adopted in 1987. FDA expected that requests to charge in a clinical trial would be limited to requests to charge for the sponsor's drug being tested in the trial. In fact, the agency received few such requests.

Far more common have been requests to charge for approved drugs in trials when the drugs needed to be obtained from another entity. These approved drugs may have been used in a trial of the sponsor's drug as an active control or in combination with the sponsor's drug. Even more common were requests to charge for approved drugs used in trials by a third party (not the holder of the approved application) that were intended to study new uses of the approved drug or to compare two drugs. FDA concluded that requests to charge for investigational drugs in these

situations may be appropriate, but that the criteria for evaluation of such requests are different from those that apply when the request to charge is for the sponsor's own drug being tested in a clinical trial. Accordingly, the agency concluded that the 1987 charging rule needed to be revised to provide criteria for charging for approved drugs used in clinical trials.

Second, the provisions of the 1987 charging rule related to treatment use allowed charging patients for investigational drugs only when those drugs were provided under a treatment IND or treatment protocol. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule that adds to part 312 (21 CFR part 312) a new subpart I concerning "Expanded Access to Investigational Drugs for Treatment Use" (referred to in this document as the "expanded access final rule" or "subpart I"). The expanded access final rule retains the treatment IND and treatment protocol provisions in the 1987 charging rule with minor modifications, and provides for two additional types of expanded access for treatment use: Expanded access for individual patients and expanded access for intermediate-size patient populations. The 1987 charging rule needed to be revised to provide authority to charge for investigational drugs for these two new categories of expanded access.

Third, the 1987 charging rule needed to be revised to specify the types of costs that can be recovered. The language of the 1987 charging rule was not very specific and did not provide sufficient guidance to sponsors on the costs that could be recovered. Moreover, because of the justifications for charging in a clinical trial differ from the justifications for charging for expanded access use, the agency believed that the costs appropriate for recovery would also differ.

The reasons FDA believed the 1987 charging rule needed to be revised are described more fully in the sections II.B, C, and D of the preamble to the proposed rule (71 FR 75168 at 75170 through 75171).

Accordingly, we proposed to remove paragraph (d) of former § 312.7 (paragraph (d) discussed charging for and commercialization of investigational drugs). We proposed to add new § 312.8 containing the following:

- General requirements for charging for investigational drugs,
- Specific requirements pertaining to charging for investigational drugs in a clinical trial,

- Requirements for charging for investigational drugs for treatment use under proposed subpart I (described in the proposed rule on expanded access to investigational drugs for treatment use (expanded access proposed rule) (71 FR 75147, December 14, 2006)), and

- Requirements for determining what costs can be recovered when charging for an investigational drug.

We received 40 comments on the charging proposed rule, which we address in section III of this document.

II. Overview of the Final Rule, Including Changes to the Proposed Rule

The final rule revises the charging regulation at § 312.7(d) and adds new § 312.8 to clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, to set forth criteria for charging for an investigational drug for the different categories of expanded access for treatment use described in the expanded access final rule, and to clarify what costs can be recovered for an investigational drug. This final rule specifies the types of investigational uses of a drug in a clinical trial under part 312 that require prior authorization to charge and provides criteria to authorize charging for each of the uses described in the expanded access final rule.

A. General Requirements for Charging

New § 312.8(a) describes the general requirements and conditions for charging for investigational new drugs. Except for sponsors charging for a drug obtained from another entity (as described below), a sponsor who wishes to charge for an investigational drug must do the following:

- Comply with the applicable requirements for the type of use for which charging is requested (either in a clinical trial or for expanded access) (§ 312.8(a)(1)),
- Provide justification that the amount to be charged reflects only those costs that are permitted to be recovered (§ 312.8(a)(2)), and
- Obtain prior written authorization from FDA (§ 312.8(a)(3)).

Section 312.8(a)(4) provides that FDA will withdraw authorization to charge if it determines that charging is interfering with the development of a drug for marketing approval or that the criteria for the authorization are no longer being met.

In response to comments, the final rule does not require sponsors who must obtain an approved drug from another entity for use in a clinical trial to obtain FDA approval to charge for the

drug or be otherwise subject to the requirements in new § 312.8.

B. Charging in Clinical Trials

Section 312.8(b) of the final rule describes specific requirements pertaining to charging for an investigational drug in a clinical trial, including investigational use of the sponsor's approved drug. The cost of an investigational drug used in a clinical trial is an anticipated cost of drug development and should ordinarily be borne by the sponsor. Therefore, FDA believes that charging should be permitted only when three circumstances are present, as described in § 312.8(b)(1) and as follows:

First, charging should be allowed only to facilitate development of a promising new drug or indication that might not otherwise be developed, or to obtain important safety information that might not otherwise be obtained. The preamble to the 1987 charging rule made clear that there should be compelling justification for taking the unusual step of allowing charging for unproven therapy during its development, stating that "cost recovery is justified in clinical trials only when necessary to further the study and development of promising drugs that might otherwise be lost to the medical armamentarium." (52 FR 19466 at 19472). FDA believes that philosophy should continue to apply to charging in a clinical trial in this final rule. Accordingly, § 312.8(b)(1)(i) requires that a sponsor wishing to charge for its investigational drug in a clinical trial provide some evidence of potential clinical benefit that, if demonstrated in clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation, or prevention of a disease or condition. Products that are likely to meet this criterion are also likely to be eligible for fast track development programs and priority review (see FDA's guidance for industry on "Fast Track Drug Development Programs—Designation, Development, and Application Review" (January 2006), including the priority review policies for the Centers for Drug Evaluation and Research and Biologics Evaluation and Research in Appendix 3 of that guidance (available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>)).

Second, charging should be permitted only for a trial that is necessary for the development of the drug. Therefore, § 312.8(b)(1)(ii) requires that the sponsor demonstrate that the data to be obtained from the clinical trial would be essential to establishing that the drug is effective

or safe for the purpose of obtaining initial marketing approval of the drug, or that it would support a significant change in the labeling of the sponsor's approved drug. For example, the trial could be designed to provide data that would support approval of a new indication or generate important comparative safety information.

Third, charging must be necessary to the conduct of the clinical trial. Under § 312.8(b)(1)(iii), a sponsor is required to demonstrate that clinical development of the drug could not be continued without charging because the cost of the drug is extraordinary. The cost of the drug may be extraordinary because of manufacturing complexity, scarcity of a natural resource, the large quantity of drug needed (e.g., due to the size or duration of the trial) or some combination of these or other circumstances. In response to comments, this extraordinary cost criterion for charging for the sponsor's drug in a clinical trial has been revised to clarify that the resources of an individual sponsor are considered in determining whether cost is extraordinary.

Section 312.8(b)(2) provides that the authorization to charge for a drug in a clinical trial would ordinarily continue for the duration of the clinical trial because it is unlikely that the need for charging would change during the course of the trial. However, § 312.8(b)(2) gives FDA the discretion to specify a duration shorter than the length of the trial. FDA may specify a shorter duration if, for example, there is a particular concern that the authorization to charge has the potential to delay the development of a drug for marketing approval.

C. Charging for Expanded Access to Investigational Drugs for Treatment Use

Section 312.8(c) sets forth the criteria for charging for the three types of expanded access to investigational drugs for treatment use described in subpart I of part 312 (the expanded access final rule). Part 312, subpart I describes two types of treatment use (expanded access for individual patients and expanded access for intermediate-size patient populations) not previously described in FDA's regulations and, therefore, not specifically contemplated by the 1987 charging rule. FDA's goal in permitting charging for the treatment uses described in subpart I is to facilitate access to investigational drugs in situations in which a sponsor might not be able to provide a drug for such use absent charging, or to facilitate broader access to an investigational drug

for treatment use than would be possible absent charging.

The agency's principal concern with charging patients in expanded access settings for investigational drugs is that charging not interfere with the development of drugs for commercial marketing. Accordingly, § 312.8(c)(1) requires a sponsor wishing to charge for an investigational drug for any of the three types of expanded access under part 312, subpart I to provide reasonable assurance that charging will not interfere with developing the drug for marketing approval.

For the types of expanded access to investigational drugs described in proposed subpart I, FDA believes it is less likely that the limited numbers of patients who might obtain individual patient expanded access to an investigational drug (§ 312.310) or intermediate-size patient population expanded access (§ 312.315) would impede development of a drug or indication. The potential to interfere with drug development is greatest for treatment use under a treatment IND or treatment protocol (§ 312.320).

Treatment INDs or treatment protocols can attract large numbers of patients and thus have the potential to significantly affect enrollment in the clinical trials needed to establish safety and effectiveness. Accordingly, § 312.8(c)(2) sets forth specific information that would be required to reasonably assure FDA that charging for an investigational drug under a treatment IND or treatment protocol will not interfere with drug development. Sponsors are required to provide evidence of sufficient enrollment in any ongoing clinical trials needed for marketing approval to reasonably assure FDA that the trials will be completed as planned (§ 312.8(c)(2)(i)). Sponsors are also required to provide evidence of adequate progress in the development of the drug for marketing approval (§ 312.8(c)(2)(ii)). Such evidence could include successful meetings with FDA before submission of a new drug application (NDA), submission of an NDA, or completion of other significant drug development milestones. Sponsors are also required to submit information under their general investigational plans (§ 312.23(a)(3)(iv)) specifying the drug development milestones they plan to meet in the coming year (§ 312.8(c)(2)(iii)).

Section 312.8(c)(3) specifies that the authorization to charge be limited to the number of patients authorized to receive the drug for treatment use, if there is a limitation. For example, the authorization to charge for an investigational drug under an individual

patient expanded access submission is limited to a single patient. Similarly, the authorization to charge under an intermediate-size patient population expanded access submission is limited to the number of patients permitted to receive the drug under that particular intermediate-size patient population expanded access IND or protocol.

Section 312.8(c)(4) provides that FDA will ordinarily authorize charging for expanded access for treatment use under part 312, subpart I to continue for 1 year from the time of FDA authorization and that FDA may reauthorize charging for additional periods upon request. It also provides FDA the discretion to specify a shorter authorization. The final rule limits the authorization to charge to a period of 1 year or less to permit the agency to periodically assess whether the criteria for charging continue to be met. FDA anticipates that it will exercise its discretion to specify a shorter duration when there is a particular concern that charging could interfere with drug development.

D. Recoverable Costs

Section 312.8(d) describes the kinds of costs that are recoverable when charging for an investigational drug in a clinical trial and for expanded access for treatment use under part 312, subpart I. The purpose of permitting charging for an investigational drug in a clinical trial is to permit a sponsor to recover the costs of making a drug available to study subjects when those costs are extraordinary. Thus, § 312.8(d)(1) limits cost recovery to the direct costs of making the investigational drug available in these situations. Indirect costs can not be recovered.

Section 312.8(d)(1)(i) describes direct costs as costs incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.

Indirect costs are costs that are not attributable solely to making the drug available for the investigational use for which charging is requested (for example, expenditures for physical plant and equipment that are incurred primarily for the purpose of producing large quantities of the drug for commercial sale after approval, or for

making the drug available for a variety of investigational uses). Indirect costs are not appropriate for cost recovery for investigational uses because these costs would be incurred even if the clinical trial or expanded access use for which charging is authorized did not occur. Section § 312.8(d)(1)(ii) states that indirect costs include costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of the drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

Sponsors who provide investigational drugs for expanded access for treatment use for intermediate-size patient populations and for treatment INDs and treatment protocols incur costs in addition to the anticipated and ordinary costs of drug development. The purpose of permitting cost recovery for expanded access use is to encourage sponsors to make investigational drugs available for treatment use. Thus, § 312.8(d)(2) permits a sponsor to recover the costs of administering treatment use programs for intermediate-size patient populations and for treatment INDs and treatment protocols, as well as the direct costs of the drug. The final rule does not authorize sponsors to recover administrative costs associated with expanded access for individual patients because these costs would be so minor. Section 312.8(d)(2) provides that in addition to the direct costs of the drug described in § 312.8(d)(1), a sponsor may recover the costs of monitoring the expanded access use, complying with IND reporting requirements, and other administrative costs directly associated with making a drug available for treatment use under §§ 312.315 and 312.320.

Section 312.8(d)(3) provides that, to support its calculation for cost recovery, a sponsor must provide supporting documentation to show that the cost calculation is consistent with the relevant requirements in § 312.8(d). The proposed rule has been revised to state that the documentation must be accompanied by a statement that a certified public accountant has reviewed and approved the calculations.

III. Comments on the Proposed Rule

A. Overview of Comments

The agency received 40 comments on the proposed rule. Comments were

received from individuals (persons with serious diseases,¹ persons with family members with serious diseases, and other interested persons), health care and consumer advocacy organizations, pharmaceutical and biotechnology companies, health insurance companies, trade organizations, a State government, an academic medical center, and a venture capital company.

Some comments from individuals were supportive of the charging regulation to the extent that it may make it easier to develop drugs for serious diseases in some cases and make investigational drugs more broadly available for treatment use under expanded access programs. Other comments from individuals were concerned that charging, in the absence of reimbursement for investigational drugs by health insurance companies, would limit enrollment in clinical trials and expanded access programs to those who can afford to pay for the drug.

Health care and consumer advocacy organizations were generally supportive of the proposed rule. Some stated that the rule struck the appropriate balance between facilitating development of costly therapies, including drugs for rare diseases, and increasing access to investigational drugs for treatment use. One advocacy organization expressed concern about the effects of charging on equitable access across different economic strata, arguing that the ability to enroll in clinical trials and expanded access programs may be restricted to wealthier individuals. One organization was skeptical of the agency's assertion that facilitating charging for investigational drugs made available under expanded access programs would increase access.

FDA believes this final rule will facilitate development of some costly therapies that might not have been developed absent cost recovery and will encourage expanded access programs. FDA also acknowledges, however, that the rule has the potential to create certain inequities. Issues related to equitable access are discussed in greater detail in responses to comments 36 through 39.

The major concerns of pharmaceutical and biotechnology companies and their trade organizations were the requirements pertaining to charging for approved drugs being evaluated in a clinical trial under an IND. These companies were most concerned with the requirements pertaining to charging for approved drugs that must be

obtained from another entity for use in a trial. An academic medical center was very supportive of FDA's efforts to clarify the charging requirements pertaining to approved drugs used in a trial under an IND. As discussed in greater detail in responses to comments 27 and 31, FDA has revised the proposed rule so that sponsors need not obtain authorization from FDA to charge for approved drugs obtained from another entity not affiliated with the sponsor.

The primary concern of health insurance companies and their trade organization was that the new charging regulation may create pressure on third-party payers to reimburse, or lead to legislation requiring them to reimburse, for investigational drugs.

Reimbursement issues are discussed in greater detail in comments 63 through 65.

A major concern for a small biotechnology company, a venture capital firm, and a State health agency was the narrowing of the cost recovery provision in the proposed rule to permit recovery of direct costs only for an investigational drug used in a clinical trial, and to specifically exclude recovery of substantial capital expenditures incurred for purposes of large-scale manufacturing and general research and development costs. These comments were concerned that this narrowing would make it more difficult for entities with limited resources to develop expensive new therapies. FDA continues to believe that these expenditures are not appropriate for cost recovery during the development of a new drug. These concerns are discussed in greater detail in responses to comments 1 and 46.

B. General Comments

(Comment 1) Two comments stated that charging for investigational drugs to treat rare diseases or conditions (orphan drugs) should be subject to less stringent criteria than charging for drugs to treat non-orphan diseases. The comments maintained that drugs to treat orphan diseases are commonly developed by small companies or not-for-profit entities that have limited or no ability to raise money from capital markets. Therefore, less restrictive charging criteria are needed to permit these entities to recover their development costs.

(Response) FDA does not believe there is justification for different and less stringent cost recovery criteria for investigational drugs for orphan diseases than non-orphan diseases. As stated in the preamble to the proposed rule, FDA does not believe that charging

¹ Unless otherwise indicated, "serious diseases" in this final rule refers to serious or immediately life-threatening diseases or conditions.

for an investigational drug in clinical studies intended to support approval of the drug is the appropriate mechanism to recoup research and development costs beyond those costs directly associated with making the drug available under criteria described in this charging rule (71 FR 75168 at 75171) (see response to comment 46 for further discussion). FDA believes sponsors intending to develop orphan products should pursue orphan product designation from FDA to assist with development and recovery of investment (21 CFR part 316). Such designation provides for tax credits for the costs of clinical research associated with development of an orphan drug and 7 years of marketing exclusivity after an orphan drug is approved. In addition, sponsors that obtain orphan designation may be eligible to receive grants from FDA of up to \$350,000 per year for 4 years to defray directly the costs of clinical research (for more information, see Office of Orphan Products Development, <http://www.fda.gov/orphan/index.htm>). Moreover, orphan designation and grant funds from FDA often provide incentives for additional investment from other sources. This final rule is intended only to address the situation in which the cost of the drug itself is so high that a sponsor needs to recover costs associated with making the drug available to be able to conduct or continue the trial.

(Comment 2) One comment mentioned that it is not clear if the rule applies to both unapproved drugs and approved drugs under investigation for new indications.

(Response) The rule applies to both unapproved drugs and, in certain situations, approved drugs under investigation for new indications (see also response to comment 4).

(Comment 3) One comment suggested that to improve the readability of the proposed rule, the rule should have different provisions for company-sponsored expanded access programs than for investigator-sponsored expanded access programs. The comment also suggested that there should be different provisions for new molecular entities than for approved products being studied for new indications.

(Response) FDA does not believe there is a need for separate provisions for expanded access depending on whether the sponsor of the IND is a manufacturer or a noncommercial sponsor such as an individual physician. In either case, FDA's primary concern is whether the IND would somehow interfere with drug

development, so the criteria would be the same for both groups. We also do not believe that separate provisions are needed regarding the amount charged because, in both cases, the amount charged would be limited to costs.

Based on changes made to the proposed rule, FDA also does not believe there is any need to divide the rule into requirements applicable to charging for new molecular entities and requirements applicable to charging for approved drugs under investigation for new uses. FDA has revised the proposed rule to eliminate the requirement that a sponsor who obtains an approved drug from another source to use in a trial as an active control or in a trial intended to obtain additional information about the approved drug (e.g., to study a new indication, to study a safety endpoint) must obtain prior authorization to charge for the approved drug when used for an investigational purpose (see comments 27 and 31). FDA has retained the requirement that a sponsor obtain permission to charge for its own approved drug in a trial of that drug. In this scenario, FDA believes the same criteria as would apply to charging for an unapproved drug should apply. Therefore, a separate provision is not needed.

(Comment 4) One comment stated that the proposed rule's restrictions on charging should not apply to approved drugs and that investigators and others charging for approved drugs should be permitted to charge their usual amounts and to receive the customary insurance reimbursement. The comment also noted that restricting charges for approved drugs in clinical trials would be administratively burdensome to investigators.

(Response) FDA agrees in part and disagrees in part. FDA agrees that a sponsor that is not the marketer of an approved drug (i.e., is not the entity that holds the approved application) should not be required to obtain FDA approval to charge for the drug when it is used in a clinical trial for any purpose—e.g., used for its approved indication as an active control or in a trial of a new indication for the drug (see comments 27 and 31 discussing in greater detail the revision to the final rule to accommodate this change). Accordingly, the provisions in the proposed rule requiring prior authorization to charge in these situations have been deleted from this final rule. However, FDA believes a sponsor seeking to charge for its own approved drug in a trial of a new use or to obtain important safety information about the drug should be treated differently. In these situations, the sponsor is ordinarily conducting the

trial to enhance or preserve the commercial value of the drug. Therefore, as is the case with a request to charge for a new molecular entity, the sponsor should be required to overcome the presumption that the cost of the drug is a normal cost of the business of drug development, a cost that should ordinarily be borne by the sponsor of the trial. Therefore, FDA believes the sponsor should be required to obtain prior authorization to charge and should meet the same burden for charging for the approved drug in a clinical trial as it would be required to meet for charging for a new molecular entity. That is, the requirements in § 312.8(b)(1) apply with equal force to charging for the sponsor's unapproved drug and charging for the sponsor's approved drug in a trial of a new use or a trial that could otherwise result in an important labeling change. It is beyond the scope of the regulation and FDA's authority to regulate insurance reimbursement with respect to clinical trials involving approved drugs.

C. General Criteria for Charging

Proposed § 312.8(a) set forth the general requirements and conditions for charging for investigational drugs. A sponsor that wishes to charge for an investigational drug must:

- Comply with the applicable requirements for the type of use for which charging is requested (either in a clinical trial or for expanded access) (proposed § 312.8(a)(1)).
- Provide justification that the amount to be charged reflects only those costs that are permitted to be recovered (proposed § 312.8(a)(2)), and
- Obtain prior written authorization from FDA (proposed § 312.8(a)(3)).

1. Justification for the Amount To Be Charged

(Comment 5) One comment asked that the following language be added at the end of § 312.8(a)(2) and (c)(1) of the proposed rule: "Any such charges found to be recoverable costs as determined under [§ 312.8(d)] shall be minimized and/or terminated to the greatest degree or at the earliest opportunity possible consistent with the criteria in this rule. If circumstances supporting charging under this rule are no longer met, charging shall terminate."

(Response) FDA does not believe it is necessary to insert additional language concerning how long and how much to charge because the language essentially repeats the requirements that are already in other parts of the rule. Section 312.8(b)(2) and (c)(4) of the final rule specify how long it is permissible to charge in a clinical trial and for an

expanded access use, respectively. Section 312.8(a)(4) permits FDA to withdraw the authorization to charge at any time if it determines that charging is interfering with the development of a drug for marketing approval or that the criteria for the authorization are otherwise no longer being met. Section 312.8(d) specifies what costs can be recovered during whatever time period charging is authorized.

2. Prior Written Authorization to Charge

The requirement in the proposed rule to obtain prior written authorization from FDA to charge for any investigational drug is a change from the requirements under the 1987 charging rule. Under the 1987 charging rule, a sponsor was required to obtain prior written authorization to charge for an investigational drug in a clinical trial (§ 312.7(d)(1)), but a sponsor of a treatment IND or a treatment protocol under § 312.34 was permitted to commence charging 30 days after receipt by FDA of an information amendment concerning charging, unless FDA notified the sponsor to the contrary (§ 312.7(d)(2)).

(Comment 6) One comment requested that FDA retain the provision in the 1987 charging rule (§ 312.7(d)(2)) that allowed authorization to charge for an investigational drug under a treatment IND or treatment protocol to go into effect automatically 30 days after receipt by FDA of the information amendment, unless the sponsor is notified to the contrary by FDA (§ 312.7(d)(2)), and further, that FDA make this provision applicable to all expanded access uses. The comment argued that the requirement for prior authorization would result in delay in the availability of investigational drugs for expanded access uses. One comment requested that FDA add the following language after the provision requiring prior written authorization to charge for an investigational drug: "Such authorization shall not be unreasonably withheld." Two comments agreed with FDA's decision to require prior written authorization from FDA to charge for drugs obtained through expanded access programs.

(Response) FDA does not agree that charging for expanded access uses should be permitted without prior written authorization to charge from FDA. FDA believes it is important to determine, in advance of any patient being charged, that the criteria for charging are met (in particular, the requirement that charging not interfere with drug development) and that the amount to be charged is consistent with the cost recovery requirements.

FDA also does not believe that this provision will delay access to investigational therapies by patients with serious diseases who lack therapeutic alternatives. When there is a pressing need for cost recovery to make an investigational therapy available, FDA will ordinarily be able to expedite review of a charging request. For a new IND, FDA anticipates that, in most cases, it will be able to make a charging determination at the same time it makes a determination on the underlying expanded access IND. When the need to charge becomes evident after an expanded access IND is ongoing, FDA anticipates that a sponsor would be able to foresee the need to charge sufficiently far in advance of that need to be able to make a charging submission and obtain a timely FDA determination.

FDA also does not believe it is necessary to specify that the authorization to charge "shall not be unreasonably withheld." The Administrative Procedure Act provides that an agency decision may be set aside by the courts if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" (5 U.S.C. 706(2)(A)). The agency believes this language provides the appropriate standard for FDA's decision of whether to allow charging for an investigational drug.

3. Withdrawal of Authorization to Charge

Proposed § 312.8(a)(4) specified that FDA will withdraw the authorization to charge if it determines that charging is interfering with the development of a drug for marketing approval or that the criteria for the authorization are otherwise no longer being met.

(Comment 7) One comment recommended that the rule include an additional requirement specifying that FDA notify the sponsor of a proposal to withdraw authorization to charge and that FDA provide the sponsor an opportunity to respond.

(Response) FDA expects in most cases to provide reasonable notice before withdrawing an authorization to charge to allow sponsors an opportunity to address the agency's concerns. We are not amending the proposed rule as requested, however, because the agency believes we should have the flexibility, when warranted, to withdraw an authorization to charge without providing advance notice to the sponsor. Sponsors can request review of FDA's withdrawal of an authorization to charge using dispute resolution processes.

4. Lack of Timeframe for FDA Response

(Comment 8) Two comments recommended that the final rule include a general timeframe for FDA to decide whether to permit charging. One of the comments recommended that FDA decide all charging requests within 30 to 60 days.

(Response) FDA does not believe it should commit to a specified time period for review that would apply to all charging requests. In many cases, FDA anticipates being able to make a determination on a request to charge at the same time it responds to the underlying IND submission (when the submissions are made at the same time). However, in FDA's experience, charging requests can present challenging issues that require some discussion between FDA and the sponsor. Thus, it is difficult to estimate reliably a time period for making a charging request determination that would apply uniformly to all charging requests. For this reason, FDA is not prepared to commit to a 30-day timeframe for making charging request determinations. FDA also does not foresee the need for a 60-day maximum review time.

D. Charging in a Clinical Trial

Proposed § 312.8(b) described specific requirements pertaining to charging for an investigational drug in a clinical trial. This provision described criteria for charging for an investigational drug in three situations:

- Charging for the sponsor's own drug in a clinical trial (§ 312.8(b)(1)).
- Charging for an approved drug that a sponsor must obtain from another entity for use as an active control or in combination with another drug in a clinical trial designed to evaluate the safety and effectiveness of the sponsor's investigational drug (§ 312.8(b)(2)), and
- Charging for an approved drug that must be obtained from another entity in a clinical trial designed to evaluate the approved drug (e.g., for another indication) (§ 312.8(b)(3)).

1. General Comments

(Comment 9) Several comments stated that permitting charging for the investigational drug in clinical trials would make it even more difficult to enroll subjects into clinical trials and, therefore, could increase the time to complete trials and delay bringing new drugs to market. Three comments stated that charging could discourage enrollment by patients who lack the resources to pay for the investigational drug. One comment stated that charging for nonreimbursed, investigational

therapies could discourage physicians from recommending enrollment in trials to their patients who are eligible.

(Response) As was the case with the prior charging rule, the provisions concerning charging for the sponsor's investigational drug in this final rule are intended to help sponsors develop important new therapies that would be very difficult or impossible to develop absent charging. In FDA's experience, sponsors have rarely found it necessary to charge for such therapies in clinical trials to develop a drug for marketing approval. FDA anticipates that charging for the sponsor's drug in a clinical trial will continue to be an unusual circumstance. FDA recognizes that charging could make it difficult to enroll subjects in clinical trials and may have a disproportionate impact on enrollment of patients who cannot afford to pay for the investigational drug. FDA expects, however, that sponsors will monitor clinical trial accrual rates and take whatever steps are necessary to ensure that subjects are able to enroll. For example, in FDA's experience, sponsors who have charged for an investigational drug in a clinical trial have made provision to enroll subjects unable to pay.

(Comment 10) Two comments stated that the financial burden for conducting clinical trials, including supplying the investigational drug, should be carried by the sponsors, who stand to benefit from the drug if commercialized.

(Response) FDA agrees that, in most circumstances, sponsors should bear the costs of making an investigational drug available in a clinical trial. The preamble to the proposed rule stated: "Generally, the costs of conducting a clinical trial are costs that the sponsor should bear. Conducting a clinical trial is part of the drug development process, and drug development is an ordinary business expense for a commercial sponsor" (71 FR 75168 at 75170). The preamble to the proposed rule also clarified that the philosophy underlying the 1987 charging rule—that charging for an investigational drug in a clinical trial should be an exceptional circumstance and justified only when necessary to further the study of a promising drug that might otherwise not be developed—was intended to apply to this charging rule (71 FR 75168 at 75170).

(Comment 11) One comment stated that FDA should include in the codified portion of the rule the language from the preamble of the 1987 charging rule that: "FDA * * * [presumes] that supplying investigational drugs to subjects participating in clinical trials without

charge is part of the normal cost of doing business."

(Response) FDA does not believe it is necessary to include the suggested language in this final rule. The preamble to the proposed rule contained language similar to the language in the preamble to the 1987 charging rule, stating that: "Generally, the costs of conducting a clinical trial are costs that the sponsor should bear. Conducting a clinical trial is part of the drug development process, and drug development is an ordinary business expense for a commercial sponsor" (71 FR 75168 at 75170). Thus it is clear that FDA intends that the presumption that the cost of an investigational drug should ordinarily be borne by the sponsor and charging is justified only in exceptional circumstances be carried forward to this rule. That presumption is implicit in the stringent criteria in § 312.8(b)(1) for allowing charging for a sponsor's drug in a clinical trial. FDA does not believe it is necessary to state the presumption in the codified language.

(Comment 12) One comment stated that FDA should consider working with pharmaceutical firms to develop better ways of funding clinical trials of investigational drugs. The comment recommended that FDA evaluate practical ways the pharmaceutical industry can fund patient expenses for investigational drugs used in clinical studies and that one option would be for FDA to evaluate the viability of establishing a common patient pool funded by pharmaceutical firms on a voluntary or required basis.

(Response) The agency believes that the comment raises a valid concern. This charging rule is intended to allow a sponsor to recover its costs associated with making an investigational drug available to clinical trial subjects when the cost of the drug is so high that the study could not be conducted without charging. The rule is not intended to help defray other costs associated with the conduct of a trial. However, in FDA's experience, the drug cost is usually not the largest expense associated with clinical trials. Typically, the costs of administering and monitoring a clinical trial are much greater than the cost of the drug. At present, FDA is focusing its collaborative efforts with industry on improving the efficiency of the clinical trial process through various Critical Path programs (e.g., Clinical Trial Transformation Initiative, <http://www.fda.gov/oc/initiatives/criticalpath/clinicaltrials.html>). FDA encourages efforts to develop alternative mechanisms to finance important clinical research by private sector

interests or nonregulatory governmental bodies, but believes such efforts would be best administered by private sector interests or nonregulatory governmental bodies.

(Comment 13) One comment recommended that the title of the rule be changed from "Charging for Investigational Drugs" to "Charging for Drugs Used in Clinical Trials" because the rule also would permit sponsors to charge for approved drugs, which, the comment asserts, are not investigational.

(Response) FDA disagrees. The rule addresses charging for investigational drugs both in clinical trials and in expanded access programs under new subpart I. Because the recommended title would seem to exclude expanded access uses, that title is too narrow. Moreover, the use of an approved drug in a trial of a new use is an investigational use and thus clearly covered by the rule and its title. See response to comment 15 for discussion of a minor change to the section's title.

(Comment 14) Two comments stated that permitting charging for an investigational drug in a clinical trial—because it might exclude economically disadvantaged persons from trial participation—could exacerbate existing problems with underrepresentation of economically disadvantaged and minorities in such trials, and thus may limit generalizability of trial results.

(Response) FDA does not believe that inability to participate in a clinical trial because a subject cannot pay for the drug will have a meaningful effect on generalizability of trial results. Many factors affect participation in clinical trials, including geographic location, ability to qualify for the trial, demographic representation at trial sites, and an insufficient number of slots for all who might like to participate. The effects of charging on the nature of the trial population would probably be of limited significance relative to other factors that could affect generalizability. In addition, in FDA's experience, sponsors that charge subjects for investigational drug in a clinical trial typically make provision for subjects who are unable to pay for the drug, thus mitigating any potential effect on generalizability due to underrepresentation of individuals from lower economic strata.

(Comment 15) Two comments recommended that the rule include a provision stating that the rule does not apply to clinical trials that are exempt from the requirement to have an IND.

(Response) FDA did not intend that the charging regulation apply to clinical trials that are exempt from the IND requirements under § 312.2(b). To make

this clearer, FDA has changed the title of § 312.8 to “Charging for investigational drugs under an IND.”

(Comment 16) Two comments stated that permitting charging for unapproved drugs in clinical trials has the potential to adversely affect FDA resources.

(Response) As discussed in greater detail in section I of this document, FDA believes it is important to provide an option to charge for investigational drugs in certain circumstances and, also, that it is important for FDA to regulate charging to prevent commercialization of unapproved drugs and unapproved indications. In FDA’s years of experience reviewing charging requests under the 1987 charging rule, such requests have been infrequent and the resources required to conduct such reviews did not have a negative effect on FDA’s mission to ensure the safety and effectiveness of new drugs. The proposed rule expanded the scope of INDs for which sponsors may seek cost recovery to include the three types of expanded access INDs under new subpart I. However, in response to comments, the final rule no longer requires sponsors that must obtain an approved drug from another entity to obtain FDA authorization to charge for that approved drug. Thus, FDA anticipates only a modest increase in the number of requests to charge due to this final rule.

In addition, the cost calculation was perhaps the most time-consuming aspect of preparing and reviewing charging requests under the 1987 charging rule. This final rule clarifies and simplifies the scope of recoverable costs. Thus, FDA anticipates that it will typically take less time to prepare and review a charging submission under the new rule than under the 1987 charging rule.

(Comment 17) One comment stated that the rule should differentiate between different phases of testing of an unapproved drug because the justification for allowing recovery and the supporting evidence will vary for different clinical trials in different phases of drug development.

(Response) FDA believes the criteria described in § 312.8(b)(1) concerning charging for a sponsor’s drug provide sufficient flexibility to evaluate requests to charge for a drug in clinical trials in different phases of drug development (also see response to comment 19 discussing the variable basis for assessing whether a drug has a potential clinical benefit that would be a significant advantage over available products and response to comment 20 discussing when a clinical trial would

be considered essential to establishing that the drug is effective and safe).

2. Charging for the Sponsor’s Own Drug in a Clinical Trial

Proposed § 312.8(b)(1) set forth three criteria, in addition to the general criteria in § 312.8(a), that needed to be met to permit a sponsor to charge for its own investigational drug in a clinical trial.

a. *Significant advantage over available therapy.* Section 312.8(b)(1)(i) of the proposed rule provided that a sponsor who wishes to charge for its investigational drug, including investigational use of its approved drug, must provide evidence that the drug has a potential clinical benefit that, if demonstrated in the clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation, or prevention of a disease or condition.

(Comment 18) One comment stated that this criterion is not meaningful as it would apply to all drugs that are selected to be developed by pharmaceutical and biotechnology companies.

(Response) FDA does not agree that all drugs selected to be developed for marketing offer a potential significant advantage over available therapy. Companies often deliberately develop drugs that offer only modest advantages over existing therapy or appear to be similar to existing therapy. There may be good commercial and clinical reasons to pursue such development. For example, there is likely to be variation in response to a pharmacologic intervention, both in desired treatment effect and incidence of adverse effects, in different individuals. Thus, the availability of similar therapies can provide alternatives for those who have inadequate responses to a drug or experience an adverse reaction even if a significant advantage has not been clinically shown for any of the therapies. This criterion is intended to distinguish those types of drugs from those for which there are preliminary clinical data suggesting a significant advantage in the therapy for a given disease and for which the development program is geared toward establishing that advantage.

(Comment 19) One comment asked for clarification about the type and degree of evidence needed to show a significant advantage, especially at the beginning of large phase 3 trials. Another comment recommended that this criterion concerning a significant advantage be replaced with “evidence of potential advantage over available therapy.” The

comment stated that the significant advantage standard would be likely to prevent a sponsor from charging for its own drug because the standard presumes that comparative studies have been conducted against all the other products.

(Response) The amount and type of data needed to demonstrate a potential clinical benefit that would be a significant advantage over existing therapy will vary with the stage of development. For a request to charge for a large phase 3 trial, ordinarily the clinical data developed in phase 2 will need to confirm or be consistent with a potential significant advantage to satisfy this criterion. For a request to charge for a trial in an earlier phase of development, more preliminary data consistent with a potential significant advantage will suffice. FDA does not agree that comparative data will always be necessary to demonstrate a potential significant advantage over existing therapy. The agency believes that the need to provide comparative data is a matter of judgment. For example, there may be noncomparative phase 2 data and a plausible pharmacologic basis that suggest a significant advantage over existing therapy, and the phase 3 trial for which charging is requested may be a comparative design intended to demonstrate that advantage. Similarly, comparative data are not needed if the drug is intended to treat a disease or subpopulation with a disease, for which there is no satisfactory existing therapy (see also FDA guidance for industry entitled “Fast Track Development Programs—Designation, Development, and Application Review” (June 2006), especially section III.B.2, discussing demonstrating a drug’s potential at various stages of development).

FDA also does not agree that charging for an investigational drug in a clinical trial should be permitted on the basis of only a potential advantage over existing therapy, without regard to the significance of the advantage. FDA continues to believe that, as was articulated in the preamble to the proposed rule (71 FR 75168 at 75171), the cost of making a drug available to study subjects during development should ordinarily be borne by the sponsor. Charging for drugs in this situation should be reserved for the exceptional circumstance in which it is necessary to continue development of a drug that offers a potential significant advantage over existing therapy.

b. *Essential to safety or effectiveness.* Section 312.8(b)(1)(ii) of the proposed rule provided that a sponsor that wishes to charge for its investigational drug, including investigational use of its

approved drug, must demonstrate that the data to be obtained from the clinical trial would be essential to establishing that the drug is safe or effective for the purpose of obtaining initial approval of a drug, or would support a significant change in the labeling of an approved drug (e.g., new indication, inclusion of comparative safety information).

(Comment 20) One comment stated that the criterion to show that data obtained from the clinical trial are essential to show safety or effectiveness or make a significant labeling change would make it unreasonably difficult for a sponsor to obtain authorization to charge because it would require a sponsor to show that all other trial components of the development program have been identified and marketing approval could not be obtained without completion of the trial for which charging is requested. The comment recommended that, instead, the criterion should be that the study is a phase 2 or 3 protocol that was not put on hold by FDA (§ 312.42) or the trial was agreed to by FDA through the special protocol assessment process (see FDA guidance for industry entitled "Special Protocol Assessment" (May 2002)). Another comment stated that this criterion is vague and overly broad because, arguably, all clinical trials conducted in a drug development program would be essential to show safety and effectiveness.

(Response) FDA does not agree that this provision is too restrictive. The phrase "essential to establishing that the drug is effective or safe for the purpose of obtaining initial approval of a drug" is intended to limit charging—whether in comparative trials, trials of a new use of an approved drug, or other trials—to those trials that will generate effectiveness or safety data on the endpoint or endpoints intended to establish safety or effectiveness (e.g., clinical outcome on the disease of interest), trials that would provide direct corroborative support for such trials, and trials that were necessary prerequisites to the major safety and effectiveness trials (e.g., essential to refining the study design). Such trials would include later phase (e.g., phase 2 and 3) controlled clinical trials evaluating the clinical endpoints that would establish safety and effectiveness (e.g., trials designed to demonstrate the drug's potential clinical advantage), but could also include important clinical pharmacology studies (e.g., thorough QT prolongation studies, drug-drug interaction studies), safety studies, and other types of studies that would provide essential corroboration for the data from the major safety and

effectiveness trials, or aid in the design of those trials.

FDA does agree that its determination, pursuant to a special protocol assessment, that a phase 3 study design and protocol are adequate to provide effectiveness data that would support approval of a marketing application would, in most cases, mean that the clinical trial is essential to establishing that the drug is effective or safe for the purpose of obtaining initial approval of the drug.

FDA does not agree that this provision is overly broad. FDA acknowledges that the trials conducted as part of a clinical development program typically build on one another. However, it is very unlikely that all such trials would be considered essential because they provide the data on the endpoints that establish safety and effectiveness, essential corroboration for those data, or are essential prerequisites to the major safety and effectiveness studies (e.g., because they enable the design to be refined so that the data will support approval).

c. *Extraordinary cost.* Section 312.8(b)(1)(iii) of the proposed rule provided that a sponsor that wishes to charge for its investigational drug, including investigational use of its approved drug, must demonstrate that the clinical trial could not be conducted without charging because the cost of the drug is extraordinary. The proposed rule stated that the cost may be extraordinary due to manufacturing complexity, scarcity of a natural resource, the large quantity of drug needed (e.g., due to the size or duration of the trial), or some combination of these or other extraordinary circumstances.

(Comment 21) Several comments had significant concerns about the extraordinary cost criterion. Two comments maintained that this provision is too vague and subjective for a regulatory requirement. They argued that whether a cost is extraordinary depends to a certain extent on the resources and perspective of the sponsor, i.e., what may be an extraordinary cost for a small company with limited resources may not be so for a larger company with more resources. One of these comments requested additional guidance, either in the rule or in a separate guidance document, on the meaning of extraordinary cost. Two comments stated that this requirement is more stringent than the 1987 charging rule, which requires only that the sponsor provide a written explanation for why charging is necessary for the sponsor to undertake or continue the trial. These comments recommended that FDA delete the extraordinary cost

criterion and replace it with the requirement from previous § 312.7(d)(1) requiring a full written explanation of the reasons charging is necessary for the sponsor to undertake or continue the clinical trial or expanded access. One comment requested that FDA clarify how extraordinary cost is to be determined for a large company with numerous corporate affiliates, each with separate budgets.

(Response) In the proposed rule, FDA attempted to describe the concept of extraordinary cost in a way that would make the determination independent of the relative resources of a sponsor. FDA perceived that this approach would be fairer than an approach based on sponsor resources, arguably making cost recovery equally accessible to all sponsors. FDA continues to believe that there are potential scenarios in which a drug cost would be so great that it would be considered extraordinary for any sponsor no matter how great a sponsor's resources. And FDA believes that the parameters set forth in the final rule—that the cost may be extraordinary due to manufacturing complexity, scarcity of a natural resource, the large quantity of drug needed (e.g., due to the size or duration of the trial), or some combination of these or other extraordinary circumstances—provide a functional objective test for whether a cost is extraordinary.

However, FDA also acknowledges that, as a practical matter, whether a drug cost is extraordinary in any given case will often be a function of the resources of a given sponsor. FDA believes that the rule should reflect the reality that a sponsor seeking cost recovery for a drug used in a clinical trial will more often be a sponsor with relatively fewer resources compared to the larger, established pharmaceutical and biotechnology companies. Accordingly, FDA has revised the extraordinary cost criterion in § 312.8(b)(1)(iii) to clarify that a sponsor can demonstrate a cost is extraordinary relative to the resources available to that sponsor. This revision is also responsive to the comments suggesting that we retain the requirement in the previous regulation that a sponsor provide a written explanation of why charging is necessary to conduct the study. The sponsor would be able to provide such an explanation to demonstrate that the cost is extraordinary for that sponsor.

(Comment 22) One comment stated that extraordinary cost is not a meaningful distinguishing criterion in the current environment as, arguably, most new therapies have extraordinary costs.

(Response) FDA does not agree that the concept of extraordinary drug cost is meaningless in the current environment. Extraordinary cost in this rule does not refer to the amount that would eventually be charged for a marketed drug in a commercial setting. Arguably, such costs are often extraordinary compared to historical pricing. Extraordinary cost in this rule refers only to the actual cost of the drug product in the clinical trial. This rule is primarily intended to provide cost recovery in clinical trials in cases in which the drug product itself is expensive to provide because of difficulty in manufacturing costs, scarcity of a natural resource needed to manufacture the drug, the large quantity of clinical supply needed to conduct studies, or other extraordinary circumstances, and therefore represents a substantial added cost above and beyond the routine costs associated with the conduct of the study.

(Comment 23) Two comments stated that FDA lacked the expertise to decide whether the cost of a drug is extraordinary and would need to review factual analyses about the sponsor's costs, comparative costs of other treatments, and arguments about what costs are ordinary versus extraordinary.

(Response) FDA does not believe that it will be difficult to differentiate drugs that are truly extraordinarily costly by objective measures from those that are not, or that such determinations will require special expertise. FDA believes it has enough accumulated experience with the vast array of drugs within its purview to have the ability to make such determinations about the relative costs of various drugs.

(Comment 24) Two comments expressed concerns with the requirement in § 312.8(b)(1)(iii) that a sponsor "[d]emonstrate that the trial *could* not be conducted without charging because the cost of the drug is extraordinary" (emphasis added). The comments stated that the more appropriate inquiry is whether a sponsor *would* not conduct a trial absent cost recovery because the cost is extraordinary, so, presumably, it would not be in the sponsor's commercial interest to conduct the trial. Similarly, another comment stated that companies may choose not to develop a drug because it would not be lucrative, but that does not mean the drug could not be developed.

(Response) The charging regulation is not intended to provide a mechanism to subsidize drug development generally or to provide an incentive to reconsider development of a drug that a sponsor has elected not to develop because it

was not predicted to be profitable (e.g., would not generate enough revenue to recoup development costs and provide a profit). The intent of the final rule is to address the situation in which the very high, near-term cost of making the drug available to subjects in a clinical trial is a deterrent to development, not the drug's long-term, potential profitability. Therefore, FDA believes that the appropriate inquiry is whether a trial *could* not be conducted without charging because the cost of the drug is extraordinary.

(Comment 25) One comment stated that the need to charge could be for reasons other than extraordinarily high manufacturing costs. The comment maintained that small biotechnology companies have difficulty obtaining funding for clinical trials even when the product is promising and the rule should recognize a sponsor's inability to obtain funding as a reason for charging in a clinical trial.

(Response) As discussed in the preceding comment response, charging for investigational drugs under this rule is not intended to provide funding for clinical trials or drug development generally. The intent is to address the situation in which there is a very high cost associated with making a drug available to clinical trial subjects and that drug cost prevents continued development unless the cost of the drug can be recouped during development. Therefore general development costs, such as costs associated with conducting and monitoring a clinical trial, should not be incorporated in the amount charged for the investigational drug and the lack of funding for such costs is not an independent basis for permitting charging for the study drug (but could be a factor in assessing whether the cost is extraordinary for a given sponsor under § 312.8(b)(1)(iii)).

FDA recognizes that in most drug development scenarios, the costs associated with the conduct of clinical trials and drug development generally are greater than the costs of the investigational drug product, and the development costs may be a deterrent to continuing development of a drug. However, FDA does not believe that incorporating those costs into an amount charged for the investigational drug is the appropriate mechanism to address that situation. If a sponsor wishes to recover from trial subjects other costs associated with the conduct of a clinical trial (e.g., the costs of medical care necessitated by participation in a clinical trial), FDA believes that recovery should occur independent of any charge for the drug product.

(Comment 26) One comment maintained that the extraordinary cost requirement, when applied to charging for the sponsor's approved drug in a trial evaluating a new use of that drug, would discourage manufacturers from developing new uses for approved products.

(Response) FDA believes that the criteria for permitting charging should be the same for charging for the sponsor's investigational drug in trials to support initial marketing approval as for charging in trials of a sponsor's approved drug for a new indication. In each, the cost of the drug is a routine business expense that would ordinarily be recouped after approval of the drug or new indication, and subjects are being asked to pay for an unapproved product or unapproved use in a setting in which charging for the drug is not the norm. The agency is aware that there are many factors that a sponsor weighs in determining whether to develop an approved drug for a new use. FDA does not believe that limiting charging for the sponsor's approved drug in a clinical trial to situations in which the cost of the drug is extraordinary would, in most cases, be the deciding factor in a sponsor's decision to develop or not develop a new indication.

3. Charging for an Approved Drug Obtained From Another Entity for Use as an Active Control or in Combination With Another Drug

Proposed § 312.8(b)(2) described the criteria for charging for an approved drug obtained from another entity for use as an active control or in combination with another drug. To charge in this situation a sponsor must:

- Demonstrate that the clinical trial is adequately designed to evaluate the safety and effectiveness of the sponsor's drug and
- Demonstrate that the holder of the approved application is not providing the drug to the sponsor free of charge.

(Comment 27) Many comments expressed concerns with the provisions in the proposed rule concerning charging for approved drugs obtained from another entity for use as an active control or in combination with another drug. Three comments stated that FDA approval should not be required to charge for approved drugs when the drugs are used for their approved or medically accepted indications and at approved or medically accepted doses and dose regimens. One comment opined that the cost of approved drugs used in a trial for medically accepted purposes is not a drug development expense that should be borne by the sponsor. Two comments stated that the

rule should not distinguish between an approved drug obtained from another entity and an approved drug that is the sponsor's own drug and charging should be permitted for both. Another comment noted that the rationale that trial subjects should not be charged for exposing themselves to the risks of an unproven drug does not apply to approved drugs used for a medically accepted purpose. One comment stated that pharmaceutical companies seldom charge patients for the cost of an approved drug used in a clinical trial. Two comments stated that the investigator commonly buys approved drugs and bills the patient's health insurance or the investigator writes a prescription for the patient, who fills the prescription at a pharmacy that bills the patient's insurance.

Several comments also raised concerns that the charging regulation might interfere with routine reimbursement by third-party payers for approved drugs used for their approved indications in clinical trials. Some comments stated that, when approved drugs used as comparators are charged for in a clinical trial, they are ordinarily dispensed through the normal distribution channel—either an inpatient or outpatient pharmacy—and third-party payers routinely reimburse for such uses. One comment asked FDA to clarify that the proposed rule does not apply to a situation in which the sponsor is not involved in directly supplying approved drugs used as comparators or in combination and does not incur direct acquisition or handling costs that it then seeks to pass on to trial subjects, such as when the drug is dispensed from a pharmacy.

One comment stated that requiring sponsors to seek authorization to charge in cases in which the sponsor is not directly acquiring an approved drug from another entity, such as cases in which the approved drug is obtained or prescribed by investigators and subjects are billed by the investigator or pharmacy, would dramatically alter existing practice without benefiting trial subjects. The comment stated that a large number of clinical studies would need to be submitted for FDA review, dramatically increasing the administrative burden on FDA to review charging requests for affected trials and on sponsors in making submissions.

(Response) The agency agrees that requiring sponsors to obtain authorization to charge for approved drugs obtained from another entity for use as active controls or in combination with another drug, or for other uses is not necessary. We recognize that one of the major rationales for limiting

charging—that the safety and effectiveness of the drug is unproven—is often not present in this situation. Moreover, FDA believes there would almost never be a basis to deny a request to charge for an approved drug for use as active control or in combination with another drug under the criteria in the proposed rule. FDA also acknowledges the potential for significant administrative burdens associated with complying with the proposed charging requirements if, as the comments stated, the current practice in many cases is simply to have the approved drug dispensed from a pharmacy and have patients or third parties pay the usual cost for the drug. Moreover, FDA does not want to impose a regulatory requirement that might somehow interfere with the way in which drug costs are reimbursed by third-party payers. Accordingly, in the final rule, FDA has revised proposed § 312.8(a) and deleted proposed § 312.8(a)(2) and (a)(3), to clarify that a sponsor need not obtain authorization to charge for an approved drug used for an approved indication in a clinical trial done under an IND.

(Comment 28) Three comments stated that approved drugs used as active controls or in combination with another drug are not investigational because they are approved and are not being “investigated” in the clinical trial.

(Response) FDA disagrees. When an approved drug is used as an active control or in combination with another drug (e.g., as standard therapy in a study comparing standard therapy to standard therapy plus a new investigational therapy), the treatment effect of the active control or the standard therapy is being measured and compared to the new therapy. Therefore, the approved drug is part of the clinical investigation, and hence an investigational drug for purposes of part 312. Notwithstanding that such use is subject to part 312, FDA has revised the proposed charging rule so that sponsors are no longer required to obtain authorization to charge for approved drugs obtained from another entity for use as active controls or in combination with another therapy (as discussed in the preceding comment response).

(Comment 29) One comment argued that sponsors should be able to charge for approved drugs without FDA authorization when used in clinical trials for “medically accepted” uses, which the comment defined as uses supported by a recognized compendium such as U.S. Pharmacopeia Drug Information (USP DI).

(Response) As discussed in the responses to comments 27 and 31, FDA

has revised the proposed rule to remove the requirement that a sponsor obtain prior approval to charge for an approved drug that the sponsor must obtain from another source for use as an active control or in combination with another drug, or in a trial evaluating the approved drug for a new use or to obtain important safety information. However, the final rule retains the requirement that a sponsor studying its own approved drug for a new indication or to support another type of significant labeling change must obtain approval to charge for the drug in the study. FDA does not agree that whether the use of the drug is “medically accepted” by a recognized compendium should be a distinguishing criterion for determining whether the sponsor should be required to obtain authorization to charge for its drug in that situation.

(Comment 30) One comment asked how a trial blind could be maintained if there is charging for a competitor's product used as an active control, but not for the sponsor's investigational drug.

(Response) We note that the final rule removes the requirement of the proposed rule that sponsors seek FDA authorization to charge for a competitor's product used as an active control. In general, FDA believes that maintaining the trial blind is the responsibility of the sponsor.

4. Charging for an Approved Drug Obtained From Another Entity in a Clinical Trial of the Drug

Proposed § 312.8(b)(3) provided that, for a sponsor to charge for an approved drug obtained from another source in a clinical trial to evaluate that drug, it must:

- Demonstrate that the clinical trial is adequately designed to evaluate the safety or effectiveness of a new indication or to provide important safety information related to an approved indication and
- Demonstrate that the holder of the approved application is not providing the drug to the sponsor free of charge.

(Comment 31) Two comments stated that the requirement that a sponsor seeking to charge for an approved drug obtained from another source must demonstrate that the trial design is adequate to evaluate the effectiveness of the new indication is unnecessary because it essentially duplicates what a sponsor is required to demonstrate to be allowed to proceed with the trial under the IND review process. The comments argue that the fact that FDA has not placed the trial on clinical hold (§ 312.42) should be enough evidence that FDA considers the trial of adequate

design. One comment stated that whether the drug is available without charge does not require FDA review. One comment asked FDA to clarify what constitutes sufficient evidence that the sponsor charging for a drug has not received the drug free of charge. Another comment suggested that additional criteria be added as a safeguard to ensure that drug is not being made available free of charge, such as representation by the sponsor that the manufacturer is not funding or supporting the trial in any way.

(Response) FDA acknowledges that the proposed criteria for obtaining authorization to charge for an approved drug that the sponsor must obtain from another entity in a trial of a new use of that drug, or to obtain important new safety information, do not present a significant barrier to obtaining cost recovery. FDA intended to present a relatively low barrier to encourage the kinds of trials that might not be of commercial interest to the drug manufacturer or to otherwise encourage trials that would further elucidate the characteristics of approved drugs. FDA agrees that, for phase 2 and 3 trials, the fact that the trial has not been placed on clinical hold would ordinarily be sufficient to satisfy the criterion that the trial is adequately designed to evaluate the unapproved drug for a new indication. FDA also acknowledges that it intended to rely primarily on the representations of the sponsor for assurance that the drug was not being made available free of charge.

In light of these comments, FDA now recognizes that, based on the criteria in the proposed rule, there would seldom be a basis to deny a request to charge for an approved drug that a sponsor must obtain from another source to study a new use or to obtain important new safety information. FDA also recognizes that the cost recovery calculation for this type of use would usually be very straightforward—ordinarily, the sponsor's acquisition cost if the sponsor purchases the drug directly or the cost of the drug when dispensed from a pharmacy. Therefore, FDA concludes that to require submission of a request to charge for an approved drug obtained from another source would often be a needless administrative burden for the sponsor and FDA. Accordingly, we have decided not to finalize proposed § 312.8(b)(3) in this final rule.

(Comment 32) One comment stated that the ability to charge for an investigational drug obtained from another entity for use in a clinical trial of the drug should be limited to nonprofit organizations. The comment further recommended that the

organization be required to demonstrate that it sought grant funds for the trial and any denial of such funds was not due to lack of merit in the research plan.

(Response) FDA does not agree that the ability to charge for an approved drug obtained from another entity should be limited to nonprofit organizations. As discussed in the previous response, FDA has removed from this final rule the proposed requirement that a sponsor obtain prior approval to charge for an approved drug obtained from another entity for use in a trial of the approved drug. Thus, any type of sponsor can charge for such drugs without obtaining authorization from FDA.

FDA hopes that sponsors that must obtain a drug from another entity would ordinarily explore all reasonable financing options (e.g., grants from various sources, funding from the drug manufacturer, a drug supply from the drug manufacturer) before seeking to charge trial subjects for the drug. However, FDA does not believe that it is necessary to specify in regulation that a sponsor exhaust all available alternative financing options before charging for the study drug.

5. Duration of Charging in a Clinical Trial

(Comment 33) One comment interpreted the provision stating that the authorization to charge for a drug in a clinical trial will usually last for the duration of the trial, unless FDA specifies a shorter period, to mean that FDA's approval of the IND (after 30 days) constitutes authorization to charge for an approved drug in a trial of a new indication for the drug as long as the protocol states that the sponsor or investigators may charge for the drug.

(Response) FDA disagrees with this interpretation. Section 312.8(a)(3), which applies to all requests to charge, requires that a sponsor obtain prior written authorization from FDA to charge for an investigational drug. A sponsor must specifically request to charge under the applicable paragraph in § 312.8 and obtain authorization to charge pursuant to that request before it can charge for a trial drug. No provision in this final rule should be construed to mean that FDA's failure to place a protocol on clinical hold constitutes implicit authorization to charge for an investigational drug, notwithstanding that the protocol contains a provision stating that the sponsor intends to charge.

E. Charging for Expanded Access to Investigational Drugs for Treatment Use

Proposed § 312.8(c) set forth criteria for charging for the three types of expanded access to investigational drugs for treatment use described in new subpart I of part 312—individual patient INDs, intermediate-size patient population INDs, and treatment INDs (see the expanded access final rule published elsewhere in this issue of the **Federal Register**). FDA's primary concern with charging patients in expanded access settings is that charging not interfere with the development of investigational drugs for commercial marketing. Therefore, under proposed § 312.8(c)(1), a sponsor seeking to charge for expanded access use must provide reasonable assurance that charging will not interfere with developing the drug for marketing approval. To provide such assurance for a treatment IND or protocol under § 312.320, a sponsor must include evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trials will be successfully completed as planned (§ 312.8(c)(2)(i)); evidence of adequate progress in the development of the drug for marketing approval (§ 312.8(c)(2)(ii)); and information submitted under a sponsor's general investigational plan specifying the drug development milestones the sponsor plans to meet in the next year (§ 312.8(c)(2)(iii)).

Proposed § 312.8(c)(3) provided that the authorization to charge for an expanded access use is limited to the number of patients authorized to receive the drug under the treatment use protocol or IND, if there is a limitation.

Proposed § 312.8(c)(4) provided that the authorization to charge for expanded access may continue for 1 year from the time of FDA authorization and that sponsors may request that FDA reauthorize charging for additional time periods.

1. General Comments

(Comment 34) One comment objected to the idea that sponsors could only charge for expanded access if the cost was extraordinary.

(Response) FDA believes this comment misread the proposed rule. The cost of an investigational drug need not be extraordinary for a sponsor to be able to charge for the drug under an expanded access IND or protocol in subpart I. That extraordinary cost criterion in the proposed § 312.8(b)(1)(iii) applied only to charging for a sponsor's investigational drug in a clinical trial of that drug under

proposed § 312.8(b)(1). Moreover, this criterion has now been eliminated in the final rule (see comments 21 through 26).

(Comment 35) One comment stated that there is a conflict between the proposed rule on charging and the proposed rule on expanded access because the charging rule would not permit charging for expanded access for individual patients or intermediate-size patient populations if there were no ongoing or planned clinical trial that would support marketing approval. One comment asked that charging for individual patient expanded access be permitted. The comment also stated that it was not clear if charging was permitted for intermediate-size patient population expanded access. One comment stated that sponsors should be permitted to charge for investigational drugs for all types of expanded access programs, provided that charging will not impede drug development.

(Response) FDA believes these comments misread the proposed rule. Proposed § 312.8(c)(1) stated that a sponsor who wishes to charge for an investigational drug for any treatment use under subpart I of part 312 must provide reasonable assurance that charging will not interfere with developing the drug for marketing approval. Moreover, the preamble to the proposed rule specifically stated that one of the major reasons that FDA was revising the 1987 charging rule was to provide authority to charge for investigational drugs under the two new categories of expanded access for treatment use—individual patient and intermediate-size population expanded access INDs (71 FR 75168 at 75169 through 75170). For expanded access under a treatment IND or treatment protocol, the proposed rule stated that such assurance must also include the specific types of evidence in § 312.8(c)(2), including evidence of sufficient enrollment in any ongoing clinical trials needed for marketing approval. However, the specific types of evidence identified apply only to requests to charge for expanded access use under new § 312.320 (treatment IND or treatment protocol) (see § 312.8(c)(2)). Because individual patient INDs (new § 312.310) and intermediate-size patient population INDs can occur earlier in drug development and typically involve much smaller numbers of patients, FDA did not think it would be helpful to specify in the rule how to provide reasonable assurance that charging will not interfere with developing the drug for marketing approval for those types of expanded access program. To clarify that the evidentiary requirements apply only to treatment INDs or treatment

protocols, we have revised § 312.8(c)(2) to describe § 312.320 as covering treatment INDs and treatment protocols, rather than merely citing to the section as the proposed rules had done.

2. Increasing Access

In the preamble to the proposed rule, FDA identified the costs associated with making investigational drugs available for treatment use under expanded access programs as a potential obstacle to the availability of such drugs (section II.C of the proposed rule). By facilitating charging for such use, FDA stated that it hoped there would be greater access to investigational drugs (section VI.E of the proposed rule).

(Comment 36) Several comments expressed concerns about the implications of permitting charging for investigational drugs for treatment use under expanded access programs on how such drugs are allocated. Some comments stated that the proposed rule may not increase expanded access because third-party payers are not likely to reimburse for investigational therapies, thus depriving patients not able to afford such drugs. One comment added that neither patients nor insurers should pay for investigational drugs or treatments and that the proposed rule will significantly exacerbate the current problems of access to, and affordability of, health care. Another comment stated that, although the poor may qualify for company-sponsored assistance to pay for investigational drugs, middle-class patients may not be eligible for such programs yet still be unable to afford such drugs. Two comments stated that permitting charging only for direct costs may not increase access because it will not provide enough financial incentive for companies to offer access. One comment agreed that permitting charging for investigational drugs made available under expanded access programs will result in greater access to investigational drugs.

(Response) FDA recognizes that permitting cost recovery for expanded access to investigational drugs for treatment use will not remove all barriers to access. The agency shares the concerns about equitable access to such drugs among patients with varying financial resources. FDA's goal, with this cost recovery provision, is to enable willing sponsors to make a drug available that could not otherwise be made available or to make a drug more widely available than would be possible absent cost recovery, thus potentially benefiting more individuals than would have benefited absent charging. FDA has no control over reimbursement policy. FDA hopes that sponsors that charge for

investigational drugs under expanded access programs will also make provision for those who cannot afford such therapies.

FDA believes that permitting sponsors to recover all costs associated with making an investigational drug available and administering an expanded access program provides a reasonable incentive for sponsors to make investigational drugs available for treatment use. As discussed in greater detail in comment 46, FDA believes the cost recovery provision, to the extent it allows companies to recover all the direct costs associated with making the drug available and administering the expanded access program, removes a significant obstacle to making drugs available for treatment use for some sponsors (e.g., sponsors with limited resources for expanded access programs) while preventing commercialization of investigational drugs.

(Comment 37) One comment stated that FDA should closely monitor expanded access programs for which it permits cost recovery to ensure that sponsors honor any commitments to make drugs available to those who cannot afford them.

(Response) FDA hopes that sponsors would, of their own initiative, honor their commitments to make investigational drugs available to those who cannot afford them. However, FDA cannot require a sponsor to honor a commitment to provide a drug to those who cannot afford it, or otherwise compel a sponsor to provide expanded access. FDA also recognizes that circumstances may change such that a sponsor is no longer able to honor a commitment to make investigational drugs available to those who cannot afford to pay for them.

(Comment 38) One comment stated that permitting charging for investigational drugs for expanded access under subpart I will create a dichotomy between rich and poor because patients who can afford to pay for investigational drugs can be guaranteed access under treatment use protocols, but those who cannot will be forced to enroll in clinical trials with only a chance that they will receive the investigational drug in question.

(Response) FDA does not agree that this rule will lead to a situation in which those with fewer resources disproportionately bear the burdens of participating in clinical trials. A sponsor cannot charge for an investigational drug under a treatment IND unless there is evidence of sufficient enrollment in any ongoing clinical trials needed for marketing approval to provide FDA

reasonable assurance that the trials will be successfully completed (§ 312.8(c)(2)(i)). FDA anticipates, therefore, that in most cases, the majority of subjects needed to be enrolled in a trial will have been enrolled before the drug is available under a treatment IND in which the sponsor charges for the drug, so the trial will be fully enrolled. In addition, access to investigational drugs under an individual patient or intermediate-size population expanded access program is usually limited to individuals who are ineligible to enroll in controlled clinical trials. Section 312.310(a)(2) provides that FDA must determine that a patient seeking access to a drug under an individual patient IND cannot obtain the drug under another IND or protocol, which would include a clinical trial or a larger expanded access IND. Section 312.315(a)(2) explains that the intermediate-size patient population IND for a drug being developed is intended to address the situation in which patients requesting access to a drug are unable to participate in a clinical trial of the drug because, for example, they do not meet enrollment criteria, enrollment is closed, or the trial site is not geographically accessible. For these reasons, FDA believes this charging rule will not have a significant impact on the distribution of individuals participating in clinical trials and expanded access programs based on relative wealth.

(Comment 39) One comment stated that poor and lower- to middle-class patients should not be required to pay any costs associated with an investigational drug and that health insurance plans should be required to cover all costs associated with such drugs. Another comment stated that the rule should specify that patients who are uninsured, or those whose insurance excludes payment for investigational drugs, cannot be charged for an investigational drug. One comment recommended that permission to charge by commercial sponsors be tied to a requirement that a percentage of drugs will be provided at no cost to the uninsured and those whose insurers do not cover the costs. Two comments recommended that the rule specify that a certain percentage of an investigational drug for which charging is permitted be made available free of charge.

(Response) The agency cannot require third-party payers to cover the costs of investigational drugs made available under expanded access programs. We also cannot require sponsors to provide a drug free of charge to those who lack insurance or whose insurance does not

cover investigational drugs. The agency encourages sponsors to include provisions in their expanded access programs to assist patients who are unable to pay for investigational drugs. The details of such plans (e.g., the percentage of patients eligible to obtain a drug free of charge or the percentage of drug supply that will be made available free of charge) should be determined based on the circumstances of the particular expanded access program.

3. Ethical Considerations

(Comment 40) Two comments stated that there are ethical concerns with charging patients for expanded access use of investigational drugs that may have no benefit and pose safety concerns.

(Response) In determining whether to permit an expanded access use of an investigational drug, FDA assesses whether the potential risks are reasonable in light of the potential benefits, sometimes on the basis of quite limited clinical evidence. Therefore, FDA agrees that there is a risk that the investigational drug will have no benefit and, therefore, that a patient will pay for an investigational drug that provides no benefit. However, if a drug has a potential benefit that is reasonable in light of the risks associated with the drug, and the sponsor must charge to make the drug available, FDA believes the public health is best served by making the drug available to patients for a fee, even if the potential benefit is not realized in a given patient. FDA believes that the ethical concerns expressed in these comments can be addressed by an informed consent that accurately reflects the costs, potential risks, and potential benefits.

4. Non-Interference With Drug Development

(Comment 41) One comment asked that FDA define what it means to interfere with the development of a drug for marketing approval.

(Response) FDA will use several criteria to determine whether charging for an investigational drug in a treatment IND will interfere with drug development. These criteria were described in the proposed rule. Proposed § 312.8(c)(2) described specific criteria needed to provide FDA reasonable assurance that charging for an investigational drug under a treatment IND or treatment protocol (new § 312.320) is not interfering with drug development. Proposed § 312.8(c)(2)(i) required sponsors to provide evidence of sufficient enrollment in any ongoing clinical trials

needed for marketing approval. Proposed § 312.8(c)(2)(ii) required sponsors to provide evidence of adequate progress in the development of the drug for marketing approval. Such evidence could include successful meetings with FDA before submission of an NDA (e.g., a pre-NDA meeting), submission of an NDA, or completion of other significant drug development milestones. Sponsors would also be required to submit information under their general investigational plans (§ 312.23(a)(3)(iv)) specifying the drug development milestones they plan to meet in the coming year (proposed § 312.8(c)(2)(iii)). FDA could then evaluate actual progress made versus planned progress to assess the impact, if any, of charging for an investigational drug under a treatment IND. Negative effects on these criteria would be considered indications of interference with drug development.

The proposed rule did not provide specific criteria for individual (new § 312.310) and intermediate-size patient population access INDs (new § 312.315). The kinds of situations that present with these types of INDs can vary greatly, from situations in which there is no drug development to assess, to anywhere along the spectrum from very early in drug development to the last stages of drug development. The scope can range from a single isolated incidence of an individual patient treatment use for a use not being developed to a late stage intermediate-size population IND for over 100 patients. The agency believes the factors that are relevant to such a determination will be as varied as the timeframes and scopes for these types of INDs. Therefore, FDA does not believe it is necessary or helpful to try to describe in regulation specific criteria that a potential sponsor of an individual patient or intermediate-size population IND must meet to provide reasonable assurance of non-interference with drug development. However, because the populations are smaller than for a treatment IND, the risk of interference with drug development is less than with a treatment IND, so FDA does not believe it will be difficult to demonstrate non-interference with drug development for most individual patient and intermediate-size population INDs.

5. Treatment INDs or Treatment Protocols

For treatment INDs or treatment protocols (new § 312.320), the proposed rule included additional criteria for charging. Section 312.8(c)(2) of the proposed rule provided that for a

treatment IND or protocol, the sponsor must provide:

- Evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trial(s) will be successfully completed as planned,
- Evidence of adequate progress in the development of the drug for marketing approval, and
- Information submitted under the general investigational plan (§ 312.23(a)(3)(iv)) specifying the drug development milestones the sponsor plans to meet in the next year.

(Comment 42) One comment stated that “evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval” (§ 312.8(c)(2)(i)) and “evidence of adequate progress in the development of the drug for marketing approval” (§ 312.8(2)(ii)) are too vague and do not provide adequate safeguards to ensure that charging for an investigational drug under a treatment IND will not interfere with a drug’s development for marketing. The comment asked that FDA also require a sponsor to submit a copy of, or cross-reference to, its general investigational plan, including a development timeline and clinical trial accrual estimates. The comment stated that when requesting reauthorization, a sponsor should be required to show that its actual enrollment is no more than 5 percent less than its original estimates or, if lower, provide a satisfactory explanation for the deviation from planned accrual (e.g., smaller than anticipated population with the disease of interest from which to draw subjects). One comment stated that determining whether charging is interfering with the development of a drug for marketing approval would require FDA to analyze patterns of enrollment in clinical studies and the causes of insufficiencies in enrollment, and assess what delays are unacceptable.

(Response) FDA acknowledges that applying the criteria concerning drug development progress involves judgment, but does not agree that these criteria are too vague. Modern drug development involves the progressive development of a body of evidence to support a marketing application and generally follows a relatively predictable course. For given diseases, it is possible to predict timeframes for development generally and specific components of development (e.g., individual clinical trials) with some precision. It is also true that initial time expectations can be overly optimistic and require adjustment. However, FDA believes a marked deviation from expectations that coincides with the

beginning of an expanded access program can be easily recognized and interpreted as related to the availability of the drug under a treatment IND. For this reason, FDA believes that the identified criteria provide a reasonable basis upon which to judge drug development progress, both before and after the initiation of a treatment IND, to determine if progress is adversely affected.

FDA does not believe a 5-percent decrease in clinical trial accrual from a planned clinical trial accrual rate would be a useful benchmark for determining whether a treatment IND is interfering with drug development. Typically, planned accrual rates are crude estimates and lack the precision needed to make a 5-percent deviation meaningful. In addition, the precision with which accrual rates can be predicted likely varies for different diseases based on their prevalence and other factors. For these reasons, FDA does not believe that specifying a percentage deviation from expected clinical trial accrual would be useful for evaluating potential interference with drug development by a treatment IND. FDA also does not agree that determining whether charging for a treatment IND is affecting drug development will require comprehensive analyses of clinical trial accrual patterns. FDA anticipates that a finding that reauthorization is not appropriate because charging is interfering with enrollment in clinical trials will ordinarily be based on very strong evidence of a significant effect contemporaneous with onset of an access program, and not on subtle deviations from historical accrual patterns for clinical trials in the disease of interest.

6. 1-Year Authorization

Section 312.8(c)(4) of the proposed rule provided that charging for any type of expanded access to an investigational drug for treatment use may continue for 1 year from the time of FDA authorization unless FDA specifies a shorter period. It also provided that a sponsor may ask FDA to reauthorize charging for additional periods. The preamble to the proposed rule stated that FDA will ordinarily authorize charging for the drug for a period of 1 year, unless “there is a particular concern that charging would interfere with drug development” (71 FR 75168 at 75172).

(Comment 43) One comment stated that the 1-year authorization period was unnecessary because FDA can always withdraw authorization if the criteria are no longer being met. The comment

added that the provision could delay getting drugs to patients if there were a delay in reauthorizing charging.

(Response) The agency does not believe it is reasonable to place the burden on FDA to investigate whether the criteria for charging continue to be met because FDA does not have independent access to the information needed to make that determination. FDA would need to request that the sponsor provide the necessary information. Therefore, FDA believes it would be more efficient if that sponsor simply provided to FDA the information on an annual basis. We do not agree that requiring that charging be reauthorized annually will delay patient access to investigational drugs provided sponsors make a timely and complete submission seeking reauthorization to charge. In most cases, FDA believes the determination will be straightforward and the review will be completed expeditiously.

(Comment 44) Another comment recommended reducing the time that a sponsor may charge before seeking reauthorization to charge from 1 year to 6 months because charging for investigational drugs always presents a risk of compromising enrollment in clinical trials.

(Response) FDA believes the 1-year anniversary is a reasonable point in time to re-evaluate the charging request for most authorizations to charge. If FDA has concerns about charging for a particular treatment IND, for example, where there is a concurrent clinical trial still enrolling subjects, the rule provides FDA the option to specify a shorter period in which to re-evaluate whether the criteria for charging continue to be met.

F. Costs Recoverable When Charging for an Investigational Drug

Proposed § 312.8(d) described the types of costs that a sponsor can recover when charging for an investigational drug in a clinical trial and for treatment use under an expanded access IND. Proposed § 312.8(d)(1) provided that a sponsor may only recover the direct costs of making an investigational drug available.

Proposed § 312.8(d)(1)(i) described direct costs as those incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging

is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.

Proposed § 312.8(d)(1)(ii) described indirect costs (those costs that can not be recovered when charging for an investigational drug) as costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of the drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

1. Direct and Indirect Costs

(Comment 45) One comment stated that FDA lacked the expertise to decide whether the price proposed by the sponsor would only cover direct costs. The comment stated that FDA accountants would need to scrutinize each sponsor's asserted direct costs to ensure fairness and consistency in its handling of the policy and that distinguishing between direct and indirect costs is likely to be complicated.

(Response) The agency believes that, when charging for investigational drugs, a sponsor of a clinical trial or expanded access program should not be permitted to commercialize (e.g., profit from the sale of) the drug. Thus, the proposed rule set forth criteria that permit a sponsor to recover only costs specifically attributable to making the investigational drug available in the trial or expanded access program for which cost recovery is authorized (i.e., only those costs that would not have been incurred but for the provision of the drug). We believe the direct cost provision as proposed, by differentiating between direct costs and indirect costs, and not providing for apportionment of indirect costs (e.g., overhead and general research and development costs) simplifies the cost recovery calculation to the extent possible and makes clear FDA's objectives concerning what costs can be recovered. Therefore, FDA does not anticipate major controversies concerning cost recovery calculations under this rule, or the need to rely heavily on financial experts to adjudicate such calculations. In the event of a significant controversy, FDA expects that it will be able to require the sponsor to produce supporting documentation prepared by an independent financial expert attesting

that the calculation is consistent with the cost recovery provisions in this rule.

(Comment 46) Several comments argued that sponsors should be permitted to charge for other types of costs in addition to those provided for in the proposed rule. One comment stated that cost recovery should include the costs of clinical trials, all related research and development costs, and administrative, labor, and other costs. Two comments stated that FDA should permit some cost recovery for research and development costs in clinical trials. One of the comments requested that FDA reconsider its decision to exclude research and development costs from the cost recovery calculation. The comment argued that FDA could provide criteria to better define recoverable research and development costs, thus avoiding the subjectivity and arbitrariness concerning recovery of research and development costs in the 1987 charging rule. One comment asked that cost recovery be permitted for production fixed costs such as capital investment and fixed manufacturing expenses. Two comments agreed that sponsors should only be permitted to charge for direct costs. One of the comments agreed with the statement in the proposed rule that provision of unapproved drugs should ordinarily be considered part of the cost of doing business and that charging for indirect costs and overall development costs should not be permitted. One comment stated that the proposed rule's description of recoverable costs is subject to varying interpretations by accounting professionals and would thus result in inconsistent application of the cost recovery provisions.

(Response) FDA does not agree that the cost recovery provision should provide for recovery of research and development costs incurred to develop the drug for marketing approval. For a drug that has not yet been approved for any purpose, the intent of permitting charging for that drug in a clinical trial is to provide the opportunity to recoup the cost of making the drug available when the cost of that drug is extraordinary in relation to drug costs generally, or in relation to the resources of the sponsor, and therefore, highly burdensome for a sponsor. The intent is not to subsidize the overall development of the drug. In general, the costs associated with drug development are very large, so it is not reasonable to expect the relatively small number of patients participating in a clinical trial (compared to those who will obtain a drug once it is on the market) to be able to meaningfully subsidize those costs.

The intent of allowing cost recovery for expanded access uses is to remove any financial disincentive for a sponsor to make a drug available by permitting the sponsor to recover direct costs of making the drug available plus monitoring and administrative costs directly associated with the expanded access use. The intent is not to allow a sponsor to begin recouping its general drug development investment in advance of marketing approval. FDA believes that allowing recovery of those generalized costs prior to marketing approval would be effectively permitting commercialization of an unapproved drug.

The agency also does not agree that the cost recovery provision should provide for recovery of capital investment and fixed manufacturing costs, which are incurred by the sponsor primarily for the purpose of manufacturing sufficient quantities of the drug for commercial sale. These costs also should be recouped during commercial marketing of the drug.

(Comment 47) One comment asked that FDA revise the proposed rule to permit cost recovery for the cost of drug delivery, which includes formulation, packaging, instrumentation, monitoring, disposables, setup, nursing, and similar costs.

(Response) It is not necessary to make the suggested revisions because such costs can be recovered without authorization from FDA. Section 312.8(d)(1) is intended to permit a sponsor to recover its direct costs incurred in making a drug available from the onset of manufacturing to the point it arrives at the destination to which it was shipped, or acquisition, shipping, and handling costs for a drug acquired from another source (e.g., where manufacturing is outsourced). Subsequent costs incurred at a clinical trial site (e.g., a hospital or clinic), including pharmacy costs (e.g., the cost to reformulate a drug for infusion), nursing costs (e.g., costs associated with administering a drug and monitoring study subjects), equipment costs (e.g., intravenous (IV) administration sets), and costs for study-related procedures (e.g., chemistry labs, radiographic procedures), are outside the scope of this rule. That is, the costs of these items and services can be recovered without prior authorization from FDA (also see response to comment 64, which includes a link to the Center for Medicare and Medicaid Services (CMS) policy concerning reimbursement for clinical trial related items and services).

(Comments 48) One comment stated that there might be substantial differences in the amount charged per

patient for the same drug if the cost were allocated across a small population clinical trial compared to a large population trial.

(Response) We agree that this result is possible. For example, if a sponsor is permitted to charge for a drug in a small clinical trial, and the sponsor then submits a separate request to charge for the drug in a larger subsequent trial of the same drug, the drug cost may be lower in the larger trial due to economies of scale. FDA believes the higher cost for the smaller population is probably unavoidable and is a reasonable outcome for cost recovery purposes.

(Comment 49) One comment stated that limiting the amount of cost recovery for an approved drug to acquisition and handling costs, instead of permitting investigators and pharmacies to seek normal reimbursement amounts, would create serious administrative problems because it would require investigators to establish separate billing and inventory accounting systems for trial drugs. The comment added that, to the extent that community pharmacies are furnishing drugs in clinical trials, the proposal to limit what they can charge does not seem feasible, because they would not even be aware of the customer's status as a clinical trial subject.

(Response) As discussed in comment 27 and 31, FDA has revised the proposed rule so that sponsors that must obtain the study drug or an active control from another entity (i.e., a sponsor who is not the applicant who holds the approved application for a drug and commercially markets the drug) are not required to obtain authorization to charge for the drug. FDA believes such sponsors should be able to cause the approved drug to be distributed to trial subjects through ordinary distribution channels for approved drugs (e.g., an inpatient or outpatient pharmacy) pursuant to a physician's order or prescription and to cause subjects to be charged the same amount that would be charged to a patient who received the drug in the course of clinical practice. As discussed in comment 26, sponsors that conduct trials of their own approved drug (e.g., a drug that the sponsor commercially markets) must obtain prior authorization to charge for the trial drug pursuant to the criteria set forth in § 312.8(b)(1) of this final rule. Such sponsors are permitted to recover only their direct costs for making the trial drug available to subjects as described in § 312.8(d) of this final rule.

(Comment 50) One comment was concerned that limiting the amount a

sponsor would be able to charge for an approved drug in a clinical trial to cost only would have implications for the rebates and discounts that must be made to eligible entities (private entities receiving grants under the Public Health Service Act, and certain hospitals) under the Medicaid Rebate and the 340B Program (section 340B of the Public Health Service Act (42 U.S.C. 256b)). The comment stated that rebates and discounts for a drug under these programs are based in part on the "best price" to any purchaser during each calendar quarter and was concerned that if the amount charged under this rule were included in the "best price" determination, the sponsor could incur a large liability for rebates and discounts to eligible entities. The comment stated that such pricing could also be construed to establish most favored customer pricing that could be used to set prices under the Federal Supply Schedule contracts with the Federal Government.

(Response) FDA believes that recovery of drug costs associated with making an approved drug available to subjects in a clinical trial is distinct from the commercial sale of drugs. The former does not involve a commercial sale of the drug and is not intended to make a drug available for use in a clinical practice setting. FDA believes that the primary objective of programs for Medicaid and the 340B program (by which certain federally funded grantees and safety net providers may purchase prescription drugs at significantly reduced prices) and of those agencies that administer Federal Supply Schedules for pharmaceuticals (e.g., the Veterans Administration) is to obtain fair pricing relative to the prices paid by other entities in the commercial marketplace for drugs used in clinical practice settings (e.g., in a hospital, for outpatient use), and not relative to the amount a sponsor charges in the unusual circumstance in which it seeks to recover its drug cost in a clinical trial. However, sponsors who intend to charge for an approved drug in a clinical trial should consult with CMS concerning the implications of cost recovery on the best price determination. Sponsors should also consult with the agencies that administer Federal Supply Schedule contracts for pharmaceuticals concerning the implications for prices under those contracts.

(Comment 51) One comment asked that FDA permit cost recovery for direct manufacturing costs for equipment and reusable supplies used to manufacture the investigational drug and marginal

costs to produce additional investigational drugs.

(Response) The intent of the cost recovery provision is to permit cost recovery for whatever direct costs are attributable to providing the amount of drug needed for the clinical trial or expanded access use. The rule purposefully excludes many other costs (e.g., overhead, depreciation, reusable supplies, equipment, manufacturing facility) that would be incurred even if the amount of drug needed was not produced, but a small fraction of which could be apportioned to the drug supply produced under general accounting principles. FDA believes these costs would ordinarily be a very small percentage of the total cost when apportioned to the amount of drug produced for a clinical trial or expanded access program, so permitting recovery for these types of costs would create needless complexity and administrative burdens. For example, FDA would need to retain personnel with financial expertise to assess a relatively small number of very complex cost recovery calculations. FDA also believes permitting cost recovery for a broader array of costs might invite expansive and unwarranted interpretations of allowable costs, which would create additional administrative burdens.

(Comment 52) Three comments stated that FDA should allow charging for the market value of an approved drug being studied for a new indication. One comment stated that when charging for approved drugs, normal charges incurred at the site at which the drug is dispensed (e.g., outpatient or inpatient pharmacy) should be permitted.

(Response) As discussed in comment 31, FDA has revised the proposed rule to eliminate the requirement for prior approval to charge for an approved drug being studied for a new indication when the sponsor must obtain the drug from another entity. In this situation, the sponsor can cause the drug to be distributed to subjects through ordinary distribution channels for marketed drugs (e.g., inpatient or outpatient pharmacies).

However, a sponsor must obtain prior approval to charge, and may recover only the sponsor's direct costs for making a drug available, in the sponsor's trial of a new indication or use of its own approved drug. FDA believes that entities that are marketing an approved drug should generally not charge for the drug in such trials. As discussed in comment 26, sponsors that also market the approved trial drug should not be able to commercialize an unapproved use by charging subjects

market value for the drug in a trial of the unapproved use.

2. Recoverable Costs for Expanded Access Uses

Proposed § 312.8(d)(2) provided that when charging for an expanded access use under proposed § 312.315 (intermediate-size patient population IND or intermediate-size patient population protocol) and § 312.320 (treatment IND or treatment protocol), a sponsor may recover, in addition to the direct costs of the investigational drug as described in proposed § 312.8(d)(1)(i), the costs of monitoring the expanded access IND or protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access use.

(Comment 53) Two comments recommended that sponsors be allowed to charge a reasonable administrative fee, rather than basing charging on an FDA-reviewed calculation of direct costs. The comments suggested that the fee could be set by the sponsor after consultation with patient groups or based on a comparison of the cost of treatment with other drugs in the class or other therapies. The comments further stated that this proposal would simplify the administrative burden and encourage sponsor participation in expanded access programs.

(Response) FDA believes its proposed approach to determining what costs can be recovered for making investigational drugs available for expanded access uses—permitting a sponsor to recover its direct drug costs plus costs of monitoring the expanded access IND or protocol, regulatory compliance associated with the IND or protocol, and other direct administrative costs—is preferable because it simply permits a sponsor to recover all costs it incurs to provide the drug under the expanded access IND or protocol. An administrative fee approach involving consultation with affected patient groups and comparisons of treatment costs for similar or related treatment options seems to add needless complexity and invite arbitrary cost recovery determinations. In addition, this approach would provide FDA no tangible criteria by which to assess whether the amount charged represents commercialization of an unapproved drug.

(Comment 54) Two comments asked FDA to clarify the evidence required to support the amount to be charged under an expanded access program, especially for orphan indications. One of the comments asked that FDA develop

guidance with examples of acceptable cost recovery determinations.

(Response) The recoverable costs for orphan indications under an expanded access program will be the same as for other indications: The direct costs of the drug plus its monitoring, regulatory compliance, and other administrative costs. FDA believes the rule clearly reflects this intent and no additional criteria or guidance are needed concerning what costs can be recovered for investigational drugs for orphan indications. As discussed in the response to comment 48, it is likely that the unit cost of a drug will increase as the size of the population to be treated decreases, but this correlation is unavoidable and does not require any special considerations in the cost recovery calculation. Although FDA believes the cost recovery provisions are sufficiently clear, FDA will evaluate how the rule is implemented and, if there is confusion concerning recoverable costs for expanded access purposes, FDA will consider developing guidance to assist implementation.

(Comment 55) One comment stated that sponsors will continue to be reluctant to charge for a product made available for an expanded access use where the safety and efficacy is unproven, for which there is no reimbursement to help patients pay such costs, and where the allowable charges are limited to the “direct costs” of manufacturing and distributing the proposed product.

(Response) FDA is not advocating that sponsors charge for investigational drugs in expanded access programs. The purpose of permitting cost recovery for expanded access use is to remove any financial disincentive to making a drug available for such use. FDA hopes that sponsors that have the resources to make investigational drugs available for expanded access use will continue to make such drugs available free of charge.

(Comment 56) One comment stated that monitoring or reporting costs for expanded access appear to be excluded by the rule.

(Response) The comment misinterpreted the proposed rule. Proposed § 312.8(d)(2) specifically provided that, for expanded access to an investigational drug for treatment use under proposed §§ 312.315 (intermediate-size patient population) and 312.320 (treatment IND or treatment protocol), in addition to the direct costs described in proposed paragraph (d)(1)(i) of § 312.8, a sponsor may recover the costs of monitoring the expanded access IND or protocol, complying with IND reporting

requirements, and other administrative costs directly associated with these two types of expanded access.

3. Supporting Documentation

Proposed § 312.8(d)(3) provided that a sponsor must provide supporting documentation to show that its cost recovery calculation is consistent with the recoverable costs requirements in paragraphs (d)(1) and, if applicable, (d)(2).

(Comment 57) One comment asked FDA to clarify that if the sponsor challenges FDA’s calculation or authorization of recoverable costs, any affected person, including patients, may be a party to that review.

(Response) If FDA determines that the amount sought to be charged must be lowered by a specified amount and the sponsor formally disputes that determination, third parties would not be allowed to be party to the dispute resolution without the sponsor’s consent because the discussion would invariably involve commercial confidential information. A sponsor’s formal dispute of an FDA denial of a charging request would present the same problem for third parties seeking to be a party to the dispute resolution. Therefore, FDA believes it cannot provide for third-party participation in formal disputes concerning charging determinations without the consent of the sponsor disputing the FDA determination. Moreover, FDA anticipates that most disputed issues with a charging request will be resolved informally in discussions between FDA and the sponsor seeking charging, so a formal dispute will be rare.

(Comment 58) One comment stated that the rule should provide that documentation of recoverable costs follow accepted accounting practices. Another comment stated that it would be difficult for FDA to verify the costs requested, pointing out that the proposed rule stated that if requester’s supporting documentation relies on financial information or accounting methods beyond the expertise of FDA reviewers, FDA may request that a sponsor provide independent certification.

(Response) FDA agrees that the documentation provided to support a calculation of recoverable costs for charging purposes should be prepared by a professional who is competent to make the required determinations. FDA also agrees that it may lack expertise to verify the costs requested. Accordingly, the proposed rule has been revised to state that the documentation must be accompanied by a statement that a

certified public accountant has reviewed and approved the calculations.

(Comment 59) One comment noted that the proposed rule needs to address the tax implications for sponsors of investigational drug charges.

(Response) It is not within FDA's expertise to interpret the tax implications of these charging regulations. Sponsors and individuals who take advantage of the cost recovery option afforded by these regulations are responsible for determining the tax consequences of that cost recovery.

4. Authority to Set Pricing

(Comment 60) Two comments stated that FDA has no statutory authority to regulate the price for which medicine is sold, whether it is approved or unapproved, and such regulation is outside FDA's statutory mission to ensure the safety and effectiveness of marketed drug products.

(Response) The comment misunderstands FDA's statutory basis and goals for regulating charging. FDA is not setting a price for a medication for commercial sale. This final rule intends only to permit recovery of certain costs associated with making an investigational drug available in a clinical trial or for an expanded access use, not to permit FDA to set the price for commercial sale of drugs. In the preamble to the proposed rule, FDA discussed its legal authority (71 FR 75168 at 75173, citing 52 FR 19466 at 19472 (May 22, 1987)). FDA concluded that permitting a sponsor to charge an amount greater than necessary to recover its costs (i.e., to permit a sponsor to profit) would be considered commercialization. For that reason, FDA stated that sponsors could only recover their costs associated with making an investigational drug available. This final rule merely refines what would be considered allowable costs to address some confusion and varied interpretations with the 1987 charging rule.

(Comment 61) One comment asked for clarification about what would be an acceptable independent certification for cost recovery calculations.

(Response) Independent certification from an outside accountant is likely to be adequate documentation concerning the recoverable costs that can be incorporated into the unit cost of the investigational drug. The final rule states that the documentation must be accompanied by a statement that an independent certified public accountant has reviewed and approved the calculations.

5. Confidentiality

(Comment 62) Three comments expressed concern about the confidentiality of the documentation used to support cost calculations. Two comments stated that financial information should be considered proprietary and should not be available to the public either before or after approval.

(Response) FDA will maintain the confidentiality of documentation submitted to support charging requests in a manner consistent with the requirements of 21 CFR part 20. The sponsor is responsible for ensuring that the party providing the certification keeps confidential the information relied on in making that certification.

6. Effect on Payment Systems (CMS and Insurance)

(Comment 63) Several comments expressed concern about the relationship between the proposed rule and payment systems, specifically systems of CMS and health insurance companies. One comment suggested that there should be regulatory changes to require Medicare Part D and other third-party payers to pay for investigational drugs used in clinical trials for which FDA has permitted charging. The comment suggested that the proposed rule could also be revised to provide that FDA authorization to charge for an investigational drug in an expanded access program constitutes approval of the drug so that third-party payers such as insurance companies and Medicare Part D would reimburse patients. Two comments stated that if Medicare covers a drug used in a clinical trial under its coverage with evidence development policy (see CMS "Coverage with Evidence Development," http://www.cms.hhs.gov/CoverageGenInfo/03_CED.asp (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**)), FDA should permit charging for the drug. Another comment recommended that FDA advise CMS to develop a reimbursement model for drugs being used under expanded access programs because private health insurers will then follow suit and there will be more equitable access to investigational drugs. One comment suggested that FDA should require insurers to agree that investigational drugs will be listed on a reimbursable formulary for the indications tested in trials or used in expanded access programs.

(Response) FDA authority to provide for an exception to the general prohibition on charging for investigational drugs, and its policies concerning charging, are distinct from CMS authority to identify the medical interventions for which it will reimburse. FDA has no authority to require that CMS reimburse for investigational drugs for which FDA has permitted charging. Similarly, FDA has no authority to dictate reimbursement policy to private health insurers. FDA notes that there is a trend toward providing reimbursement for medical care related to participation in a clinical trial, and reimbursing for investigational uses of products when there is a certain level of evidence to support the use. FDA believes these are encouraging developments and hopes that third-party payers will continue to develop policies to provide reimbursement for investigational therapies in appropriate circumstances.

7. Collaboration With CMS and the National Cancer Institute

(Comment 64) One comment stated that it would be useful if FDA, CMS, and the National Cancer Institute were to collaborate on the reimbursement implications of this new rule to ensure there are no obstacles to Medicare payment for these investigational drugs.

(Response) FDA discussed the implications of the proposed charging regulation with CMS prior to publishing the proposed rule so CMS could assess the implications of the rule on its reimbursement programs. FDA has also discussed this final rule with CMS. Under current part B policy, CMS does not cover the costs of an investigational drug used in a clinical trial unless the drug is otherwise covered outside the clinical trial. However, certain routine costs associated with medical care obtained due to clinical trial participation may be covered (see Medicare Clinical Trial Policies, <http://www.cms.hhs.gov/ClinicalTrialPolicies/> (follow link to Current Policy, NCD for Routine Costs in Clinical Trials (310.1))). In Part D, the statute clearly defines the drugs that may be covered under the program (and their accepted indications).

(Comment 65) One comment asserted that States will create mandated insurance coverage to mirror the proposed rule expansion. The comment stated that if health insurers are required to cover the cost of these drugs, they will need to increase premiums and that increasing premiums will cause more people to become uninsured.

(Response) Currently, States generally do not mandate reimbursement for

investigational medical interventions. That States may, at some point in the future, begin to institute policies mandating coverage of investigational drugs for which FDA has authorized charging is speculative, and thus not a basis for modifying current FDA policies. In addition, the likelihood that this final rule will further reduce access to health insurance because of increased costs associated with reimbursement for investigational therapies seems remote even if reimbursement were required, as investigational drugs provided under this regulation would constitute only a tiny fraction of overall drug use.

G. Miscellaneous Comments

1. Promotion

(Comment 66) One comment pointed out that FDA regulations at § 312.7 prohibit promotion of an investigational drug and asked that FDA clarify that this final rule permits an approved drug to be promoted outside of a clinical trial for its approved uses, even if the drug is used in a clinical trial.

(Response) FDA agrees with the comment. Nothing in this final rule should be construed as a constraint on a manufacturer's ability to promote an approved drug for its approved indications.

2. Liability

(Comment 67) One comment notes that there are potential liability concerns that need to be addressed that may result from subjects experiencing serious adverse events when charged for an investigational drug not approved by FDA.

(Response) When the amount charged for the investigational drug is merely the sponsor's cost, and subjects have given their informed consent to participate in a trial in which there is charging for study drug, FDA does not believe there would be a meaningful difference in a sponsor's product liability exposure when it charges for the drug compared to when it does not.

3. Product Labeling

(Comment 68) One comment pointed out that § 312.6(a) requires that the immediate package of an investigational new drug bear a label advising that the drug is limited by law to investigational use. The comment expressed concern that the proposed rule could be interpreted as requiring approved drugs to bear that statement.

(Response) FDA does not interpret this final rule as requiring use of the statement required by § 312.6(a) on the label of an approved drug product. The labeling approved for marketing of the

product is acceptable. However, nothing in this final rule prevents a sponsor from designating a clinical supply of approved drug for use only in a clinical investigation and labeling the product in the manner provided by § 312.6(a).

4. Analysis of Impact

(Comment 69) One comment disputed FDA's conclusion that Executive Order 12866 does not apply because the proposed rule is not an economically significant regulatory action. The comment maintained that expanding the scope of treatment uses for which charging is permitted to include charging for drugs made available under intermediate-size patient populations and for individual patients could result in a significant financial impact. The comment also noted that one of the reasons for allowing charging in clinical trials is that the development of the investigational drug may be extraordinarily expensive. The comment stated that since FDA is predicting that requests for charging in clinical trials, and hence charging for extraordinarily expensive drugs will increase, there would likely be a significant financial impact. The comment asked that FDA perform an economic impact analysis or provide a better reason the Executive order does not apply.

(Response) Based on our analysis (incorporating changes made to the proposed rule), we conclude that the final rule is not economically significant as defined under Executive Order 12866. The comment does not provide any data or alternative analyses that would lead the agency to change this conclusion. Historical data indicate that only a very small percentage of all INDs submitted to FDA for clinical trials or treatment use include requests to charge for the drug. FDA expects only a slight increase in the already limited number of requests to charge as a result of the final rule. Our analysis of impacts predicts only a slight increase in charging for individual patient INDs, and a modest increase in charging for intermediate-size patient population INDs (see section VI.E.2 of this document) (upper bound of less than 800 total patients affected). Because provisions for allowing charging in a clinical trial have been in the regulation since 1987, and this rule merely clarifies the criteria for allowing such charging, FDA does not anticipate a meaningful increase in charging requests in that setting. Thus, we do not believe that the final rule will have a significant economic or financial impact.

(Comment 70) One comment disputed FDA's assertion in the proposed rule that the "costs [associated with making

investigational drugs available for treatment use] would not be excessive and would be justified by the primary benefit of this proposed rule, making investigational drugs available for treatment use that could not be otherwise made available without charging" (71 FR 75168 at 75175). The comment stated that there is little evidence for these claims, arguing that the costs are likely to be very high in some cases and relatively low in other cases.

(Response) FDA agrees that there will be a range of costs for investigational drugs made available for treatment use and subject to charging, and that costs could be quite high in some cases. However, the differing costs of drugs across different expanded access programs does not undermine FDA's conclusion that costs of this final rule are justified in light of the potential benefits associated with broader access to investigational drugs for treatment use. That conclusion is not intended to imply that costs and benefits are offset in each individual case in which there is charging for drugs made available for treatment use, so variation in cost across different expanded access programs does not undermine the overall conclusion.

(Comment 71) One comment reviewed claims data on the treatment of diseases likely to fall under the FDA's proposed rule changes. The comment assumed that physicians would request access to investigational drugs only when available therapies have failed or when conventional therapies do not exist. The comment also assumed that, depending on the circumstances, investigational drugs will be used as first-line therapy, second-line therapy, monotherapy and combined therapy with FDA-approved medications. Based on these assumptions, the comment estimated the additive cost of the proposed rule as it would apply to enrollees in commercial/private health plans to be \$273,700,000. The comment expressed the belief that these estimates actually understate the burden to private sector payers, because they exclude potential annual costs to Medicare Advantage plans.

(Response) Based on our analysis, we concluded that the costs of the final rule will be small. In response to the comment, we have included estimates of the number of individual patients charged for investigational drugs under current rules, and the number of additional patients we expect may be charged for investigational drugs under this final rule. FDA's estimates indicate that, on average, as many as 12,566 patients per year may be charged for

investigational drugs under current rules. In addition, we estimate that as many as 770 additional patients per year may be charged for investigational drugs under this final rule. These estimates are based on assumptions used in our analysis of impacts for the proposed rule that were not substantively challenged in any of the comments received.

The estimate of 67,500 patients affected per year in the comment draws no distinction between patients who may be charged for investigational drugs under current rules and those additional patients who may be charged under this final rule. In assessing the impact of the final rule, it is the incremental effect, or additional patients that may be charged for investigational drugs, that must be considered. Patients who may be charged for investigational drugs under current rules are not relevant to an analysis of impacts for this final rule. The comment appears to assume that all patients who may be eligible to obtain an investigational drug under an expanded access IND would seek access, and that an appropriate drug would be available in all cases. In addition, the comment appears to assume that all patients with access to investigational drugs will also be charged for those drugs. Our analysis of historical data indicates that, on average, only about 1.1 percent of all IND submissions per year are associated with charging requests.

The only direct costs that are relevant to this final rule are the costs to drug sponsors to prepare and submit charging requests to FDA. The comment did not provide an estimate of these costs.

IV. Legal Authority

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the act) to permit charging for an investigational new drug under the conditions set forth in this final rule. This final rule clarifies and slightly expands the charging scheme that is already in place. It is based on the agency's² authority to issue regulations pertaining to the investigational use of drugs, section 505(i) of the act (21 U.S.C. 355(i)), its authority pertaining to expanded access to unapproved drugs for treatment use, section 561 of the act (21 U.S.C. 360bbb), and its general grant of rulemaking authority for the efficient

enforcement of the act, section 701(a) of the act (21 U.S.C. 371(a)).

Section 505(i) of the act directs the agency to issue regulations exempting from the operation of the new drug approval requirements drugs intended solely for investigational use by experts qualified by scientific training and expertise to investigate the safety and effectiveness of drugs. It is this authority that underlies FDA's IND regulations in part 312. The final rule adds to and clarifies the previous IND regulations by revising the 1987 charging rule to explain the circumstances under which charging for an investigational drug is appropriate in a clinical trial and to clarify what costs can be recovered.

Section 561 of the act, added by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), provides additional authority for this final rule. One of that section's preconditions to providing an investigational drug for treatment use is that the sponsors submit a protocol consistent with regulations issued under section 505(i) of the act (see section 561(b)(1), (b)(4), and (c) of the act). This rulemaking sets out the circumstances under which charging for an investigational drug is appropriate for treatment use in an expanded access program as well as in a clinical trial and clarifies what costs can be recovered.

Section 701(a) of the act gives FDA the authority to issue regulations for the efficient enforcement of the act. Further discussion of FDA's legal authority regarding charging can be found at 52 FR 19466 at 19472 (May 22, 1987).

V. Environmental Impact

The agency has determined, under 21 CFR 25.30(h), 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.

VI. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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). The agency believes that this final rule is not an

economically significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that will minimize any significant impact of a rule on small entities. Our economic analysis for the proposed rule did not indicate any significant new regulatory burden, and we did not receive any comments that would cause us to reconsider this determination. Therefore, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

Preparing additional charging requests accounts for the anticipated costs of this final rule. The agency estimates that, the cost for a sponsor to prepare and submit a charging request is approximately \$2,500, and that these costs will be widely dispersed among affected entities. Because such requests are rare, the incremental number of requests generated by this final rule, as well as the total costs of the rule, will probably be quite small. Permitting charging for a broader range of treatment uses for investigational drugs will increase sponsors' incentives to undertake such activities, thereby promoting development of new products, as well as the development of new uses for already approved products. Due to uncertainty with respect to the potential magnitude of such benefits, and a lack of necessary data, FDA did not generate quantitative estimates of expected benefits.

A. Objectives of the Final Rule

The objectives of the final rule are to clarify and expand on 1987 charging rule that permits sponsors to charge patients for investigational drugs. Under this 1987 charging rule, FDA could authorize charging for an investigational drug used in a clinical trial or under a treatment IND or protocol. The final rule describes more specifically the types of

² In light of section 903(d) of the act (21 U.S.C. 393(d)), and the Secretary of Health and Human Service's delegations to the Commissioner of Food and Drugs, statutory references to "the Secretary" in the discussion of legal authority have been changed to "FDA" or "the agency."

costs that can be recovered when charging for an investigational drug. The final rule also adds provisions that permit charging for investigational drugs for all of the various types of expanded access use described under final subpart I of part 312.

B. The Need for the Final Rule

The final rule is needed to establish charging provisions for additional types of expanded access use other than the treatment IND or protocol. Elsewhere in this issue of the **Federal Register**, FDA is amending part 312 of its regulations by adding subpart I concerning expanded access to investigational drugs. In addition to the treatment IND or protocol previously described in FDA regulations, the expanded access final rule specifically authorizes expanded access use for individual patients, including in emergencies, and expanded access use for intermediate-size patient populations. The expanded access final rule is intended to improve access to investigational drugs for patients with serious diseases who have exhausted other therapeutic options and may benefit from such therapies. This final rule is necessary to establish provisions that permit charging for investigational drugs for all of the categories of expanded access use described under final subpart I.

The final rule is also needed to clarify and better explain the types of costs sponsors are permitted to recover through charging. The 1987 charging rule describing the costs a sponsor can recover when charging for an investigational drug has proven difficult to interpret and apply. Some sponsors have interpreted the language broadly to permit recovery of costs much greater than those directly attributable to providing the investigational drug for the approved treatment use. In addition, ambiguities in the 1987 charging rule may have caused inefficiencies leading some drug sponsors to devote more resources than necessary to the preparation and submission of charging requests.

C. Why Allow Charging?

The expense of conducting a clinical trial is considered a normal cost of drug development that should be recovered through sales after marketing approval. However, in some clinical trial settings, a sponsor may incur extraordinary costs compared to typical drug development expenses. Such a cost burden may arise because of unusually high manufacturing costs, the quantity of the drug required, the number of patients involved, the expected duration of treatment, or some combination of these

factors. The agency believes that allowing cost recovery through charging may be appropriate in these instances, but only as a last resort source of funding to facilitate development of a promising new therapy that could not otherwise be developed.

In some clinical trials, it may be necessary for a sponsor to obtain an approved drug from another entity. The approved drug may be used as an active control or in combination with the sponsor's drug in a clinical trial designed to evaluate the effectiveness or safety of the sponsor's investigational drug. In these situations, the trial subjects typically must receive some therapy for their disease because using a placebo control will be unethical. In addition, the subjects often will be treated with the approved drug in the course of medical practice if they were not participating in the clinical trial. FDA had proposed criteria for charging in these situations that presented a much lower threshold than for charging for the sponsor's own investigational drug. Based on comments received, FDA has elected not to require sponsors who must obtain an approved drug from another entity for use as an active control, or in combination with the sponsor's own drug, to obtain authorization to charge for the drug and otherwise fulfill the requirements in § 312.8. Under this final rule, such sponsors can charge at their own discretion in this circumstance.

In other situations, an approved drug must be obtained by a third party (not the holder of the approved application) to study the drug in a clinical trial for a new use or to obtain important safety information about an approved indication. Researchers conducting such clinical trials are primarily noncommercial entities who are not in the business of drug development. Typically, these sponsor-investigators conduct relatively small trials at a single site. Since such sponsors lack the resources of commercial sponsors and do not conduct the research for commercial purposes, they will not be able to recover the cost of obtaining the approved drug by marketing the drug, for example, for a new indication. The agency believes these kinds of trials should be encouraged because they may yield important data about less commercially viable uses of a drug or additional drug safety information. FDA had proposed criteria for charging in these situations that presented a much lower threshold than for charging for the sponsor's own investigational drug. Based on comments received, FDA has elected not to require sponsors who must obtain an approved drug from

another entity for a study of the approved drug (e.g., a study of a new use) to obtain authorization to charge for the drug and otherwise comply with the requirements of § 312.8. Under this final rule, such sponsors can charge at their own discretion in this circumstance.

In contrast to clinical trials, granting expanded access to investigational drugs for treatment use primarily benefits individual patients and is not intended typically to generate data needed to support marketing approval. Thus, the costs to sponsors associated with making a drug available for expanded access are not considered typical drug development expenditures. For this reason, the agency believes that it is generally more appropriate to permit sponsors to charge for expanded access to investigational drugs for treatment use. Allowing charging in expanded access settings may also provide financial incentives for sponsors to make investigational drugs more widely available in these situations.

D. Baseline for the Analysis

During the period 1997 through 2005, FDA received an average of 2,046.6 INDs per year. During this same period, the agency received an annual average of 22.6 requests to charge patients for investigational drugs. Thus, only about 1.1 percent ($0.011 = 22.6 / 2,046.6$) of all INDs received by the agency on an annual basis were associated with charging requests. Similarly, FDA received an average of 4.6 treatment IND or protocol submissions and 1.1 treatment IND or protocol charging requests per year during this period. Thus, requests to charge under treatment INDs or protocols were associated with about 0.05 percent ($0.0005 = 1.1 / 2,046.6$) of all INDs received by the agency, and approximately 23.9 percent ($0.239 = 1.1 / 4.6$) of all treatment IND or protocol submissions per year.

FDA also received an average of 55 other IND submissions and 15.6 other charging requests per year during this period. These requests were to charge patients for expanded access to investigational drugs in situations other than individual patient or emergency INDs, and treatment INDs or protocols. Such situations generally included requests to charge for expanded access in intermediate-size patient populations and under clinical trials. Because the intermediate-size patient population IND or protocol was not previously established in regulation, a more precise distribution of other charging requests cannot be determined. Nevertheless, other charging requests were associated

with about 0.76 percent ($0.0076 = 15.6 / 2,046.6$) of all INDs received by the agency, and approximately 28.4 percent ($0.284 = 15.6 / 55$) of all other IND submissions each year from 1997 through 2005.

Finally, FDA received an average of 659 individual patient or emergency IND submissions and 5.9 charging requests for individual patient or emergency INDs per year. Thus, single patient or emergency IND charging requests are associated with about 0.29

percent ($0.0029 = 5.9 / 2046.6$) of all INDs, and approximately 0.9 percent ($0.009 = 5.9 / 659$) of all single patient or emergency INDs received by the agency each year. This information is summarized in table 1 of this document.

TABLE 1.—BASELINE DATA FOR AVERAGE ANNUAL NUMBER OF IND SUBMISSIONS AND CHARGING REQUESTS BY CATEGORY

Category	All Charging Requests	Treatment IND/ Protocol Requests	Other Charging Requests	Individual Patient/ Emergency Requests
Number of charging requests	22.6	1.1	15.6	5.9
Percent of all INDs	1.1%	0.05%	0.76%	0.29%
Average number of submissions		4.6	55	659
Percent of submissions		23.9%	28.4%	0.9%

One comment submitted in response to the proposed rule provided an estimate of the number of patients that might be affected by this final rule. As part of our response, we have generated estimates of the number of patients receiving investigational drugs and subject to charging requests under current rules, in place since 1987. Based on the information presented in table 1 of this document, FDA currently receives an average of 5.9 charging requests for individual patient or emergency INDs per year. Thus, approximately 5.9 individuals per year may currently be charged for

investigational drugs under single patient or emergency INDs. FDA believes that it is reasonable to assume that a typical intermediate-size patient population will include between 10 and 100 individuals. Given that FDA currently receives an average of 15.6 charging requests for such submissions per year, we estimate that between 156 and 1,560 individuals may currently be charged for investigational drugs under intermediate-size patient populations. A treatment IND or protocol can vary significantly in size and may include between 100 and 10,000 patients. Thus,

an average of 1.1 treatment IND or protocol charging requests per year could affect between 110 and 11,000 individuals. Based on this information, FDA estimates that between 272 and 12,566 individuals may currently be charged for investigational drugs each year under rules in place since 1987. The wide range of these estimates reflects significant variation in the number of patients enrolled in intermediate-size patient populations, and treatment INDs or protocols. These estimates are summarized in table 2 of this document.

TABLE 2.—APPROXIMATE NUMBER OF INDIVIDUALS AFFECTED ANNUALLY BY CHARGING RULES FOR INVESTIGATIONAL DRUGS IN PLACE SINCE 1987

Category	Average Number of Requests	Number of Patients	Minimum Number of Individuals	Maximum Number of Individuals
Individual patient or emergency IND	5.9	1	5.9	5.9
Small patient population/other	15.6	10—100	156	1,560
Treatment IND or protocol	1.1	100—10,000	110	11,000
Total			272	12,566

E. Nature of the Impact

The final rule will affect patients who lack effective therapeutic alternatives for serious diseases; sponsors that develop drugs to treat such diseases; and FDA in determining whether to authorize charging for investigational drugs. By clarifying requirements and establishing the full range of situations in which it may be appropriate to charge for an investigational drug, the final rule will improve patient access by providing a financial incentive for sponsors to make promising therapies more widely available. Thus, this final

rule should help to facilitate patient access to drugs that could not be provided without charging and permit sponsors to study drugs that might otherwise be too costly to develop. By describing in regulation the full range of treatment use situations in which charging for an investigational drug may be permitted, this final rule will likely increase the volume of charging requests for treatment use somewhat. However, by clarifying the circumstances under which charging will be permitted and specifying the types of costs that sponsors can recover,

this final rule should also make the process of obtaining authorization to charge more transparent and more efficient. Given the small percentage of all INDs that include charging requests, FDA believes that the impact of the final rule will be small. This final rule could also increase treatment expenses for some patients who obtain investigational drugs for which charging is permitted or for third-party payers if they choose to reimburse patients for some or all of the costs of such drugs. The agency believes that such costs will not be excessive and will

be justified by the primary benefit of this final rule, making investigational drugs available for treatment use that could not otherwise be made available without charging. The potential impact of specific provisions of the final rule is discussed in greater detail in the following paragraphs.

1. Charging in a Clinical Trial

Since 1987, FDA regulations have permitted charging for investigational drugs in clinical trials intended to support marketing approval. This final rule is intended only to clarify the situations in which charging for a sponsor's investigational drug in such a clinical trial is appropriate. Therefore, FDA does not expect this final rule to have a substantial effect on the number of requests to charge for sponsors' investigational drugs in clinical trials to support initial marketing approval.

Based on comments received, FDA has elected not to require sponsors who must obtain an approved drug from another entity for use as an active control or in combination with the sponsor's drug to obtain authorization to charge for the drug. In addition, FDA has elected not to require sponsors who must obtain an approved drug from another entity for a study of the approved drug (e.g., a study of a new use) to obtain authorization to charge for the drug. Under this final rule, such sponsors can charge for investigational drugs under these circumstances at their own discretion. Therefore, our original conclusion in the proposed rule that

there would not be a substantial impact on the number of charging requests in clinical trial situations is unchanged in the final rule.

2. Charging for Expanded Access Uses Described Under Final Subpart I

One comment submitted in response to the proposed rule provided an estimate of the number of patients that might be affected by this final rule. As part of our response, we have generated estimates of the number additional patients that may be charged for investigational drugs under this final rule. Information presented in tables in the analysis of impacts section of the expanded access final rule, published elsewhere in this issue of the **Federal Register**, will be used to generate these estimates.

FDA estimates that the expanded access final rule will generate between 132 and 395 additional single patient or emergency IND submissions per year. Information presented in table 1 of this document indicates that approximately 0.9 percent of all single patient or emergency INDs are associated with charging requests. Thus, the agency estimates that this final rule will generate between 1.2 ($1.2 = 132 \times 0.009$) and 3.5 ($3.5 = 395 \times 0.009$) additional charging requests for single patient or emergency INDs. These figures imply that approximately 1.2 to 3.5 additional patients may be charged each year for investigational drugs as a result of this final rule.

Similarly, the agency estimates that the expanded access final rule will generate between 3 and 27 additional intermediate-size patient population IND submissions per year. Information presented in table 1 of this document indicates that approximately 28.4 percent of all such IND submissions are associated with charging requests. Therefore, the agency estimates that this final rule will generate between 0.85 ($0.85 = 3 \times 0.284$) and 7.67 ($7.67 = 27 \times 0.284$) additional charging requests for intermediate-size patient population submissions per year. The agency believes it is reasonable to assume that an intermediate-size patient population will generally include between 10 and 100 individual patients. These figures imply that approximately 8.5 ($8.5 = 0.85 \times 10$) to 767 ($767 = 7.67 \times 100$) additional patients may be charged for investigational drugs under intermediate-size patient populations each year as a result of this final rule.

Because current regulations allowing charging for investigational drugs under a treatment IND or protocol are not significantly altered by this final rule, the agency does not anticipate that the final rule will lead to a change in the number of requests to charge. Therefore, FDA expects that between 10 ($9.7 = 1.2 + 8.5$) and 770 ($770.5 = 3.5 + 767$) additional patients may be charged for investigational drugs per year as a result of this final rule. The results of these calculations are summarized in table 3 of this document.

TABLE 3.—APPROXIMATE NUMBER OF ADDITIONAL INDIVIDUALS THAT MAY BE CHARGED FOR INVESTIGATIONAL DRUGS UNDER THIS FINAL RULE

Category	Number of Additional Submissions	Number of Additional Charging Requests	Number of Individuals per Request	Total Number of Individuals
Individual patient or emergency IND	132—395	1.2—3.5	1	1.2—3.5
Small patient population/other	3—27	0.85—7.67	10—100	8.5—767
Treatment IND or protocol	0	0	100—10,000	0
Total				10—770

3. Costs Recoverable When Charging for an Investigational Drug

Finally, § 312.8(d) of the final rule clarifies and better explains the types of costs sponsors are permitted to recover through charging. In particular, sponsors are limited to recovery of the direct or marginal costs associated with making an investigational drug available for the approved treatment use. Direct costs that are recoverable under the final rule include per unit manufacturing costs and shipping and handling costs.

In addition, the final rule permits sponsors to recover the costs of monitoring an expanded access protocol, complying with IND reporting requirements, and other administrative costs directly associated with expanded access for an intermediate-size patient population and for a treatment IND or treatment protocol.

4. Summary

The agency does not expect the number of requests to charge for a sponsor's drug in a clinical trial, or to

charge for an investigational drug under a treatment IND or treatment protocol, to be affected because the final rule does not significantly change the 1987 charging rule. We estimate that final provisions allowing charging for single patient or emergency INDs and intermediate-size patient populations will affect between 10 and 770 individuals.

F. Benefits of the Final Rule

Because FDA currently has no data that will allow us to predict the extent

to which the final amendments to existing regulations will generate direct benefits for consumers, it is not possible to accurately quantify the magnitude of any expected incremental benefits at this time. We expect the number of requests to charge for investigational drugs for expanded access use to increase somewhat. However, the number of additional patients who will gain access to investigational drugs as a result and the extent to which these patients will benefit from such access are highly uncertain. Establishing in regulation all of the situations in which charging is permissible and clearly specifying the types of costs that are eligible for recovery will ease the administrative burdens associated with obtaining authorization to charge and will improve patient access to investigational drugs for treatment use. Private benefits will accrue to individual patients receiving the drugs, whereas additional social benefits will accrue if others in society also value these individual patient benefits. Because the overall impact of the final rule is expected to be small, the potential for any new regulatory benefits is somewhat limited.

In formulating the final rule, FDA considered the interests of patients, drug sponsors, and the general public. Concerning charging for investigational drugs in expanded access settings, the agency concluded that seriously ill patients could often benefit from increased access to investigational drugs that have not yet been approved for marketing. On the other hand, greater patient access to investigational drugs outside of the clinical trial setting could have the potential to delay approvals of drugs to treat serious diseases (e.g., by reducing incentives for potential subjects to enroll in clinical trials). If allowing charging were to adversely affect the drug approval process, the general population will experience diminished social benefits due to the reduced or delayed availability of new therapies approved for marketing by FDA.

The final rule addresses this tension by allowing sponsors to charge for investigational drugs in expanded access settings as long as the sponsor provides reasonable assurance that charging will not interfere with development of the drug for marketing approval. In this way, the final rule will address the interests of those patient populations that will benefit from having greater access to investigational drugs and the broader interests of society in having safe and effective therapies approved for marketing and widely available.

The final rule limits sponsors to recovery of the direct or marginal costs associated with making the drug available. Direct costs that are recoverable under the final rule include per unit manufacturing costs and shipping and handling costs. Indirect or fixed costs incurred for joint or common objectives and physical plant and equipment expenditures for producing marketable quantities of the drug are specifically excluded under the cost recovery provisions of the final rule. The agency believes that these cost recovery provisions will prevent sponsors from inappropriately shifting the normal financial risks associated with new drug development onto patients when they charge for drugs in clinical trial settings. For expanded access use, the limitation to direct cost recovery will also ensure that drug development costs that properly belong to sponsors are not shifted to patients.

G. Costs of the Final Rule

Although the final rule largely clarifies current agency practice, some additional paperwork costs will be incurred to the extent that the rule increases the total number of sponsor requests to charge patients for investigational drugs. The information requirements associated with the final rule are not expected to impose a significant burden. Drug sponsors who wish to charge for investigational drugs will need to review the rule to become familiar with its provisions and to gather the evidence and information necessary to support charging requests. Because of the lack of data described previously in this document, we are unable to generate quantitative estimates of compliance costs at this time. The agency expects that any incremental cost burdens will likely be small and widely dispersed among affected entities for a number of reasons.

First, regulations covering charging for investigational drugs in clinical trials and under treatment INDs or treatment protocols have been in place since 1987. As a result, the primary incremental impact of the final rule will be limited to the new charging provisions for the new types of expanded access for treatment use described under final subpart I of part 312. Second, the agency does not expect that these final charging provisions will lead to a large increase in the total number of charging requests. Because it is not usually extraordinarily expensive to make an investigational drug available to a single patient or a limited number of patients, the agency does not anticipate that the number of charging requests for expanded access to

investigational drugs for single patients or intermediate-size patient populations will increase substantially. Finally, requests to charge are relatively infrequent and the expense necessary to prepare a charging request will ordinarily be small compared to the overall cost of preparing the expanded access submission.

The agency estimates that, on average, 48 hours will be needed to prepare a request to charge under the final rule. This estimate is based on FDA's experience in reviewing charging requests under the 1987 charging rule and on a projection of the increased paperwork burden associated with the final rule.

FDA's experience implies that 80 percent, or about 38 hours, of this burden will be associated with establishing that the amount proposed to be charged is limited to the direct costs of making the drug available. The agency believes that the cost justification portion of the charging request will need to be performed by a cost accountant qualified to assess the direct costs of charging. Information available on the Internet indicates that median total compensation for a Cost Accountant IV (senior level) is approximately \$117,000 per year in 2008 or about \$56 per hour (\$116,857 / 2,080 hours).³ Thus the cost associated with certifying the amount to be charged is expected to be about \$2,130 (\$56 per hour x 38 hours) per charging request.

The remaining burden (20 percent or about 10 hours) for the preparation of a charging request will consist of a brief demonstration that the criteria for charging that are not related to the amount to be charged have been met. When the request is to charge for a drug used in a clinical trial, this information will ordinarily be available as part of the normal drug development process. When the request is to charge for a drug for expanded access, the primary criterion is to show that charging will not interfere with development of the drug for marketing. FDA believes that preparation of this portion of the charging request will likely be performed by a mid-level regulatory affairs specialist. Information available on the Internet indicates that the total median compensation for a Regulatory Affairs Specialist II (intermediate level) is approximately \$100,000 or about \$48 per hour in 2008 (\$99,930/2,080

³ See http://swz.salary.com/salarywizard/layouts/scripts/swzl_newsearch.asp, last viewed 7/10/08. (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**.)

hours).⁴ Thus, the cost to demonstrate that a charging request meets appropriate criteria is about \$480 (10 hours x \$48 per hour) per charging request.

Based on the figures presented previously in this document, FDA estimates the cost to prepare and submit a charging request will thus be about \$2,610 (\$2,130 + \$480). The total costs associated with this final rule will probably be widely dispersed among affected entities because charging requests are rare, and thus, a particular sponsor will be expected to submit such a request very infrequently.

A significant concern with the final rule relates to the potential effect on access to investigational therapies for economically disadvantaged individuals and the uninsured. Allowing sponsors to charge could impose a significant financial burden on many seriously ill individuals who lack therapeutic alternatives and could preclude access by some needy patients. However, in the past, many companies that have provided investigational drugs for treatment use have often included assistance programs to cover the costs for those who could not otherwise afford them. FDA expects this practice will continue.

H. Minimizing the Impact on Small Entities

The agency does not believe that the final rule will have a significant economic impact on a substantial number of small entities. Nevertheless, in the proposed rule, we recognized our uncertainty regarding the number and size distribution of affected entities, as well as the economic impact of the final rule on those entities, and requested detailed comment on these important issues. We received no comments that would cause us to change our determination that the final rule will not have a significant economic impact on a substantial number of small entities.

According to agency records, the majority of treatment INDs and treatment protocols (approximately 92 percent) are submitted by commercial sponsors and government agencies that are not likely to meet Small Business Administration (SBA) criteria defining a small entity in the relevant industry sector. Thus, the agency believes that the vast majority of requests to charge under expanded access submissions will not be submitted by small entities.

Most single patient INDs are for treatment use and are submitted by individual physicians, and these entities will be classified as small entities.

However, for reasons discussed previously, we do not anticipate that the volume of requests to charge for individual patient expanded access will increase substantially. Because expanded access for intermediate-size patient populations is not currently tracked by the agency, no data exist that will allow the agency to identify either the number of sponsors in this category or the number that will qualify as small entities. FDA believes that requests to charge for investigational drugs in clinical trials of a sponsor's drug will generally be submitted by large commercial drug sponsors. In sum, the agency believes that some entities submitting charging requests will meet SBA small businesses criteria. As discussed in section VI.E of this document, the agency expects that any incremental burden associated with the final rule will be small and widely dispersed among affected entities.

I. Alternatives

FDA considered several alternatives to the final rule. Each is discussed in the following paragraphs:

- Do not revise the 1987 charging rule.

FDA considered and rejected this alternative because the 1987 charging rule does not address all of the types of expanded access to investigational drugs for treatment use specified under final subpart I of part 312. Furthermore, the cost recovery provisions in the 1987 charging rule were vague and ambiguous and thus in need of clarification.

- Retain the proposed requirements that would have required sponsors who must obtain an approved drug from another entity for use in the study evaluation to obtain authorization from FDA to charge.

FDA considered this alternative. However, FDA believes the comments made a persuasive case for not requiring authorization to charge in these settings. The most common requests to charge are for approved drugs in trials when the drugs must be obtained from another company. For reasons discussed in section VI.C of this document, FDA believes that charging for investigational drugs in these situations is appropriate without prior authorization from FDA.

- Do not permit charging for expanded access for individual patients or for intermediate-size patient populations.

FDA considered not revising the 1987 charging rule concerning charging for

treatment use and thus permitting charging only for treatment INDs and treatment protocols. However, elsewhere in this issue of the **Federal Register**, the agency is finalizing its regulations concerning the treatment use of investigational drugs to specifically authorize expanded access for individual patients and for intermediate-size patient populations. The purpose of those regulations is to expand access to investigational drugs. In some situations, permitting sponsors to charge for investigational drugs to be used by individual patients or by intermediate-size patient populations may be the only way that such patients can receive access to these therapies because sponsors may not be willing to provide the drugs free of charge. Thus, consistent with the philosophy of the expanded access rule, the agency decided to permit charging for investigational drugs in all expanded access settings to improve access to investigational drugs for patients with serious diseases who lack other therapeutic options and who may benefit from such therapies.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that 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 PRA). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Charging for Investigational Drugs Under an IND

Description: The final rule describes the types of investigational uses for which a sponsor may be able to charge, including uses for which charging was not previously expressly permitted, and the criteria for allowing charging for the identified investigational uses. The rule authorizes sponsors to request to charge for investigational drugs used in clinical trials and for investigational drugs for expanded access for treatment use. The rule also describes the types of costs that can be recovered when charging for an investigational drug.

Section 312.8(a)(1) provides that a sponsor who wishes to charge for an investigational drug must meet the criteria applicable to the specific sections of the proposal relating to

⁴ See http://swz.salary.com/salarywizard/layouts/scripts/swz1_newsearch.asp, last viewed 7/10/08. (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**.)

charging in a clinical trial or charging for expanded access.

Section 312.8(b) describes the requirements for charging in a clinical trial.

Section 312.8(b)(1) describes criteria for charging for the sponsor's own drug in a clinical trial. To charge in this situation, the sponsor must show the following three things. The sponsor must:

- Provide evidence that the drug has a potential clinical benefit that, if demonstrated in the clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation, or prevention of a disease or condition;
- Demonstrate that the data to be obtained from the clinical trial would be essential to establishing that the drug is effective or safe for the purpose of obtaining initial approval of a drug, or would support a significant change in the labeling of an approved drug (e.g., new indication, inclusion of comparative safety information); and
- Demonstrate that the clinical trial could not be conducted without charging because the cost of the drug is extraordinary to the sponsor.

Section 312.8(c) describes criteria for charging for an investigational drug in an expanded access setting. The general criterion to charge for expanded access for treatment use is that the sponsor provide reasonable assurance that charging will not interfere with developing the drug for marketing approval.

For treatment use under a treatment IND or treatment protocol, the sponsor must also provide the following:

- Evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trial(s) will be successfully completed as planned,
- Evidence of adequate progress in the development of the drug for marketing approval, and
- Information submitted under its general investigational plan (§ 312.23(a)(3)(iv)) specifying the drug development milestones the sponsor plans to meet in the next year.

Section 312.8(a)(2) provides that a sponsor who wishes to charge for an investigational drug must justify the amount to be charged.

Section 312.8(d) describes more specifically the costs that are potentially recoverable. Section 312.8(d)(1) provides that a sponsor may recover only the direct costs of making the investigational drug available. Section 312.8(d)(1)(i) defines direct costs as costs incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source and direct costs to ship and handle (e.g., store) the drug.

Section 312.8(d)(1)(ii) states that indirect costs include costs that are incurred primarily to produce the drug for commercial sale. Such costs include, for example, costs for facilities and equipment that are used to manufacture the supply of investigational drug but that are primarily intended to produce large quantities of drug for eventual commercial sale and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or expanded access for which charging is authorized did not occur.

Section 312.8(d)(2) provides that when the sponsor is charging for making the drug available for expanded access for an intermediate-size patient population or for a treatment IND or protocol under subpart I, the sponsor may also recover the costs of monitoring the protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access in addition to the sponsor's direct costs.

Description of Respondents: Licensed physicians and manufacturers, including small business manufacturers.

Estimates of Reporting Burden: Table 4 of this document presents the estimated annualized reporting burden for the total number of charging requests we expect to receive under the final rule. The estimates in table 4 have been derived in the following manner. Based on baseline data presented in section VI of this document, "Analysis of

Economic Impacts," we estimate that we will receive a total of approximately 34 charging requests annually under the final rule. This estimate is the sum of the average number of charging requests we currently receive annually (i.e., 22.6), plus the additional charging requests, as described in the analysis of economic impacts, that we expect to receive annually as a result of the amendments in the final rule (i.e., 3.5 + 7.67). Concerning the number of respondents, our experience has been that, in general, a single sponsor does not make multiple requests to charge for investigational drugs in the same year. However, we anticipate that multiple requests may increase somewhat if, as we expect, the number of individual patient treatment uses increases. Thus, we have assumed that the number of annual respondents will be approximately 30.

The largest portion of the paperwork burden associated with the final rule is to justify the request to charge by showing that the amount proposed to be charged is limited to the direct costs of making the drug available (§ 312.8(d)(1)). When the sponsor requests to charge for making the drug available for expanded access by an intermediate-size patient population or through a treatment IND or treatment protocol, the sponsor may also recover the costs of monitoring the treatment use protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access (§ 312.8(d)(2)). The sponsor also needs to support its suggested charge for these expenses. The remaining portion of the paperwork burden associated with the final rule is to show that the criteria applicable to the specific type of charging request (i.e., the type of clinical trial (§ 312.8(b)) or type of expanded access (§ 312.8(c))) have been met. Thus, we estimate that the average number of hours needed to prepare a request to charge for an investigational drug under the final rule is 48. This estimate is based on our experience in reviewing charging requests in the past and, as explained previously, on a projection of the increased paperwork burden associated with the final rule.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.8	30	1.13	34	48	1,632

¹ There are no capital costs or operating and maintenance costs associated with this collection.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has 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, the agency has 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.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 371, 381, 382, 383, 393; 42 U.S.C. 262.

■ 2. Section 312.7 is amended by removing paragraph (d) and by revising the section heading to read as follows:

§ 312.7 Promotion of investigational drugs.

* * * * *

■ 3. Section 312.8 is added to subpart A to read as follows:

§ 312.8 Charging for investigational drugs under an IND.

(a) *General criteria for charging.* (1) A sponsor must meet the applicable requirements in paragraph (b) of this section for charging in a clinical trial or paragraph (c) of this section for charging for expanded access to an

investigational drug for treatment use under subpart I of this part, except that sponsors need not fulfill the requirements in this section to charge for an approved drug obtained from another entity not affiliated with the sponsor for use as part of the clinical trial evaluation (e.g., in a clinical trial of a new use of the approved drug, for use of the approved drug as an active control).

(2) A sponsor must justify the amount to be charged in accordance with paragraph (d) of this section.

(3) A sponsor must obtain prior written authorization from FDA to charge for an investigational drug.

(4) FDA will withdraw authorization to charge if it determines that charging is interfering with the development of a drug for marketing approval or that the criteria for the authorization are no longer being met.

(b) *Charging in a clinical trial—*(1) *Charging for a sponsor's drug.* A sponsor who wishes to charge for its investigational drug, including investigational use of its approved drug, must:

(i) Provide evidence that the drug has a potential clinical benefit that, if demonstrated in the clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation, or prevention of a disease or condition;

(ii) Demonstrate that the data to be obtained from the clinical trial would be essential to establishing that the drug is effective or safe for the purpose of obtaining initial approval of a drug, or would support a significant change in the labeling of an approved drug (e.g., new indication, inclusion of comparative safety information); and

(iii) Demonstrate that the clinical trial could not be conducted without charging because the cost of the drug is extraordinary to the sponsor. The cost may be extraordinary due to manufacturing complexity, scarcity of a natural resource, the large quantity of drug needed (e.g., due to the size or duration of the trial), or some combination of these or other extraordinary circumstances (e.g., resources available to a sponsor).

(2) *Duration of charging in a clinical trial.* Unless FDA specifies a shorter period, charging may continue for the length of the clinical trial.

(c) *Charging for expanded access to investigational drug for treatment use.*

(1) A sponsor who wishes to charge for expanded access to an investigational drug for treatment use under subpart I of this part must provide reasonable assurance that charging will not

interfere with developing the drug for marketing approval.

(2) For expanded access under § 312.320 (treatment IND or treatment protocol), such assurance must include:

(i) Evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trial(s) will be successfully completed as planned;

(ii) Evidence of adequate progress in the development of the drug for marketing approval; and

(iii) Information submitted under the general investigational plan (§ 312.23(a)(3)(iv)) specifying the drug development milestones the sponsor plans to meet in the next year.

(3) The authorization to charge is limited to the number of patients authorized to receive the drug under the treatment use, if there is a limitation.

(4) Unless FDA specifies a shorter period, charging for expanded access to an investigational drug for treatment use under subpart I of this part may continue for 1 year from the time of FDA authorization. A sponsor may request that FDA reauthorize charging for additional periods.

(d) *Costs recoverable when charging for an investigational drug.* (1) A sponsor may recover only the direct costs of making its investigational drug available.

(i) Direct costs are costs incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.

(ii) Indirect costs include costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

(2) For expanded access to an investigational drug for treatment use under §§ 312.315 (intermediate-size patient populations) and 312.320 (treatment IND or treatment protocol), in

addition to the direct costs described in paragraph (d)(1)(i) of this section, a sponsor may recover the costs of monitoring the expanded access IND or protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access IND.

(3) To support its calculation for cost recovery, a sponsor must provide supporting documentation to show that the calculation is consistent with the requirements of paragraphs (d)(1) and, if applicable, (d)(2) of this section. The documentation must be accompanied by a statement that an independent certified public accountant has reviewed and approved the calculations.

Dated: July 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-19004 Filed 8-12-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 316

[Docket No. FDA-2006-N-0238] (formerly Docket No. 2006N-0062)

RIN 0910-AF14

Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on access to investigational new drugs for the treatment of patients. The final rule clarifies existing regulations and adds new types of expanded access for treatment use. Under the final rule, expanded access to investigational drugs for treatment use is available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application (IND). The final rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies. Elsewhere in this issue of the **Federal Register**, FDA is publishing the final rule on Charging for Investigational Drugs Under an Investigational New Drug

Application which clarifies the circumstances in which charging for an investigational drug in a clinical trial is appropriate, sets forth criteria for charging for an investigational drug for the different types of expanded access for treatment use described in this final rule, and clarifies what costs can be recovered for an investigational drug.

DATES: This rule is effective October 13, 2009.

FOR FURTHER INFORMATION CONTACT:

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I. Background

In the **Federal Register** of December 14, 2006 (71 FR 75147), FDA proposed to amend its regulations permitting access to investigational drugs to treat patients with serious or immediately life-threatening diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition.

As discussed in greater detail in the preamble to the proposed rule (71 FR 75147 at 75148 to 75149), there have been several statutory and regulatory

efforts to expand access to investigational drugs for treatment use. Before 1987, there was no formal recognition of treatment use in FDA's regulations concerning INDs, but investigational drugs were made available for treatment use informally. In 1987, FDA revised the IND regulations in part 312 (21 CFR part 312) to explicitly provide for one specific kind of treatment use of investigational drugs (52 FR 19466, May 22, 1987). Section 312.34 authorized access to investigational drugs for a broad population under a treatment protocol or treatment IND when certain criteria were met. Section 312.35 described the submission requirements for such treatment use. The 1987 IND regulations also implicitly acknowledged the existence of other kinds of treatment use, notably use in individual patients, by adding a provision for obtaining an investigational drug for treatment use in an emergency situation (§ 312.36). However, § 312.36 did not describe criteria or requirements that must be met to authorize individual patient treatment use.

In response to criticisms that this lack of criteria and submission requirements resulted in inconsistent policies, inequitable access, and preferential access for certain categories of patients, Congress included in the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), which amended the Federal Food, Drug, and Cosmetic Act (the act), specific provisions concerning expanded access to investigational drugs for treatment use (Expanded Access to Unapproved Therapies and Diagnostics, section 561 of the act (21 U.S.C. 360bbb)).

FDA proposed this rule in December 2006 to further address the concerns that motivated the FDAMA changes, including problems of inconsistent application of access policies and programs and inequities in access based on the relative sophistication of the setting in which a patient is treated or on the patient's disease or condition. By describing in detail in the final rule the criteria, submission requirements, and safeguards for the different types of expanded access for treatment use of investigational drugs, FDA hopes to increase awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use. The agency believes that the final rule appropriately authorizes access to promising drugs for treatment use, while protecting patient safety and avoiding interference with the development of investigational

drugs for marketing under approved applications.

In 2007, after the proposed rule on expanded access was published, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85). One provision, codified in 505–1(f)(6) of the act (21 U.S.C. 355–1(f)(6)), requires the Secretary of Health of Human Services (the Secretary) to promulgate regulations concerning how a physician may provide a drug under the mechanisms of section 561 when the drug is subject to elements to assure safe use under a risk evaluation and mitigation strategy (REMS). The expanded access mechanisms described in this final rule can be used by a patient seeking access to a drug with a REMS in the event that the drug is not available to the patient under the criteria of the REMS, provided the drug and the patient meet the criteria for an expanded access program. Therefore, this rule fulfills the FDAAA requirement.

This final rule applies both to drug products that are subject to section 505 of the act (21 U.S.C. 355) and biological products subject to the licensing provisions of the Public Health Service Act (42 U.S.C. 201 *et seq.*) and 21 CFR part 601. This is consistent with the previous regulations on treatment use, which applied to both drug and biological products.

II. Overview of the Final Rule Including Changes to the Proposed Rule

A. Overview

The final rule amends FDA regulations by removing the current sections on treatment use of investigational drugs (§§ 312.34, 312.35, and 312.36), revising § 312.42 on clinical holds, and adding subpart I of part 312 on expanded access. Subpart I describes the following ways that expanded access to treatment use of investigational drugs are available:

- Expanded access for individual patients, including in emergencies;
- Expanded access for intermediate-size patient populations (smaller than those typical of a treatment IND or treatment protocol); and
- Expanded access treatment IND or treatment protocol (described in previous §§ 312.34 and 312.35).

The final rule provides the following: (1) Criteria that must be met to authorize the expanded access use, (2) requirements for expanded access submissions, and (3) safeguards to protect patients and preserve the ability to develop meaningful data about treatment use.

B. Changes to the Proposed Rule

The final rule has been revised in response to comments received on the proposed rule. The responses are discussed in section III of this document. The final rule:

- Revises proposed § 312.300(a) to clarify that subpart I is intended to apply not only to the use of investigational new drugs but also to approved drugs whose availability is limited because the drugs are subject to a risk evaluation and mitigation strategy (REMS) in accordance with section 505–1(f)(6) of the act.
- Also revises proposed § 312.300(a) to clarify that subpart I is intended to apply to all those with a serious disease or condition, regardless of whether the patient would currently be considered seriously ill with that disease or condition.
- Revises proposed § 312.300(b) to include a definition of “serious disease or condition.”
- Revises proposed § 312.305(c)(5) to clarify that a sponsor should make an investigator’s brochure available to licensed physicians in an expanded access program whenever such a brochure exists.
- Revises proposed § 312.310(a)(2) to omit the words “type of.”
- Revises proposed § 312.310(c)(2) to clarify that the summary of the expanded access use should include all adverse effects, not merely unexpected ones, and that the summary should be submitted to FDA.
- Revises proposed § 312.310(d)(2) to extend the time in which to make written submissions to 15 working days after FDA’s authorization of emergency use.

The agency did not propose to amend the text of § 316.40. However, because § 316.40 references the requirements of § 312.34, which is being withdrawn, FDA has revised § 316.40 to remove the reference to § 312.34.

III. Comments on the Proposed Rule

The agency received 119 comments on the proposed rule. Comments were received from individuals (persons with serious or immediately life-threatening diseases or conditions, persons with family members with such diseases or conditions, and other interested persons), healthcare and consumer advocacy organizations, healthcare professionals (physicians and pharmacists), pharmaceutical and biotechnology companies, trade organizations representing pharmaceutical and biotechnology companies, health insurance companies, a trade organization representing health

insurance companies, hospitals, a trade organization representing hospitals, and a professional society representing oncologists.

A. General Comments on the Proposed Rule

Most of the comments strongly supported the goal of expanding access to investigational drugs for treatment use. The vast majority of these comments expressed strong support for the proposed rule as a way to expand access. As a category, the largest volume of comments came from individuals, and the vast majority of those supported the proposed rule. Healthcare and consumer advocacy organizations provided the next largest volume of comments. Comments from these organizations spanned the spectrum from strongly supportive to strongly negative. Many healthcare and consumer advocacy organizations commented that they believe the rule strikes the appropriate balance between increased access and patient safety without impeding enrollment in clinical trials or otherwise jeopardizing the development of new drugs for marketing approval.

Healthcare and consumer advocacy organizations who opposed the proposed rule had widely divergent views. Some of these commenters expressed the view that the rule did not go far enough in removing the obstacles to patient access to investigational drugs for treatment use and argued that, after phase 1 safety testing, there should be largely unfettered access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions and no alternative therapies. One of these organizations urged that the rule be withdrawn and a substantially more permissive access policy (one that affords individual patients greater autonomy) be developed and implemented.

Some healthcare and consumer advocacy organizations expressed the view that the proposed rule went much too far in making investigational drugs available to patients for treatment use. One comment argued that expanded access as described in the proposed rule would eliminate the incentive for patients to enroll in clinical trials that provide the evidence necessary to make effective use of new therapies, would be harmful to patients exposed to therapies for which there is limited safety and effectiveness information, and raises issues of fairness because of the potential that the supply of the drug may not be adequate to make it available to all those seeking access. Some

comments argued that there should be access only in the very late stages of clinical development, ideally not until phase 3 testing had been completed.

Comments from pharmaceutical and biotechnology companies and their trade organizations were the next largest category of comments. These comments were generally supportive of the goal of expanding access, but expressed concern about the potential for expanded access, as described in the proposed rule, to impede drug development and add new administrative burdens or expense for companies.

FDA's response to these general comments is that we believe the final rule appropriately addresses the competing concerns surrounding expanded access. As discussed in detail in the preamble to the proposed rule (71 FR 75147 at 75160), the key question in making investigational drugs available for treatment use is how to address the various interests—individual patients' desires to make their own decisions about their healthcare, including decisions about using experimental therapies in advance of such treatments being approved for marketing, society's interest in the efficient development of new therapies to treat serious and immediately life-threatening diseases or conditions, and the need to protect vulnerable patients from unnecessary and unacceptable risks. FDA recognizes that these issues are complex and can have life-or-death implications, both for individuals seeking access to investigational drugs and for large populations of patients with a given disease or condition who desire that innovative therapies for their disease or condition be developed and marketed as quickly as possible. Therefore, it is not surprising that there are a range of perspectives about how best to reconcile these competing interests and highly impassioned defenses of the various perspectives.

FDA's perspective in attempting to address and, where possible, reconcile these different views, is intended to be consistent with its statutory mandate to ensure that drug therapies developed and marketed for serious and immediately life-threatening diseases or conditions are safe and effective (which requires substantial evidence from clinical trials) and that individuals exposed to investigational therapies under an IND, whether in a clinical trial or for an expanded access use, are not subject to unnecessary and unacceptable risks. FDA acknowledges the varied positions expressed on access to investigational drugs for treatment use. The agency recognizes that this rule

may not be satisfactory to all; sometimes it is not possible to reconcile the more disparate views. FDA has made its best effort to set forth a regulatory policy that is consistent with its statutory mandate, taking into account the views of those who commented. FDA believes it has addressed these competing issues in a way that affords patients a meaningful and reasonable measure of autonomy over their own healthcare decisions while preserving the integrity of the drug approval process and protecting patient safety.

Specific issues raised by the comments and the agency's responses follow.

B. Comments Related to the Proposed Rule as a Whole

1. Public Awareness and Physician and Patient Education Programs

(Comment 1) In the preamble to the proposed rule (71 FR 75147 at 75149), FDA stated that the major goals of this rulemaking are to broaden the scope of expanded access and to address concerns about inequities in access to investigational drugs under expanded access programs. FDA explained that by describing in detail in regulation the criteria, submission requirements, and safeguards for the different types of expanded access programs, FDA hoped to increase knowledge and awareness of expanded access programs and the procedures for obtaining investigational drugs under such programs and, as a result, facilitate wider availability of investigational drugs in appropriate circumstances. FDA also explained that it wished to address concerns that in the past, access to investigational drugs has been primarily available to patients with certain serious or immediately life-threatening diseases or condition—particularly cancers, Human Immunodeficiency Virus (HIV) disease, and HIV-related conditions—and hoped that the greater awareness and clarity fostered by this rulemaking would facilitate access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who may have been underserved in the past.

Several comments expressed the view that this rulemaking alone would not be sufficient to accomplish these goals. One comment argued that promulgating expanded access regulations is an ineffective vehicle to increase knowledge and awareness of expanded access programs because FDA regulations are not widely read by healthcare providers and consumers. Another comment stated that **Federal Register** notices are not the best way of

disseminating information to the lay public or their healthcare providers and complained that the proposed rule did not mention any additional efforts to disseminate the new policies.

Several comments recommended that FDA do more to publicize its expanded access regulations, educate and train physicians, and/or improve communications with patients and patient advocacy organizations. One comment stated that patients are sometimes confused about the reasons they are not able to enroll in an expanded access program or obtain individual access and urged FDA to consider ways to improve communication to patients about the standards for expanded access to minimize this confusion. One comment recommended that training materials and information be made available to the general public in an easily accessible format and medium, such as on FDA's Web site, so that patients and patient advocates can obtain the instructions for submitting an expanded access request. Another comment from a patient advocacy group recommended that FDA provide guidance on each of the specific types of expanded access. The comment stated that not all physicians will have the time or inclination to inform themselves about the expanded access mechanisms and processes and, therefore, it is important that patients and patient advocates be informed about expanded access and FDA's requirements for expanded access so that they can inform their physicians.

(Response) FDA believes that clearly specifying in regulations the mechanisms and processes for obtaining investigational drugs for treatment use is the essential and fundamental platform on which to build awareness of, and accessibility to, expanded access programs. FDA agrees, however, that new expanded access regulations alone will not be sufficient to increase knowledge and awareness about expanded access to an extent that will meet FDA's goals for broader and more equitable access. Therefore, in conjunction with publication of this final rule, FDA intends to develop and engage in a broad range of publicity and educational efforts in a variety of forums and media to increase awareness of the mechanisms for obtaining investigational drugs for treatment use.

(Comment 2) Some comments stated that additional steps would be needed to address complaints that access to investigational drugs was biased toward cancer and HIV disease patients. One comment recommended that FDA work more closely on early access programs with disease-specific institutes at the

National Institutes of Health (NIH) in addition to the National Cancer Institute and the Office of AIDS Research in the National Institute for Allergy and Infectious Disease. One comment recommended outreach to better inform minorities about access to investigational drugs for treatment use. The comment suggested a program specifically directed at African-American women because of their low rates of cancer survival relative to white women.

FDA's Office of Special Health Issues (OSHI) works closely with individual patients and patient organizations, including minority and special disease groups, and with the healthcare provider community and organizations. The office responds to questions about expanded access and directs inquiries for specific treatment uses of investigational products to the appropriate staff within FDA. The office maintains a Web site with general information about expanded access and other ways of getting promising therapies to seriously ill patients (see <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessToImportantNewTherapies/default.htm>).

(Comment 3) Some comments urged that all expanded access INDs and protocols be listed on ClinicalTrials.gov (<http://www.clinicaltrials.gov>), the Web site maintained by NIH that is intended to include a listing of controlled clinical trials for drugs in development. One comment asked that FDA clarify whether the public notification provision (the provision that describes what should be listed on ClinicalTrials.gov) applies to access programs for intermediate-size patient populations.

(Response) ClinicalTrials.gov is governed by section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)). The law, as amended by FDAAA, requires the registration of certain controlled clinical trials on ClinicalTrials.gov and specifically requires information to be included about whether expanded access to an investigational drug under section 561 of the act is available for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access (section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act). The ClinicalTrials.gov provisions only apply to certain controlled clinical trials (see definition of "applicable drug clinical trial" in section 402(j)(1)(iii) of the PHS Act). Thus, information about expanded access is required to appear in ClinicalTrials.gov when the drug at issue is the subject of certain controlled

clinical trials (i.e., other than phase 1 trials in which one group of participants is given an investigational drug subject to FDA's jurisdiction, while the control group receives either a standard treatment for the disease or a placebo). If expanded access is for an investigational drug that is not the subject of certain controlled clinical trials, the statute does not require information about the expanded access in ClinicalTrials.gov. Thus, for example, information about an expanded access program for an intermediate-size patient population for a drug that is being developed (see § 312.315(a)(2)) would be included in ClinicalTrials.gov as long as the other requirements for inclusion are met. However, information about an expanded access program for an intermediate-size patient population for a drug that is not being developed under a clinical trial (see § 312.315(a)(1)) and therefore is not subject to the mandatory registration provisions in section 402(j) of the PHS Act would not be required to be included in ClinicalTrials.gov.

2. Administrative Burdens Associated With Obtaining Expanded Access

(Comment 4) A number of comments, particularly from patient advocacy groups, stated that the administrative burdens associated with expanded access could undermine FDA's efforts to broaden access. The general concern was that the requirements, particularly for physicians seeking individual patient INDs, are too onerous and, therefore, physicians will be reluctant or unwilling to seek investigational drugs for treatment use for their patients. Two comments argued that the burden would be greatest in nonacademic settings because physicians in those settings are typically not as familiar with IND regulations and Institutional Review Board (IRB) requirements. The comments recommended that the requirements for expanded access for individual patients be simplified and disconnected from compliance with other sections of part 312 (e.g., investigator and sponsor responsibilities in subpart D (Responsibilities of Sponsors and Investigators)). Another comment stated that administrative burdens are a particular problem in the academic research setting, where intensive IRB approval and oversight, combined with the data collection requirements of the protocols, have forced some centers to forego participation in expanded access programs until they can find a source of funding.

(Response) FDA shares the concern that the requirements for obtaining access to investigational drugs, if

perceived as burdensome, may be a deterrent to obtaining access to investigational drugs for treatment use. However, FDA believes the evidentiary, submission, and data collection requirements are generally non-labor intensive, straightforward, and appropriate to the kind of assurances needed to permit treatment use of investigational drugs. We acknowledge that compliance with the expanded access requirements might pose particular challenges for physicians (whether in academic or nonacademic settings) who are not very familiar with IND and IRB regulations, as well as for medical centers in which existing administrative burdens already test the limits of available resources. However, we believe that the burdens associated with IND compliance and IRB review under expanded access programs have been minimized to the extent possible while still ensuring patient safety.

The majority of the data necessary to satisfy the IND submission requirements for a licensed physician obtaining an IND for an individual patient will, in most cases, be provided by reference to the content of an IND held by a sponsor who is developing the investigational drug for marketing. (In the case of treatment access to an approved drug that is subject to a REMS, reference to a sponsor's IND may not be necessary.) Therefore, in making an IND submission, the physician will ordinarily only be required to provide a narrative explaining the rationale for the intended use and dose, why there are no comparable or satisfactory therapeutic alternatives, a description of the patient's disease or condition (including recent medical history and previous treatments), and the monitoring, testing, or other procedures needed to minimize the risks of the drug to the patient. For the post-treatment submission, the physician must provide a written summary of the results of the expanded access use, including adverse effects. The information needed for each of these submissions is the same kind of information that is captured during routine patient care and, consequently, is already known to the physician or can be readily accessed. Therefore, FDA does not consider these submission requirements to be a burden that is out of proportion with the risks inherent in using an investigational product for treatment use (see response to comment 60 for discussion of IRB review issues). FDA intends to engage in educational efforts to help physicians understand the individual patient requirements and how to navigate those requirements in a way that minimizes the administrative

burdens. These efforts will be directed at physicians in both academic and nonacademic settings.

For multi-patient expanded access INDs, FDA agrees that there are steps that could be taken to minimize administrative burdens at participating sites. As with any use of investigational agents, FDA encourages the use of centralized IRBs and standardized data collection documentation across expanded access IND sites when there are multiple sites. As part of its ongoing outreach efforts on expanded access, FDA intends to work with constituents in patient advocacy, clinical settings, and the pharmaceutical industry to minimize the burdens associated with multi-patient expanded access programs generally, as well as the burdens associated with specific multi-patient access programs as they arise.

FDA does not believe that licensed physicians and sponsors should be exempt from compliance with the sponsor and investigator requirements in subpart D of part 312. It is crucial to keep in mind that expanded access involves use of an investigational therapy in a vulnerable population, so the rationale for oversight, monitoring, recordkeeping and human subject protections applicable to clinical trials is equally applicable in the treatment use context. Accordingly, § 312.305(c) of the final rule provides that investigators, sponsors, and sponsor-investigators must comply with the responsibilities for sponsors and investigators set forth in subpart D of part 312 to the extent they are applicable to the expanded access use. Section 312.305(c)(1) provides that a licensed physician under whose immediate direction an investigational drug is administered or dispensed for an expanded access use is considered an investigator. Section 312.305(c)(2) provides that an individual or entity that submits an expanded access IND or protocol is considered a sponsor. Section 312.305(c)(3) provides that a licensed physician under whose immediate direction an investigational drug is administered or dispensed, and who submits an IND for expanded access use, is considered a sponsor-investigator.

3. Equitable Access

The preamble to the proposed rule (71 FR 75147 at 75149) explains that, by describing in detail the categories of expanded access use and the criteria and submission requirements for such use, and otherwise increasing awareness of the mechanisms and processes for obtaining investigational drugs for treatment use, FDA hopes to make

investigational drugs for treatment use more accessible for diseases and conditions and in clinical settings that have purportedly been underserved by expanded access programs.

(Comment 5) Several comments agreed that certain diseases, conditions, and regions have been underserved by expanded access programs. Some comments maintained that minority populations, in particular African-Americans and women, have been underserved by expanded access programs and that these populations should be the focus of efforts to make access to investigational drugs for treatment use more equitable.

(Response) FDA agrees that regions, diseases, or populations that have been underserved by expanded access programs should be the focus of efforts to ensure more equitable access. FDA's OSHI is committed to working with any underserved constituencies to help address inequities in the access to investigational drugs for treatment use.

(Comment 6) One comment expressed concern that the implications of one of FDA's stated goals—to improve access to investigational therapies outside academic medical centers—are unknown and may be harmful. The comment suggested that a possible reason that access to investigational drugs for treatment use is more likely in academic medical centers is that these centers tend to treat more patients with serious and immediately life-threatening diseases or conditions who have exhausted all available conventional treatment options. The comment noted that there is a lack of information in the proposed rule concerning differences in patient outcomes between patients treated with investigational drugs in academic medical centers and those treated elsewhere and suggested that, absent such data, it is not necessarily desirable for the use of investigational drugs for treatment use to become significantly more prevalent outside academic medical centers.

(Response) FDA acknowledges that patients who have the diseases or conditions for which treatment use of investigational drugs is generally sought may be found in greater numbers in academic medical centers specializing in the treatment of serious and immediately life-threatening conditions. FDA does not agree, however, that the intent to facilitate access in all settings requires data on comparative quality of care across different settings, any more than it would require such a comparison among academic centers in geographic regions. FDA believes it is important to foster use of investigational drugs for treatment use in all settings in which

eligible patients receive care, provided there are appropriate controls and oversight, as set forth in this final rule.

4. Supplies of Investigational Drugs

(Comment 7) Several comments were concerned that there seemed to be an implicit assumption in the proposed rule that there will be an adequate supply of an investigational drug to meet the demand for the drug generated by potentially broader access over an indefinite period of time. Some comments pointed out that increasing demand for an investigational drug could create supply constraints, which could make it impossible to provide a drug for treatment use to all those who seek it and could also threaten the completion of clinical studies of the drug. One comment argued that expanded access programs should focus on investigational drugs with an adequate supply to meet the potential demand. Two comments stated that access should be fair and equitable in situations in which the supply cannot meet the demand. One comment recommended that the treatment IND provisions in the final rule include a way to ensure fair and equitable access in situations in which there is not enough supply of a drug to meet the demand.

(Response) FDA agrees that, in cases when there is not sufficient supply of an investigational drug to make it available to all patients who seek it, access to the drug for treatment use should be as equitable as reasonably possible. FDA does not agree that expanded access programs should be limited to only those situations in which there is an adequate drug supply for all potential subjects. Mechanisms to fairly allocate limited drug supply (e.g., lotteries) have been used in the past to provide drugs to at least some of the patients who could benefit. FDA supports the use of these mechanisms where they are needed.

However, FDA does not believe that it is necessary to include in the final rule a requirement that fair and equitable distribution mechanisms be used to allocate an investigational drug in the event of insufficient supply. Current IRB regulations require an IRB to determine that selection of subjects, in this case patients to be treated, is equitable (21 CFR 56.111(a)(3)). FDA believes that provision is adequate to ensure equitable access in cases in which the drug supply is not adequate to meet the demand.

FDA anticipates that the most appropriate distribution mechanism for a drug with limited supply will be very case specific, for example, requiring

identification of threshold clinical parameters for possible access and a mechanism to randomly select from those who meet the parameters. Therefore, FDA believes it is advisable for the sponsor to work with the relevant patient or disease advocacy organizations, professional societies, and other affected constituencies to devise the most appropriate mechanism for allocating a limited drug supply in a specific situation. However, it should be noted that FDA has no authority to compel sponsors to participate in that collaboration or to make their investigational products available for treatment use.

5. Industry Support or Incentives to Broaden Expanded Access

(Comment 8) Some comments argued that the proposed rule would not increase expanded access because a substantial increase in access would require industry support. Some comments suggested that FDA offer financial incentives to industry, such as extending periods of exclusivity or expediting drug review, to encourage drug companies to make drugs available for treatment use.

(Response) FDA is aware that, for a variety of reasons, there may be reluctance among pharmaceutical and biotechnology companies to make investigational drugs available under expanded access programs. FDA's charging rule, published elsewhere in this issue of the **Federal Register**, is intended to address concerns about financial barriers to providing access by allowing companies to charge an amount for an investigational drug that enables them to recover the costs associated with making the drug available. Other financial incentives are beyond the scope of this regulation and FDA's statutory authority. For example, FDA's existing authority to extend marketing exclusivity to induce certain behavior derives from congressional mandates.

FDA also does not believe that a promise to expedite review of new drug applications (NDAs) is a reasonable option to encourage broader access to investigational drugs for treatment use. The types of drug products that meet the requirements for treatment use—investigational therapies to treat serious and immediately life-threatening diseases or conditions—are likely to already be eligible for the shortest review times currently available (6 months). Given the complexity of NDAs, FDA does not believe it can routinely review applications in less time while maintaining the integrity of the review process.

6. Data Obtained from Expanded Access Use

(Comment 9) One comment asked whether data generated in expanded access programs must be submitted to the NDA for the drug product and, if so, how FDA evaluates this information when determining the safety and efficacy of the drug for the proposed indication and patient population. Another comment stated that FDA's historical reluctance to consider efficacy information from expanded access uses as evidence of efficacy in an NDA or supplemental NDA has been a disincentive for some companies to make a product available for expanded access. The comment maintained that it would be appropriate to consider safety and efficacy information from an expanded access IND or protocol in assessing the safety and effectiveness of a drug when the use and patient population in the expanded access IND or protocol are similar to the use and population for which approval is sought. The comment asked that FDA revise the proposed rule to explicitly inform sponsors, investigators, patients, and patient representatives that any safety and efficacy data collected in expanded access are expected to be reported in the initial NDA seeking approval for the drug or biological product. One comment argued that a company that makes a drug available for treatment use under an expanded access IND or protocol runs the risk of being adversely affected by unfavorable safety observations from use in the expanded access population, notwithstanding that the patients receiving the drug under an expanded access IND or protocol are often sicker, nonresponders to prior treatments, and otherwise not representative of the population evaluated in controlled clinical trials, but there is no commensurate benefit to the company from favorable efficacy observations in the expanded access population.

(Response) As with any IND, sponsors of expanded access INDs must provide FDA with information on patient outcomes and adverse events observed during an expanded access use. This information must be included in IND annual reports (§ 312.33) and/or IND safety reports (§ 312.32) and, typically, an NDA must also contain at least a summary of the expanded access experience with a drug. The information obtained from an expanded access use can be useful to a drug's safety assessment. For example, a relatively rare adverse event might be detected during expanded access use, or such use might contribute safety information for

a population not exposed to the drug in clinical trials. However, a control group is more important to the utility of effectiveness data than safety data. Because expanded access programs are typically uncontrolled exposure (with limited data collection), it is very unlikely that an expanded access IND would yield effectiveness information that would be useful to FDA in considering a drug's effectiveness. However, if a sponsor believes that effectiveness information from expanded access use can contribute to a determination that there is substantial evidence of effectiveness, it should submit the information and an explanation of its relevance to FDA.

There are examples in which FDA has made use of adverse events information from expanded access use in the safety assessment of a drug. There are a small number of cases in which an important adverse event was first identified during expanded access use and those adverse events were included in product labeling. This is not a negative from a public health perspective—the sooner important adverse events are identified the better. Even from the sponsor's viewpoint, early discovery of a rare adverse event is, on the whole, a benefit. Although adverse events first identified during expanded access use of certain drugs have been included in the drugs' approved product labeling, we are unaware of any cases in which adverse event information obtained from expanded access use has resulted in denial of approval for a product.

(Comment 10) One comment observed that data from expanded access might provide helpful information about use of a drug in patients who are sicker than those patients enrolled in clinical trials.

(Response) FDA agrees that expanded access use in a population with a particular disease or condition that is sicker than the population in the clinical trials might yield some helpful insights into the tolerability profile, but typically would not provide insight into the response to the drug (effectiveness) because of the uncontrolled nature of the access program and limited data collection.

(Comment 11) Some comments recommended that investigational drugs be made available for expanded access only under protocols that are designed to capture some scientific knowledge. One comment recommended that the final rule require all categories of expanded access to be conducted under a clearly defined research protocol. The comment recommended that the final rule require that: (1) An appropriate sponsor be responsible for collecting patient outcomes data, (2) reports be

submitted in a timely fashion to FDA, and (3) patients be required by FDA to participate in official data-gathering processes within a formal cohort study or patient registry.

(Response) FDA does not agree that investigational drugs should be made available only under expanded access protocols designed to obtain meaningful scientific data, or contingent on enrolling patients in a formal cohort study or registry. As explained in § 312.300(a) of this final rule, the primary purpose of expanded access is to diagnose, monitor, or treat a patient's disease or condition, not to generate scientific data intended to characterize the drug. However, FDA agrees that there should be efforts to optimize the information obtained from expanded access exposures with an eye toward detecting any unexpected outcomes or events.

(Comment 12) FDA received several comments advocating more systematic collection of data on outcomes of expanded access programs, including adverse events. One comment maintained that current data collection practices for expanded access programs rarely yield useful information and that better collection of safety data might identify previously unknown safety concerns. One comment stated that data collection should focus on elements such as drug start and stop dates, dose, patient treatment outcomes, and significant adverse events, and that collection of adverse events could use standardized reporting forms (e.g., MedWatch), which might promote more consistent collection of reliable information. One comment also stated that FDA should consider compiling a database of evidence derived from expanded access uses for use by patients, clinicians, manufacturers, and researchers to help identify areas that researchers might pursue for new treatments and therapies.

(Response) FDA agrees that more standardized data collection methods and forms could ease some of the documentation burdens associated with expanded access. However, FDA does not believe it is in a position, at this time, to be able to describe in regulation or guidance the form and content of data collection programs specific to expanded access uses. FDA is willing to participate in collaborative efforts with interested constituents to develop better data collection methods. FDA does not believe that data collected from expanded access use would, in most cases, be in a form that would be useful for hypothesis generation. It is important to note, however, that information about some expanded

access uses (those involving applicable drug clinical trials) will be included in the ClinicalTrials.gov results database (see response to comment 3 and <http://www.clinicaltrials.gov>).

7. Assessing the Impact of Expanded Access

(Comment 13) One comment encouraged FDA to develop a tracking system to evaluate how well the expanded access program is working and to identify factors, such as economic obstacles, that might be impeding access to investigational drugs for treatment use. The comment recommended that the system include information on patients and investigators, whether or not requests for expanded access are granted, and if not, the reason for not granting such requests, the outcomes of the treatments, and costs, if any, to patients who pay for their treatments.

(Response) FDA believes this final rule, in conjunction with implementation of electronic format INDs and the expanded ClinicalTrials.gov information, will make it easier for the agency to compile information about the types of diseases or conditions that are or are not being treated under expanded access INDs. That information could, for example, identify disease categories that appear to be underserved by expanded access INDs. FDA does not foresee that such information would be able to specifically identify economic or other obstacles to obtaining access for certain diseases or conditions, but it could be used to initiate discussions among patient and disease advocacy organizations, the relevant medical specialty professional society, pharmaceutical companies with products that could possibly be made available for expanded access, FDA, and other interested parties to help identify barriers to access. As to the comment's specific recommendation that a tracking system include information on patients and investigators, whether or not requests for expanded access are granted, and if not, the reason for not granting such requests, the outcomes of the treatments, and costs, if any, to patients who pay for their treatments, FDA does not believe that such a system is necessary at this time, nor do resources permit establishment of such a system.

8. Open-Label Safety Studies

In the preamble to the proposed rule (71 FR 75147 at 75155), FDA expressed concern that sponsors have used programs other than treatment INDs or treatment protocols to make

investigational drugs available to large populations for treatment use, particularly by identifying such programs as "open-label safety studies." The goal of an open-label safety study is to better characterize the safety of a drug late in its development. However, in practice, many studies that are described as open-label safety studies have characteristics that appear to be more consistent with treatment INDs or treatment protocols. FDA stated that, in the future, it intends to evaluate submissions identified as open-label safety studies to determine whether those studies are more characteristic of treatment INDs or treatment protocols. The proposed rule stated that a study described as an open-label safety study that provides broad access to an investigational drug in the later stages of development, but lacks planned, systematic data collection and a design appropriate to evaluation of a safety issue, is likely to be considered a treatment IND or treatment protocol.

(Comment 14) Several comments expressed support for FDA's position that programs that make investigational drugs available to large populations for treatment use should be treatment INDs or treatment protocols, not open-label safety studies. One comment stated that mischaracterizing a treatment IND as an open-label safety study afforded the study more credibility than it deserved. Several comments opposed FDA's position, stating that open-label safety studies are important in elucidating the safety profile of investigational drugs prior to approval, the time required for formal review could affect expediting drug development, and FDA's plan would result in fewer expanded access programs.

(Response) In enunciating this policy, FDA did not intend to limit the conduct of open-label safety studies intended to evaluate particular safety concerns, such as long-term followup of subjects initially enrolled in a randomized trial, safety studies in pediatric development programs, and other safety studies. These types of studies are legitimate open-label protocols and are an integral part of a drug development program. FDA will continue to encourage such studies as appropriate.

However, FDA continues to believe that the treatment IND process is a more appropriate vehicle for providing access to investigational drugs for treatment use to large populations outside controlled clinical trials late in a drug's development. The treatment IND provides appropriate patient safeguards and permits FDA the necessary oversight over the development program. And as FDA explained in the

preamble to the proposed rule (71 FR 75147 at 75155), authorization of expanded access use is subject to a more formal review process that explicitly considers the impact of expanded access on enrollment in any ongoing clinical trials and the progress of drug development generally. The time for review of a treatment use program should not affect the timing of drug development because the need for such an expanded access program and the protocol for the program can be considered in advance and put in place when needed. Therefore, FDA does not believe this policy will result in fewer expanded access programs.

(Comment 15) One comment asked whether only patients with a serious disease or condition could be enrolled in open-label studies that FDA would consider to be treatment INDs.

(Response) One of the threshold criteria for a treatment IND is that the population to be enrolled has a serious or immediately life-threatening disease or condition. Therefore, only protocols intended to treat patients with serious or life-threatening diseases or conditions are subject to this requirement.

It should be noted that FDA has not taken the position that the agency will consider all open-label safety studies to be treatment INDs. FDA will not consider an open-label safety study to be a treatment IND when the purpose of the study is actually to study the safety profile of the drug.

9. Insurance Coverage for Investigational Drugs and Related Patient Care Drug Coverage

(Comment 16) Several comments were concerned about the potential implications of the proposed rule on coverage decisions by health insurers and other third-party payers. Some comments were concerned that, because the drug made available is investigational, third-party payers would deny coverage for the drug and may also deny coverage for patient care necessitated by use of the drug. One comment noted an example of a patient seeking expanded access to an investigational drug who would be required to have frequent, expensive monitoring, including electrocardiograms (EKGs) and monthly Computed Tomography (CT) scans, and who might not be able to obtain access if health insurance did not reimburse for the required monitoring. One comment argued that the goals of expanded access are illusory if third-party payers do not reimburse for drug costs (if any) and routine patient care necessitated by

administration of the investigational drug.

One comment from a health insurance company stated that the design of insurance benefits already recognizes that some patients should receive benefit coverage for treatments that are not yet supported by clinical evidence, both in clinical trials and as treatment for promising but unproven treatments for life-threatening illnesses outside of clinical trials. The comment asked FDA to clarify in the rule that therapies provided under expanded access programs are experimental and not FDA-approved and that making these therapies available for treatment use does not provide evidence that such treatments are “reasonable,” “necessary,” or “medically necessary,” as defined in benefit documents. The comment stated that third-party payers would welcome a more standardized approach to the treatment of diseases without established therapies, particularly because these rules raise questions about responsibility for routine costs associated with otherwise excluded care.

(Response) FDA’s intent in promulgating the expanded access regulation is to foster the availability of investigational drugs for treatment use to as many patients with serious and life-threatening diseases as possible who lack known effective therapies for their disease or condition. FDA recognizes that determinations that investigational drugs made available under expanded access programs, and patient care related to administration of those drugs, are not reimbursable would be likely to limit access to such therapies for some patients (e.g., those who lack the financial resources to pay out-of-pocket). It is FDA’s hope, therefore, that health insurers and other third-party payers will make well-reasoned reimbursement decisions that will not impinge on the availability of investigational drugs for treatment use. To the extent that it is an insurer’s policy that care necessitated by administration of an investigational drug in a clinical trial is reimbursable, FDA believes that care associated with administration of an investigational drug in an expanded access program should be treated similarly for reimbursement purposes. However, FDA recognizes it has no inherent authority to dictate reimbursement policy.

FDA also recognizes that this final rule may have implications for health insurance coverage decisions because of existing language in health insurance contracts and how that language is interpreted with respect to costs

associated with investigational drugs and ancillary care provided under expanded access programs. FDA agrees that drugs made available under expanded access programs are typically investigational and not approved for marketing. However, FDA takes no position on how the terms “reasonable,” “necessary,” or “medically necessary” in health insurance contracts should be interpreted.

10. Waiver of Liability for Harm Related to Expanded Access

(Comment 17) One comment from a pharmaceutical company stated that the proposed rule does not address the significant liability issues for sponsors and investigators arising from making investigational drugs available for expanded access. Many comments from individuals stated that receiving investigational drugs under expanded access programs should be premised on a patient’s waiver of liability for harm resulting from treatment with the investigational drug. These comments maintained that liability should be waived for doctors, hospitals, drug manufacturers, and FDA.

(Response) FDA does not believe it is appropriate to insulate investigators or sponsors, whether they are treating physicians, hospitals or other clinical settings, or drug manufacturers, from potential liability arising from the administration or provision of investigational drugs for treatment use. In fact, FDA’s informed consent regulation, 21 CFR 50.20, states, “No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.” The scope of FDA’s liability, if any, for any harm resulting from decisions concerning expanded access to investigational drugs for treatment use is determined by statute and cannot be modified by a waiver provision in a regulation.

11. Inconsistency Between Subpart I and Subpart E

The expanded access regulations use the terms “immediately life threatening disease or condition” and “serious disease or condition.”

(Comment 18) One comment suggested that there was a discrepancy between terminology used in the proposed rule (subpart I of part 312) and terminology used in subpart E of part 312. The proposed rule uses the term “immediately life-threatening,” while

subpart E uses the term “life-threatening.” The proposed rule uses the term “serious,” while subpart E uses the term “severely debilitating.” The comment recommended that this final rule clear up the confusion arising from the use of similar but different terms in FDA regulations.

(Response) The subpart I regulations are being issued in response to a provision of FDAMA, now codified in section 561 of the act (21 U.S.C. 360bbb). The terms used in this final rule are consistent with and drawn from the terminology in section 561.

Accordingly, any change to make the terms consistent would require revision to subpart E. This final rule deals only with subpart I, and thus the comment asks for a remedy that is outside the scope of this rule.

Moreover, we note that subpart E and subpart I have different purposes. Subpart E provides procedures to expedite the development, evaluation, and marketing of new therapies. Subpart I provides procedures for making investigational drugs available when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition. Nonetheless, if subpart E were to be amended, FDA would then consider the propriety of the terminology used in subpart E.

C. Comments on Specific Provisions of the Proposed Rule

1. Scope (§ 312.300 and 312.300(a))

Proposed § 312.300(a) describes the intended scope of subpart I of part 312. It makes clear that the purpose of subpart I is to describe processes for making investigational drugs available in situations in which the primary purpose is to diagnose, monitor, or treat a serious or immediately life-threatening disease or condition in a patient who has no comparable or satisfactory alternative therapeutic options.

(Comment 19) Three comments asked that FDA clarify whether it intended that an expanded access IND be used to make an approved drug available for an unapproved indication in a situation in which a sponsor is conducting a clinical trial of the approved drug under an IND for a new indication to treat a serious disease or condition. Two of these comments urged that FDA modify the proposed rule to make clear that it applies to unapproved uses of approved drugs. The comments believed that such modification would make it more likely that health insurance companies would reimburse for unapproved use of approved drugs.

(Response) In general, for an already approved drug that is not subject to a

REMS, FDA did not intend that an expanded access IND under subpart I be used to provide the approved drug to patients with a serious disease or condition when the approved drug is being used for an unapproved indication. Regardless of whether an approved drug is being tested in a clinical trial to treat a serious disease or condition that is not part of the current approved indication, use of an approved drug off-label for an unapproved indication within the practice of medicine (i.e., to treat a patient in a clinical setting) is not subject to part 312 (the IND regulations), including subpart I. By definition, in such a case, the drug is already being legally marketed.

However, in at least two situations, expanded access under subpart I may be appropriate for drugs that are already approved: First, it is conceivable that a sponsor developing an approved drug for a new indication for treatment of a serious or immediately life-threatening disease or condition may want to make the approved drug available for the new indication under a treatment IND. For example, if the new indication involves a different route of administration or dosage form, the sponsor may prefer to provide the new dosage form under a treatment IND if it believes that failure to make the drug available under a treatment IND could lead to compounding of the drug (e.g., preparation of a new dosage form of a drug by a compounding pharmacist using the active ingredient of an approved drug product) and that such compounding could expose patients to unnecessary risks. FDA would be amenable to receiving treatment INDs for unapproved uses of approved drugs in situations in which the sponsor would prefer the use of a treatment IND to make the drug available for treatment use outside the ongoing or completed controlled trials of the unapproved use.

Second, for drugs that are subject to a REMS, expanded access under subpart I may be available to allow treatment of patients who do not otherwise meet the criteria under the REMS to receive the drug.

For these reasons, we have revised § 312.300(a) to state that subpart I contains the requirements for the use of investigational new drugs and approved drugs where availability is limited by a REMS when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition. This fulfills the mandate, codified in 505–1(f)(6) of the act, for the Secretary of Health of Human Services to promulgate regulations concerning how a physician may provide a drug under the mechanisms of section 561 of the act

when the drug is subject to elements to assure safe use under a REMS. We will assess the impact of this rule on expanded access to drugs subject to a REMS and, if appropriate, will consider issuing a guidance on this matter.

In response to the comment on insurance reimbursement, we note that FDA does not have jurisdiction over coverage decisions by health insurance companies and, in any case, is not aware that allowing expanded access to an already approved drug under subpart I would influence coverage decisions by health insurance companies.

(Comment 20) One comment notes that § 312.300(a) states that the intent is to make investigational drugs available to “seriously ill patients,” while the general criteria in § 312.305(a) require that patients to be treated with an investigational drug have “a serious or immediately life-threatening disease or condition.” The comment pointed out that a patient can have a serious disease or condition and not be seriously ill, for example, in the early stages of a progressive disease.

(Response) FDA acknowledges that the use of the term “seriously ill” in the provision describing the intended scope of the access provision could be interpreted as narrower in scope than was intended, and thus inconsistent with the term “serious or immediately life-threatening disease or condition.” Therefore, FDA has changed § 312.300(a) to make clear that subpart I is intended to apply to all those with a serious disease or condition, whether or not the patient would currently be considered seriously ill with that disease or condition.

2. Definitions (§ 312.300(b))

a. Immediately life-threatening disease or condition.

Proposed section 312.300(b) defines the term “immediately life-threatening disease” as a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

(Comment 21) One comment expressed support for the proposed rule’s definition of the term “immediately life-threatening disease” and encouraged FDA to include this definition in the final rule. One comment maintained that the proposed definition of immediately life-threatening was unnecessary because immediately life-threatening conditions are a subset of serious conditions and thus need not be defined.

(Response) The proposed rule defined the term “immediately life-threatening disease” because the evidentiary criteria

for authorizing a treatment IND under proposed § 312.320 vary depending on whether the disease or condition is merely serious or is also immediately life-threatening. There is a lower evidentiary threshold for a treatment IND for an immediately life-threatening condition. The evidentiary distinction and definition are carried over from the previous treatment IND regulation and reflect the distinction between section 561(c)(6) and (c)(7) of the act. Because the final rule retains the lower evidentiary standard for authorizing a treatment IND for an immediately life-threatening condition, FDA believes it is necessary to retain the definition.

(Comment 22) One comment from an organization representing epilepsy centers asked the agency to define immediately life-threatening in such a way that it would include status epilepticus and pointed out that the mortality rate from status epilepticus is up to 6 percent.

(Response) A disease or condition with an acute mortality rate of six percent would be considered an immediately life-threatening condition for purposes of subpart I.

b. Serious disease or condition.

In the preamble to the proposed rule (71 FR 75147 at 75151), the agency explained that, because of the difficulty in specifically describing regulatory criteria that characterize a “serious disease or condition,” the proposed rule does not provide a definition for the term. Because it is difficult to define “serious disease or condition” without appearing to exclude diseases or conditions that should be considered serious or include those that should not, FDA in the proposed rule elected to describe and illustrate by example what is meant by serious disease or condition in other regulatory settings where the seriousness of a disease or condition is an issue (e.g., Fast Track, Accelerated Approval) (see FDA’s guidance for industry entitled “Fast Track Drug Development Programs—Designation, Development, and Application Review” (Fast Track guidance) (63 FR 64093, November 18, 1998)). The preamble solicited comment on this approach for purposes of expanded access—implicitly asking whether the term should be defined or the agency’s previous practice of describing the concept and illustrating by example was acceptable.

(Comment 23) Several comments stated that FDA should define “serious disease or condition.” No comments recommended not defining the term. Three comments stated that not defining the term and relying on existing descriptions and illustrations of what is

meant by the term would make access to investigational drugs for treatment use overly broad. One of those comments argued that a definition would promote more consistent application of the rule. One comment recommended that the definition err on the side of inclusiveness. One comment asked for clarification of what is meant by serious disease or condition because it is unclear what serious conditions would have an important effect on functioning or other aspects of quality of life as well as persistent or recurrent morbidity.

Some comments provided recommendations or specific language on how to define serious disease or condition. Two comments recommended relying on existing language in the Fast Track guidance (pp. 3 to 4). One comment recommended defining serious disease or condition based on the following criteria in a 1999 Institute of Medicine (IOM) Report entitled “Definition of Serious and Complex Medical Conditions.” The IOM report gave the following examples of descriptive criteria for serious and complex medical conditions:

- Conditions that cause serious disability, such as stroke or closed head or spinal cord injuries.
- Conditions that cause significant pain or discomfort that can cause serious interruptions to life activities, such as arthritis and sickle cell disease.
- Conditions that may require frequent monitoring, such as schizophrenia and other psychotic illnesses.
- Conditions whose treatment carries the risk of serious complications, such as most cancers or conditions requiring complex surgery.

Another comment recommended that the definition of serious disease or condition be made consistent with the definition of serious adverse drug experience in § 312.32(a) (the definition used for the IND safety reporting requirements), which defines a serious adverse drug experience as including inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

(Response) Because of the support for defining the term “serious disease or condition” in the comments, FDA is providing a definition in the final rule. As recommended by some comments, FDA is basing the definition on the description of a serious disease or condition in the Fast Track guidance. That description and illustration of serious disease or condition was the result of prolonged and careful

deliberations concerning what should be considered a serious disease or condition and has served the agency well in its implementation of the Fast Track legislation. The Fast Track guidance (p. 4) states that whether a disease or condition is serious “is a matter of judgment, but generally is based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

* * * For a condition to be serious, the condition should be associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient but the morbidity need not be irreversible, provided it is persistent or recurrent.” FDA believes this definition is also conceptually consistent with the criteria identified in the IOM report, the definition of serious adverse drug experience in the IND safety reporting regulation, and the description of serious disease or condition in the preamble to 21 CFR part 314, subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses). Therefore, we have adopted this definition of serious disease or condition in § 312.300(b).

FDA recognizes, based on its own experience in trying to define and describe what is meant by serious disease or condition, that this definition will be subject to various interpretations. FDA intends to be flexible in its interpretation of the term to ensure that the definition does not thwart access to an investigational drug in a situation where access would be desirable. It is foreseeable that there might even be situations in which a serious health risk in the absence of active serious disease should be considered a serious condition. For example, it may be desirable to make an experimental vaccine available as a prophylactic measure to laboratory workers who have been inadvertently exposed to a deadly pathogen but have not yet contracted the disease. Notwithstanding the potential pitfalls in defining serious disease or condition, based on the views expressed in the comments received, FDA believes that stating a definition is preferable to providing only an explanation and illustration of the concept of serious disease or condition and will facilitate more consistent and equitable application of the expanded access regulations.

(Comment 24) One comment stated that intractable epilepsy should be considered a serious disease or

condition. Another comment was concerned that in situ breast cancer would not be considered a serious disease or condition for purposes of the expanded access regulations.

(Response) FDA agrees that intractable epilepsy and in situ breast cancer would be considered serious conditions for purposes of the expanded access regulations as each would unquestionably cause morbidity and potentially premature mortality if left untreated.

3. Requirements for All Expanded Access (§ 312.305)

Proposed § 312.305 contains the general criteria for determining whether access to investigational drugs for treatment use is appropriate under the expanded access uses described in subpart I (§ 312.305(a)), the general submission requirements for the expanded access INDs described in subpart I (§ 312.305(b)), and safeguards applicable to those expanded access uses (§ 312.305(c)).

Proposed § 312.305(a)(1) states that FDA must determine that the patient or population to be treated has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.

a. Comparable or satisfactory alternative therapy.

(Comment 25) One comment from a cancer patient appeared to assert that there should be more flexibility in assessing whether there are comparable satisfactory or alternative therapies. The comment stated that certain comparable alternative therapies may be more toxic and patients exposed to those therapies may become too sick to survive any subsequent treatment, thus barring them from access to a promising experimental treatment.

(Response) FDA shares the comment's concern that existing alternative therapies may have greater toxicity than an experimental treatment option, especially in the oncology setting. FDA believes that the relative toxicity of potential alternative therapies is clearly an element to be considered in whether there are comparable or satisfactory alternative therapies for a given patient. The potential lower toxicity of an experimental therapy would be considered in light of the more established effectiveness profile of the approved therapy, the patient's ability to tolerate the approved therapy, and other clinical factors in assessing whether the approved therapy is a satisfactory alternative therapy.

b. Risk/benefit assessment—evidentiary standards.

Proposed § 312.305(a)(2) provides that FDA must determine that the potential patient benefit justifies the potential risks of the treatment use and that those risks are reasonable in the context of the disease or condition to be treated. For individual patients, proposed § 312.310(a)(1) further provides that the physician seeking access for a patient must also determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition. For intermediate-size patient populations, proposed § 312.315(b)(1) further provides that FDA must determine that there is enough evidence that the drug is safe at the dose and duration proposed for expanded access use to justify a clinical trial of the drug in the approximate number of patients expected to receive the drug under expanded access, and proposed § 312.315(b)(2) provides that FDA must determine that there is at least preliminary clinical evidence of effectiveness, or of a plausible pharmacologic effect of the drug, to make expanded access use a reasonable therapeutic option in the anticipated patient population. For treatment INDs or treatment protocols, § 312.320(a)(3)(i) further provides that for a serious disease or condition, there must be sufficient evidence of safety and effectiveness to support the use, which would ordinarily consist of data from phase 3 trials but could consist of compelling data from completed phase 2 trials. Section 312.320(a)(3)(ii) requires that, for an immediately life-threatening disease or condition, the available scientific evidence taken as whole must provide a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an unreasonable and significant risk of illness or injury. Such evidence would ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence.

(Comment 26) One comment from a physician with investigational drug experience asked that FDA remove the requirement that the agency must determine that the potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated. The comment maintained that the seriously ill patient and his/her physician should be the ones to decide whether or not to accept the risks of the treatment and that the decision should

not be made by FDA reviewers. The comment also stated that this provision “represents a sea change” in FDA's policy because it would regulate the practice of medicine.

Another comment stated that the risk-benefit decision to be made for individual patient expanded access should be made only by the patient's physician, not also by FDA. The comment objected to the proposed criterion that FDA determine that the potential patient benefit justifies the potential risks of the treatment use and that those potential risks are not unreasonable in the context of the disease or condition to be treated (§ 312.305(a)(2)). The comment argued that, in interposing itself into the risk-benefit decision, FDA had impermissibly changed the statutory standard for deciding whether to grant individual patient expanded access. The comment recognized that section 561(b)(2) of the act requires the Secretary to determine that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug in an individual patient. However, the comment stated that this provision does not empower FDA to make a risk determination.

(Response) FDA disagrees with the recommendation to remove the requirement that the agency determine whether the potential patient benefit justifies the potential risks and whether those risks are reasonable in the context of the disease or condition to be treated. FDA also rejects the characterization of this policy as a “sea change.” This policy reflects the essence of FDA's long-standing approach to using investigational drugs for treatment use, whether under individual patient INDs or multi-patient INDs, and reflects the act's requirement of FDA involvement in a determination of the propriety of the expanded access use (see section 561(b)(2), (b)(3), (c)(6), and (c)(7) of the act). The practice-of-medicine exemption in the IND regulations applies to use of an approved drug for an unapproved use in a clinical setting, not to the use of an unapproved drug. With regard to treatment access to an approved drug subject to a REMS, because the risk profile of such a drug means that it is not available for unrestricted use, FDA maintains a role, consistent with sections 505–1(f)(6) and 561 of the act, in assessing the appropriateness of the drug for treatment use analogous to its role regarding treatment access to investigational drugs.

As to the comment that FDA has impermissibly aggregated to itself the risk benefit decision to be made for

individual patient expanded access, the comment itself acknowledges that section 561(b)(2) of the act states that the criteria for individual patient expanded access include that the Secretary determines that there is "sufficient evidence of safety and effectiveness to support the use of the investigational drug." If FDA were to accede to the comment's interpretation that the risk determination belongs solely to the physician, it would effectively read out of existence section 561(b)(2) of the act. In that section, Congress expressly directed FDA to make a determination regarding the sufficiency of the evidence of both safety and effectiveness to justify treatment use of an investigational product. While section 561(b)(1) of the act requires a physician to make a determination that the probable risk to the patient is not greater than the probable risk from the disease or condition, this finding is a necessary, but not in itself sufficient, prerequisite to providing a drug for individual treatment use. Section 561(b)(2) of the act clearly contemplates a determination by FDA regarding safety and effectiveness, and the agency cannot choose to ignore that responsibility.

(Comment 27) Some comments were concerned that the proposed rule did not provide an adequate balance between risks and benefits and, in particular, did not provide a sufficiently high evidentiary standard for providing access, and as a result would expose patients to unnecessary risks. One comment stated that because many of the drugs that would be made available under access programs are highly likely to prove ineffective in further clinical testing, exposure to such drugs may not improve patients' conditions and, in some cases, may increase patient suffering and hasten death. One comment provided an apparent illustration of the potential harm. The comment pointed out that autologous bone marrow transplants were performed on approximately 30,000 women with advanced breast cancer before it was established that such treatment did more harm than good and that, as a result, some of the women who received this treatment had increased suffering and shortened lives. One comment stated that a patient should have some assurance that an investigational drug may be potentially life-saving that would outweigh any potential negative risks of using the drug. Some comments maintained that, until there is a certain threshold of data available, there should be no access whatsoever. One comment argued that

there should be no expanded access until the completion of phase 2 testing, and then only if the phase 2 data are compelling. Another comment recommended that there be no expanded access until evidence of a drug's safety and effectiveness has been demonstrated in clinical trials that will be submitted for approval, which would usually be data from phase 3 trials but may include phase 2 data. Other comments were concerned that the proposed rule required too much evidence to obtain an investigational drug for treatment use. Those comments believe that the evidentiary standards would inappropriately deny access to investigational drugs to some patients.

(Response) The assessment of the risks and benefits of investigational therapies in the absence of complete data about the safety and effectiveness of those therapies is challenging and subject to varied interpretations and viewpoints. FDA believes the proposed rule strikes an appropriate balance and sets forth a reasonable approach to balancing risks and benefits. That approach, as outlined in the discussion above, requires an assessment of risk and benefit based on the relative seriousness of the disease or condition and the size of the population to be treated under the expanded access IND or protocol—with the evidentiary requirements decreasing as seriousness increases and the size of the population decreases. Increasing the amount of evidence needed as the size of the population exposed increases is based on FDA's considerable experience with the clinical development of drugs that demonstrates the need to cautiously increase the size of exposure in order to detect serious toxicities that occur in small percentages of those exposed (and are thus not likely to be detected in a small population exposure). Decreasing the amount of evidence needed as the seriousness of the disease or condition increases simply acknowledges that patients in greater peril are willing to assume greater risks.

FDA recognizes that investigational drugs have risks, including unknown risks, and that it is likely that some drugs made available for treatment use will ultimately be shown to have no benefit, and in fact cause harm. As a result, there is the potential for some patients to be harmed by such drugs. However, FDA believes that, on balance, more patients are likely to gain some benefit from investigational drugs than be harmed by them and, therefore, patient interests are best served by making such drugs available under appropriate programs. FDA does not believe that a lesser evidentiary

standard is warranted. FDA believes that to require less evidence would significantly increase the likelihood that patients would be more harmed than benefited by use of experimental therapies.

Conversely, FDA does not believe that there should categorically be a specified minimum amount of data, such as data from completed phase 2 or 3 trials, before any expanded access is permitted. As detailed in the preamble to the proposed rule (71 FR 75147 at 75168), FDA believes there needs to be flexibility in the evidentiary standards to be applied to the varied types of expanded access INDs and expanded access protocols that the agency is likely to receive. Moreover, even if a specified minimum amount of data for expanded access were desirable, FDA believes that completion of phase 2 or 3 testing is more than should be required for certain types of expanded access INDs and expanded access protocols.

(Comment 28) One comment argued that access has the potential to increase the risk to patients with the possibility of no commensurate benefit. The comment maintained that safety issues related to exposure to an investigational drug are best addressed in the context of clinical trials and asked FDA to require that access be provided only under a defined protocol, by a qualified investigator, with defined dosage range and adverse event monitoring procedures, and with specified time intervals for assessing response.

(Response) FDA agrees that access protocols should provide a detailed plan for the conduct of the protocol, including plans for data collection and patient monitoring commensurate with the size of the population to be treated and the nature of the use (e.g., short-term versus long-term). However, because of the broad range of potential populations for which access may be provided under an expanded access protocol—from an individual patient to many thousands of patients—and the wide range of potential risks and resulting need for variations in the intensity of monitoring, it would not be good policy to require the same level of detail and specificity for each protocol. The amount of detail and specificity required will increase with increasing size of the population, increasing complexity of the disease being treated, and greater risks associated with the use of the drug. For the same reasons, the amount of data to be collected and the potential utility of that data might vary. Accordingly, FDA believes it would not be useful to promulgate specific and uniform data collection and monitor

requirements for all expanded access protocols.

i. Individual Patient Evidentiary Standard

Proposed § 312.310(a)(1) provides that the physician seeking access for a patient must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition. Concerning the evidence needed before treating an individual patient with an immediately life-threatening illness or disease or condition, the preamble to the proposed rule stated that to support expanded access for an individual patient when the patient has an immediately life-threatening condition that is not responsive to available therapy, ordinarily, completed phase 1 safety testing in humans at doses similar to those to be used in the treatment use, together with preliminary evidence suggesting possible effectiveness, would be sufficient to support such a use. However, the preamble further stated that in some cases, there may be no relevant clinical experience, and the case for the potential benefit may be based on preclinical data or on the mechanism of action (71 FR 75147 at 75151).

(Comment 29) Several comments were concerned that the evidentiary standards applicable to individual patient expanded access allow for the possibility of making a drug available to a patient without evidence from clinical experience. One comment stated that “it is wrong to permit use in the absence of evidence in humans and to present this scenario as ‘treatment’ even for desperately ill patients.” Another comment stated that “it seems inappropriate and possibly dangerous to permit this relatively uncontrolled access to an investigational drug to represent the first human exposure to a drug.” Another comment recommended that there be at least preliminary clinical evidence (such as phase 1 safety testing) before there be any expanded access use regardless of the number of patients. One comment recommended that the final rule state that proceeding with treatment use in an individual patient should be a rare circumstance that requires, at a minimum, submission to FDA of robust evidence from nonclinical studies to show that it is reasonably safe to proceed with the proposed treatment use, and information forming the basis from nonclinical toxicokinetic studies and nonclinical pharmacology studies for selecting dosage, dosage interval, and duration of treatment for use in patients. One comment recommended that the

evidentiary threshold for individual patient expanded access be evidence from the clinical trials intended to demonstrate safety and effectiveness for marketing approval (which would ordinarily be phase 3 studies but could include phase 2 studies that support approval). The comment added, however, that this category could be used to provide continuity of care for a patient who appeared to benefit from a drug during participation in an earlier clinical trial.

(Response) FDA agrees that making an investigational drug available to an individual patient in the absence of any clinical data to support the use may carry substantial risk. FDA does not believe, however, that access under such circumstances should be entirely foreclosed by the expanded access provisions. FDA believes—and our experience has demonstrated—that there are circumstances in which such use may be appropriate. These circumstances might involve a patient with an imminently life-threatening disease or condition, a novel therapy that has a plausible pharmacologic rationale suggesting it may potentially be beneficial for that disease or condition, and robust nonclinical safety data to support the use. FDA does agree that use of an investigational drug for treatment purposes in an individual patient in the absence of any clinical data should be extremely rare. FDA anticipates that authorizing an individual patient treatment use of a drug in the absence of clinical data on use of the drug for that indication would be more likely to occur when there was some clinical data on the drug (e.g., from a study for another use) but no clinical data in the population or disease for which treatment use is sought.

However, FDA does not agree that there should be no expanded access to an investigational drug for anyone until the evidence needed to support approval is developed, which ordinarily would not occur until the completion of phase 3 clinical testing. In addition, FDA does not believe the expanded access provisions in subpart I are necessary to provide continuity of care for patients who seemed to have responded to an investigational therapy during a clinical trial. A protocol amendment adding a continuation phase to the clinical trial would ordinarily be the preferred mechanism for providing an investigational therapy to clinical trial participants who wish to continue to receive the drug after the completion of the controlled phase of the clinical trial.

(Comment 30) Two comments recommended that FDA have different evidentiary standards for individual patient expanded access for patients with a serious disease or condition and the subset of those patients with an immediately life-threatening disease or condition. For immediately life-threatening diseases or conditions, one comment recommended that there be data from completed phase 1 testing at doses similar to those to be used in the treatment use and preliminary evidence suggesting possible effectiveness. The other comment recommended that the evidentiary standard that applies to treatment INDs for immediately life-threatening diseases or conditions apply to individual patient treatment use for such conditions (i.e., the available scientific evidence taken as whole provides a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an unreasonable and significant risk of illness or injury). Such evidence would ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence. For individual patient treatment use for serious diseases or conditions, both comments recommended that there be evidence of safety and effectiveness from phase 3 trials, although in some circumstances compelling data from phase 2 trials may be sufficient (the same standard that applies to treatment INDs for serious diseases or conditions).

(Response) As discussed in the previous response, FDA believes that the suggested evidentiary requirements are too high a barrier to access for individual patient treatment use. Where the population exposed to an experimental therapy is small (in this case, a single individual), the amount of safety and effectiveness evidence needed to support the use is less than would be needed to allow exposure in the size population that might be treated under a treatment IND (often more than 1,000 patients).

In contrast to treatment INDs, which usually occur very late in a drug's development, individual patient treatment use may be sought quite early in a drug's development, and at any point during the development. Therefore, FDA also believes it is important to have flexibility in the evidentiary standards to permit it to respond appropriately to wide variations in the amount and nature of evidence that might be presented in support of an individual patient IND. Thus, FDA would prefer to avoid evidentiary standards pegged to data

from specific phases of drug development. FDA also believes a two-tiered evidentiary standard—one standard for serious diseases and conditions and a lower standard for immediately life-threatening diseases or conditions—is unnecessary for individual patient INDs because the relative seriousness of the disease or condition is an implicit component of the risk-benefit assessment for individual patient INDs, and the current evidentiary standard allows for considerable flexibility in the amount and nature of evidence needed to support an individual patient IND.

ii. *Intermediate-size patient population evidentiary requirements.*

Proposed § 312.315(b)(1) provides that, for expanded access under intermediate-size population INDs or protocols, FDA must determine that there is enough evidence that the drug is safe at the dose and duration proposed for expanded access use to justify a clinical trial of the drug in the approximate number of patients expected to receive the drug under expanded access. Proposed § 312.315(b)(2) provides that FDA must determine that there is at least preliminary clinical evidence of effectiveness or of a plausible pharmacologic effect of the drug to make expanded access use a reasonable therapeutic option in the anticipated patient population.

(Comment 31) One comment recommended that FDA have different evidentiary standards for intermediate-size expanded access for serious diseases or conditions and intermediate-size expanded access for immediately life-threatening diseases or conditions. For INDs for immediately life-threatening diseases or conditions, the comment stated that there should be some preliminary evidence of clinical effectiveness. For INDs for serious diseases or conditions, the comment recommended that there be evidence of safety data from completed phase 1 testing at doses similar to those to be used in the treatment use and preliminary evidence suggesting possible effectiveness.

(Response) Because intermediate-size population INDs can occur earlier in drug development than treatment INDs and because there are three different intermediate-size population access scenarios (for a drug being developed, for a drug not being developed, and for an approved or related drug that is not available through marketing channels), FDA must have flexibility in the evidentiary standards to permit it to respond appropriately to variations in the amount and nature of evidence that

might be presented in support of an intermediate-size population IND. Thus, FDA rejects the recommendation to have evidentiary standards pegged to data from a specific phase or phases of drug development. Again, because of the flexibility inherent in the evidentiary standards for intermediate-size patient population INDs, FDA does not believe it is necessary or useful to have different standards for serious diseases or conditions than for immediately life-threatening diseases or conditions.

iii. *Treatment IND or treatment protocol evidentiary standards.*

Proposed § 312.320(a)(3)(i) provides that for a treatment IND or treatment protocol for a serious disease or condition, there must be sufficient evidence of safety and effectiveness to support the use, which would ordinarily consist of data from phase 3 trials, but could consist of compelling data from completed phase 2 trials. Section 312.320(a)(3)(ii) provides that, for an immediately life-threatening disease or condition, the available scientific evidence taken as whole must provide a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an unreasonable and significant risk of illness or injury. Such evidence would ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence.

(Comment 32) Two comments were concerned that the proposed evidentiary standards for authorizing a treatment IND or treatment protocol were not sufficiently rigorous to protect patients. One comment recommended that, for treatment INDs or treatment protocols for serious diseases or conditions, only data from phase 3 clinical trials should be used to assess the potential benefits and risks of the drug. The comment also recommended that for a treatment IND or treatment protocol for immediately-life threatening diseases or conditions, only data from phase 3 clinical trials or compelling data from phase 2 trials should be considered. One comment objected to the proposed evidentiary standard for a treatment IND or a treatment protocol for an immediately life-threatening disease or condition because it would permit authorization of expanded access on the basis of clinical data more preliminary than phase 2 or 3 data.

Two comments were concerned that the evidentiary standards for a treatment IND were overly rigorous. One comment stated that requiring safety and effectiveness data from phase 3 or phase 2 studies limits the use of expanded

access under treatment INDs to programs initiated very late in the drug development process. The comment noted that if phase 3 data are required, a treatment IND would typically only provide access to the investigational drug for a matter of months (i.e., the time between the initiation of a treatment IND and approval of a drug for marketing would be relatively short) and thus would not meet the needs of patients or substantially help small biotech companies. The comment argued that to be truly useful, either treatment INDs or treatment protocols need to be available based upon phase 1 data (at least in cases where appropriate because of the severity of the disease and a relatively benign safety profile for the drug), the intermediate population programs need to be able to go well above 100 patients (i.e., up to 500 or 1,000 patients), or there needs to a fourth category between the intermediate and the large populations programs. Another comment stated that the proposed rule's evidentiary requirements for a treatment IND raise the bar to a level effectively equivalent to the amount of data required to obtain marketing approval.

(Response) FDA believes that the proposed evidentiary requirements for authorizing treatment use under a treatment IND effectively balance making an investigational drug available to a substantial number of patients who might benefit from the drug with simultaneously protecting those patients from unreasonable risks associated with the drug. Our experience with this standard—spanning more than two decades—supports this assessment. Moreover, the evidentiary standards provide a certain amount of flexibility, particularly in the case of a treatment IND to treat an immediately life-threatening disease or condition, so that FDA can make investigational therapies available to substantial numbers of patients as early in the development process as is reasonably possible. FDA believes that more rigorous or inflexible standards would present an inappropriate barrier to obtaining a treatment IND in some cases. FDA also believes that relaxing these standards could potentially expose significant numbers of patients receiving investigational drugs under a treatment IND to unnecessary harm. A key tenet of drug development is to gradually increase the size of the population exposed to an investigational drug so as to be able to detect relatively low-frequency, serious toxicity as early as possible, and before very large numbers of patients have been exposed. This

principle applies with equal force to the use of investigational drugs for treatment use.

FDA wishes to emphasize that the evidentiary standards for a treatment IND are not the functional equivalent of the amount and type of data needed for marketing approval. The standards provide a degree of flexibility that enables FDA to authorize a treatment IND on the basis of data often well short of that needed to obtain marketing approval. FDA also does not believe that there needs to be a fourth category of treatment use in between an intermediate-size patient population IND and a treatment IND. As discussed elsewhere in this preamble, FDA intends that there be sufficient flexibility in the size of the population that might be treated under an intermediate-size population IND to enable treatment of as many patients as is supported by the available evidence of safety and effectiveness.

(Comment 33) One comment objected to the proposed rule's evidentiary standard for a treatment IND or treatment protocol for a serious disease, asserting that it was higher than both the statutory and current regulatory standards and thus further restricted access. The comment noted that section 561(c)(1) of the act only requires "sufficient" evidence of safety and effectiveness. The comment also noted that § 312.34(a) of FDA's current regulations allows drugs to be made available during Phase 2 "in appropriate circumstances." The comment pointed out that § 312.320(a)(3) of the proposed rule provides that the evidence needed for a treatment IND or treatment protocol would ordinarily consist of data from phase 3 trials, but could consist of compelling data from completed phase 2 trials. The comment stated that, under the proposed rule, phase 2 trials would have to be completed, not merely ongoing, thus raising the standard for expanded access for treatment INDs and treatment protocols. The comment also stated that FDA has also raised the standard because the data would have to be "compelling." The comment suggested that because of design limitations, many phase 2 trials could be considered not compelling. The comment suggested that the proposed rule may result in treatment INDs and treatment protocols being less frequent than under FDA's current regulations. The comment stated that the final rule should use the language in § 312.34(a) of FDA's current regulation instead of the new proposed language in § 312.320(a)(3).

(Response) FDA does not agree that the proposed rule articulates a more

stringent evidentiary standard for a treatment IND or treatment protocol for a serious disease or condition than was contained in FDA's previous regulation in § 312.34. Section 312.34 was not specific about the nature of the evidence that would be needed to support a treatment IND for a serious, as opposed to immediately life-threatening, disease or condition. Rather, the general discussion in § 312.34(a) suggested an earliest point in time at which such a treatment IND could be allowed to proceed ("in appropriate circumstances, a drug may be made available during phase 2"). FDA has always interpreted that requirement to mean that a treatment IND for a serious, but non-life-threatening, disease or condition would have to be supported by some phase 2 data (controlled trial data on the disease of interest), but that phase 2 did not have to be completed. Or, to put it another way, at least one phase 2 trial would have to have been completed, but others could be ongoing. FDA has never interpreted this provision to mean that a treatment IND for a serious disease or condition could proceed without any phase 2 data. Therefore, FDA believes that stating in this final rule that data needed to support for a treatment IND for a serious disease or condition could consist of compelling data from phase 2 trials is consistent with the statement that a drug may be made available for treatment use during phase 2.

FDA also does not agree that characterizing the phase 2 data needed to support an treatment IND for a serious disease or condition as compelling raises the bar compared to that in § 312.34. That provision made clear that a treatment IND for a serious disease or condition would ordinarily not be permitted until some point during phase 3 or at a point when all controlled trials were completed. To permit a treatment IND to proceed during phase 2 was plainly intended to be an exceptional circumstance. FDA does not believe that ambiguous, inconclusive, or marginally statistically significant phase 2 data would justify the exceptional circumstance of permitting a treatment IND for a serious disease or condition based on phase 2 data. Therefore, FDA believes it is reasonable to characterize the phase 2 data needed as compelling. FDA also disputes the contention that the design of a typical phase 2 could not yield compelling data.

For the reasons stated previously, FDA also does not agree that there will be fewer treatment INDs and treatment protocols for serious disease or conditions because of the way FDA articulated the evidentiary standard for

a treatment IND for a serious disease or condition in § 312.320(a)(3) of this final rule.

c. Non-interference with drug development.

Proposed § 312.305(a)(3) states that, for all expanded access uses, FDA must determine that providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use. For a treatment IND, proposed § 312.320(a)(1) also requires FDA to determine that the drug is being investigated in a controlled trial under an IND designed to support a marketing application for the expanded access use, or that all clinical trials of the drug have been completed, and that the sponsor is actively pursuing marketing approval of the drug for the expanded access use with due diligence.

(Comment 34) Several comments expressed concern that the proposed rule would seriously impede the initiation and completion of clinical trials and drug development generally. A number of comments stated that, given a choice, patients would be more likely to try to obtain an investigational drug under an expanded access IND or protocol than to participate in a clinical trial of the drug (and, for example, risk randomization to another treatment). Two comments argued that making drugs more widely available under expanded access INDs would have a domino effect in which decreased enrollment in clinical trials would lead to less rigorous trial protocols, less useful data, and ultimately decrease the amount of safety and efficacy information on approved drugs.

(Response) FDA believes that the provisions in the proposed rule requiring that expanded access programs not impede clinical development of the investigational drug that is being made available for treatment use are adequate to mitigate the impact of expanded access on clinical development. In the case of individual patient expanded access INDs, an individual patient is not eligible to obtain access under an individual patient expanded access IND if the patient can participate in a clinical trial of the drug or obtain the drug under a larger access IND. In the case of an intermediate-size patient population IND for a drug being developed, the intent of such an IND is to make a drug available to patients who cannot enroll in a clinical trial; therefore, there would be no effect on

drug development. The other two intermediate-size patient population IND scenarios do not involve drugs that are being actively developed. In the case of a treatment IND, in FDA's experience, sponsors usually do not initiate treatment INDs until the clinical studies needed to support approval are completed or fully enrolled. However, it is possible to authorize a treatment IND before clinical trials needed to support marketing approval are fully enrolled. In such cases, it would be important for FDA to closely monitor the implications of the treatment IND on the rate of accrual of subjects into the clinical trial and other clinical development milestones.

(Comment 35) Some comments asked FDA to specify how it will determine that making an investigational drug available for treatment use will not interfere with clinical trials or drug development generally. One comment stated that the expanded access rule should contain more explicit criteria for determining that expanded access does not detrimentally affect clinical trials.

(Response) FDA believes the criteria are sufficiently explicit to enable FDA to meaningfully assess the impact of an expanded access program on development, and also provide FDA the flexibility to ask for varied types of assurances that access will not impede development, depending on the particular situation. For example, before authorizing a treatment IND for an investigational drug for which clinical trials are ongoing, FDA could seek specific assurances from the sponsor that the treatment IND would not interfere with accrual of patients in the clinical trial. FDA would likely request that the sponsor submit a comprehensive investigational plan with a timetable and milestones to its IND (if it had not done so already), so that FDA could periodically assess whether the treatment IND is having an effect on accrual or other parameters related to the pace of clinical development. If FDA determines that the treatment IND is slowing the pace of drug development or the sponsor is not actively pursuing marketing approval with due diligence, FDA can place the treatment IND on clinical hold. It is also worth noting that it is likely not in the sponsor's interest to delay development because it delays marketing approval and commercial sale of the drug. Therefore, sponsors are unlikely to provide expanded access in situations in which drug development would be impeded.

(Comment 36) One comment raised two objections to the provisions of the proposed rule relating to FDA's finding

of noninterference with clinical trials. First, the comment asserted that with regard to "widespread" treatment INDs, the criteria imposed by § 312.305(a)(3) were broader than the authority in section 561(c)(5) of the act and impermissibly permitted FDA to refuse to approve requests for expanded access for reasons other than the proposed treatment use's effect on enrollment of clinical trials. The comment referred to the proposed rule's criterion that providing expanded access will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use (§ 312.305(a)(3)), and urged that the final rule use statutory language rather than that used in the proposed rule.

Second, in a section related to individual patient access to investigational drugs, the comment argued that FDA lacks statutory authority for the proposed rule's product development criteria. Specifically, the comment noted that in the case of the single patient IND, Congress gave FDA authority to authorize a single patient IND if the Secretary determines that "provision of the investigational drug * * * will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval." The comment objected to the phrase "or otherwise compromise the potential development of the expanded access use" in proposed § 312.305(a)(3).

(Response) FDA disagrees with the comment. Regarding the first assertion, that FDA has applied a more stringent provision on noninterference with clinical trials than is called for in the section of the act relating to expanded access for treatment INDs, FDA disagrees that the language in § 312.305(a)(3) impermissibly expands the grounds on which FDA may reject a proposed treatment IND. Section 312.305(a)(3) provides that, for all types of expanded access, FDA must determine that providing the investigational drug for the requested use "will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use." While admittedly much of this language matches terminology found in section 561(b)(3) of the act, which applies to individual patient treatment access and access by small groups of patients, it also generally describes the type of

finding that FDA must make under section 561(c) of the act, which applies to treatment INDs.

The comment seems to be based on the mistaken assumption that under section 561(c)(5), the only determination that FDA must make is whether an investigational drug will "interfere with the enrollment of patients in ongoing clinical investigations." However, under section 561(c)(4) of the act, FDA also must determine that the sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence. Such active pursuit of marketing approval with due diligence implicitly includes a determination that the treatment use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval for the investigational drug, which is why FDA included those particular terms in the regulation. FDA could have simply restated the statutory language in the regulation, but since the regulation implementing the statute is aimed, in part, at shedding light on how FDA interprets the statute, the agency believes the proposed language provides more helpful guidance than merely restating the terms from the statute without more.

Regarding the argument that the statutory language does not allow FDA to require a determination that provision of the investigational drug for treatment use will not "otherwise compromise the potential development of the expanded access use," FDA disagrees for reasons similar to those explained previously. In § 312.305(a)(3), which is applicable to all treatment uses, FDA included this term to generically address other criteria required under different sections of section 561, including section 561(b)(4), (c)(3) and (c)(4). FDA does not intend to use this catchall language as a limitless means to deny treatment use of investigational drugs. Rather, the intent is to endow the implementing regulation with sufficient flexibility to allow FDA to address situations where potential development of the treatment use would be compromised by a particular treatment proposal, for instance, where a proposed use would usurp the entire population of patients who might be studied in controlled clinical trials. This particular regulatory language is motivated by one of the core notions underlying the act—namely, recognition that the best form of access to a drug is full marketing approval.

d. *Impeding development of related drug products.*

(Comment 37) One comment expressed concern about the potential for expanded access to impede development of other drug products being developed for the same or a similar indication as the investigational drug being sought for treatment use. The comment recommended that requests for expanded access include a statement that the public list of clinical trials has been reviewed and the patient is not eligible or is otherwise unable to participate (e.g., because of distance) in available studies. Another comment cited an example of a situation in which enrollment in a clinical trial had decreased following accelerated approval of drugs for the same use under subpart H.

(Response) FDA acknowledges the possibility that a large expanded access IND for a given product could impede concurrent development of other products for the same or a similar indication because trials for those products would be competing with the access program for the same patient population. However, requiring that the sponsor of a proposed expanded access IND demonstrate that the expanded access use will not impede development of not only its drug but of any other drug in clinical development for the same use would seem to present an unreasonable obstacle to access. For example, it is not clear how a sponsor would be able to demonstrate no effect on the development of a related therapy absent some proprietary knowledge about the development plans of the related therapy. Because there is no obvious way that the sponsor of a proposed expanded access plan could provide proof that the plan would have no effect on another company's development program, such determinations would have to rely primarily on conjecture. For that reason, such a requirement would likely be applied inconsistently and, as a result, could unnecessarily deny access to patients in desperate circumstances. FDA also does not believe that the sponsor of a competing therapy under development should have the ability to cause an ongoing expanded access IND to be put on hold, as would be the case if FDA were to require a sponsor to show that the expanded access IND would not interfere with another company's development program, and the other company were to demonstrate such interference.

FDA also acknowledges the potential for marketing approval of a related product for the same or a similar indication to impede development of drugs for that indication. However, denial or delay of marketing approval

because such approval would impede development of a competing product is clearly not in the best interests of the public health because it would deny patients access to a proven effective therapy. There do not appear to be any other regulatory options that could mitigate the impact on development or approval of a related drug.

(Comment 38) One comment stated that expanded access would be more likely to impede development in the early stages of drug development and the development of orphan drugs.

(Response) FDA agrees that expanded access has greater potential to impede development when a drug is available under an access IND early in development, particularly if the access is widespread. For this reason, FDA must determine that a patient seeking access to an investigational drug under an individual patient expanded access IND cannot participate in a clinical trial of the drug or obtain the drug under a larger expanded access IND or protocol (§ 312.310(a)(2)). Similarly, an intermediate-size patient population IND intended for a drug being developed is intended to make the drug available only to those who cannot participate in a clinical trial of the drug (§ 312.315(a)(2)). FDA believes that these provisions should minimize the potential for these types of expanded access INDs to impede drug development.

FDA also agrees that expanded access for drugs for orphan diseases has added potential to impede drug development due to the relatively smaller population from which clinical trial subjects can be drawn. FDA will carefully evaluate any expanded access submission for an orphan drug to ensure that the data needed to support approval of the orphan product will not be compromised by the expanded access use.

(Comment 39) One comment maintained that expanded access would be more likely to decrease clinical trial participation in more rural communities and that even if clinical trials were still able to accrue adequate numbers of subjects, the demographics of participation in clinical trials could be skewed toward more urban populations.

(Response) FDA disagrees. The agency believes that expanded access programs would have a neutral effect on clinical trial enrollment in rural areas because the same criteria apply in rural and more urban settings. Admittedly, patients in rural areas are more likely to be unable to enroll in a clinical trial because of geographical constraints, but providing access to those patients would have no effect on clinical trial

enrollment or the demographics of the trial because those patients would not have been able to participate in the clinical trial because of geographical constraints.

(Comment 40) One comment asked whether there have ever been any investigational drugs made available through a treatment IND that were not subsequently approved for marketing.

(Response) Yes, there have been drugs that were made available under a treatment IND that did not obtain marketing approval. However, for these drugs, the failure to obtain marketing approval was not due to the treatment IND interfering with the clinical development program.

4. Expanded Access IND Submission Requirements

Section 312.305(b) describes the content of an IND submission or protocol amendment for expanded access. In the event that a licensed physician, as opposed to a commercial sponsor, is making the IND submission, it provides that the licensed physician may provide some of the required information by obtaining a right of reference to the content of the existing IND. Proposed § 312.305(b)(2) requires that an expanded access submission include:

- A cover sheet (Form FDA 1571) meeting the requirements of § 312.23(a);
- The rationale for the intended use of the drug, including a list of therapeutic options that would ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options;
- The criteria for patient selection or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;
- The method of administration of the drug, dose, and duration of therapy;
- A description of the facility where the drug will be manufactured;
- Chemistry, manufacturing, and controls information adequate to ensure proper identification, quality, purity, and strength of the investigational drug;
- Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration proposed for the treatment use (ordinarily, information that would be adequate to permit clinical testing of the drug in a population of the size expected to be treated); and
- A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the

effects of the drug and minimize its risks.

(Comment 41) One comment asked whether the proposed submission requirements for expanded access apply to both sponsors and sponsor-investigators. The comment also asked whether some of the required information could be incorporated into the protocol rather than provided as separate documents in the IND submission, including the rationale for the intended use of the investigational drug with a list of generally available treatment options and an explanation as to why they are not preferable, criteria for patient selection, a description of the patient's disease or condition (including recent medical history), and previous treatment use (for an individual patient submission).

(Response) The submission requirements are sponsor requirements and thus are intended to apply to both sponsors and sponsor-investigators. The listing of general submission requirements in § 312.305 is not intended to convey the impression that each element of the submission be contained in a separate document. As the comment points out, certain required submission elements are topics that are appropriate for inclusion in a single protocol. Other elements, such as pharmacology/toxicology and chemistry, manufacturing, and controls (CMC), may more typically be found in separate documentation. FDA's primary concern is not with the number of individual documents submitted, but that the required elements be submitted in a form that makes the information readily accessible and leaves no question that the submission contains the necessary information.

a. Submissions for individual patient expanded access.

(Comment 42) Several comments expressed concern that individual physicians would not be able to comply with the submission requirements for expanded access for an individual patient. The comments stated that most individual physicians will not have access to the drug's CMC or pharmacology and toxicology information. One comment stated that FDA sometimes raises difficult manufacturing, pharmacology, toxicology, pharmacokinetic, clinical, and statistical issues, and these issues sometimes result in physicians withdrawing expanded access requests. One comment opined that the submission requirements for individual patient expanded access may have the unintended effect of rendering the proposed rule relatively meaningless for the vast majority of the patient

population if there is no existing IND or if the sponsor of the IND will not provide the information needed to support the expanded access request. The comment added that physicians may not know whether an IND exists or how to find that out.

(Response) In FDA's experience, the vast majority of expanded access INDs for individual patients are for investigational drugs in development, and submissions are made on behalf of patients unable to participate in clinical trials. In these situations, the submission requirements are not onerous. The commercial sponsor that is developing the drug may make a submission for individual patient access as a protocol amendment to its existing IND, in which case the licensed physician must only provide the sponsor with the required information about the individual patient. Alternatively, the commercial sponsor may elect only to provide the drug and require the physician to submit his or her own IND. In this situation, the commercial sponsor routinely permits the licensed physician to refer to any needed information in its existing IND, so, again, the licensed physician usually only has to provide the relevant information about the physician's patient. In each of these scenarios, the information the licensed physician must provide is ordinarily readily available in patient medical records.

In rare circumstances, a licensed physician may seek to obtain access for an individual patient to an investigational drug not being developed. If a drug is not being developed and has never been the subject of an IND, the submission requirements become more complex. There may be other sources that could provide some of the necessary information (e.g., materials data sheets) to minimize the burden on the physician to an extent. However, FDA must have reasonable assurances about the integrity and safety of the product, so the IND submission will require a significant amount of information concerning the manufacturing of the product and its pharmacology/toxicology profile for FDA to permit use of the drug for the expanded access use. FDA's guidance for industry entitled "Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products," provides some insight into the amount and nature of the information that would be required in these situations. However, because these situations are rare, FDA does not believe that the

submission requirements present an obstacle to the vast majority of patients who seek to obtain investigational drugs for treatment use under the expanded access regulations, and the agency is convinced that the requirements are an essential component of human subject protection.

(Comment 43) Two comments expressed the view that many parts of Form FDA 1571 may not be appropriate for use by an individual doctor for expanded access purposes. The comments asked that FDA provide a streamlined version of Form FDA 1571 that is specific to individual patient expanded access. One comment recommended that FDA encourage or require standard nomenclature on expanded access submissions so such submissions could be readily distinguished from non-expanded access submissions. The comment stated that for a treatment IND, the sponsor should make two entries to Item 11 of the 1571: Check the box for INITIAL INVESTIGATIONAL NEW DRUG APPLICATION, and enter "OTHER: Treatment IND" on the blank line. For an expanded access protocol under an existing IND, the comment suggested that the sponsor also make two entries to Item 11 of the 1571: Check the box for PROTOCOL AMENDMENT: NEW PROTOCOL, and enter "OTHER: New Protocol for Expanded Access" on the blank line.

(Response) FDA agrees that it is desirable to be able to readily distinguish expanded access submissions from non-expanded access submissions. FDA does not believe, however, that a new form specific to expanded access is necessary to accomplish this task. FDA believes that instructions for filling out Form FDA 1571 for expanded access purposes and standardized nomenclature will suffice, helping sponsors to complete the form appropriately and helping FDA to readily identify expanded access submissions. FDA may develop guidance to provide instructions for completing Form FDA 1571 and sample completed forms for each type of expanded access.

b. Intermediate-size population IND submission requirements.

In addition to the general submission requirements, proposed § 312.315(c) describes requirements specifically applicable to submissions for intermediate-size population expanded access INDs. Proposed § 312.315(c)(1) requires that the submission state whether the drug is being developed or not being developed. For a drug not being developed, proposed § 312.315(c)(2) requires that the sponsor

explain why the drug cannot currently be developed and under what circumstances the drug could be developed.

(Comment 44) One comment requested that the requirements in proposed § 312.315(c)(2) and (c)(3) be removed because they do not seem relevant to the determination of whether access is appropriate for the intermediate-size group.

(Response) FDA disagrees. One of FDA's primary concerns with making investigational drugs available for treatment use is the potential for treatment use to prevent the development of information necessary to demonstrate safety and effectiveness by usurping a population that could have been enrolled in a clinical trial. FDA believes that section 561 of the act contemplates that expanded access to investigational drugs is not appropriate when that access prevents the development of important safety and effectiveness information that could have been developed if there were no expanded access. Requiring a sponsor to explain why no development is possible when a drug is not being developed at all, or why a clinical trial cannot be conducted to study the treatment use when a drug is being developed for a use other than the treatment use, squarely addresses FDA's concerns.

(Comment 45) One comment recommended that before concluding that a patient or patient population is ineligible to enroll in a clinical trial for purposes of this requirement, the investigator, sponsor, and FDA should carefully consider whether the clinical study protocol could be amended to include the patient population contemplated for treatment use without affecting the safety of the subjects or the integrity of the study.

(Response) FDA agrees that the optimal solution would be to somehow incorporate the potential intermediate-size treatment use population in an ongoing clinical trial by modifying the inclusion/exclusion criteria while not compromising safety or study integrity, or to enroll that population in a new study. FDA expects that sponsors would have explored all reasonably possible avenues for studying the patient population before seeking an expanded access IND for treatment use in that population and that the submission would explain why those avenues were foreclosed. By requiring the sponsor to explain why the population for which an intermediate-size expanded access IND is sought is not eligible to be enrolled in a clinical trial, FDA is encouraging, at least implicitly, this thought process.

(Comment 46) One comment asked where in the electronic common technical document (eCTD) to include the submission information that is specific to intermediate-size patient population INDs.

(Response) The eCTD does not distinguish INDs of different-size patient populations. The information specific to an intermediate-size patient population IND would go in the same location as one for a treatment IND or a single patient treatment IND.

5. Safeguards for Expanded Access

Proposed § 312.305(c) explains how the responsibilities of sponsors and investigators set forth in subpart D (Responsibilities of Sponsors and Investigators) of part 312 apply to expanded access INDs. Proposed § 312.305(c)(1) states that a licensed physician under whose immediate direction an investigational drug is administered or dispensed for expanded access use is considered an investigator for purposes of part 312 and, therefore, must comply with the responsibilities for investigators set forth in subpart D to the extent they are applicable to the expanded access use. Proposed § 312.305(c)(2) states that an individual or entity that submits an expanded access IND or protocol under subpart I is considered a sponsor for purposes of part 312 and must comply with the responsibilities for sponsors set forth in subpart D to the extent they are applicable to the expanded access use. Proposed § 312.305(c)(3) states that a licensed physician under whose direction an investigational drug is administered or dispensed, and who submits an expanded access IND, is considered a sponsor-investigator and must comply with the responsibilities of sponsors and investigators in subpart D to the extent applicable to the expanded access use.

Proposed § 312.305(c)(4) provides that for all expanded access INDs, investigators are responsible for reporting adverse events to the sponsor, ensuring that the informed consent requirements in part 50 (21 CFR part 50) are met, ensuring that an IRB review of the expanded access use is obtained in a manner consistent with the requirements of part 56 (21 CFR part 56), and maintaining accurate case histories and drug disposition records and retaining records in a manner consistent with the requirements of § 312.62.

a. "Person" v. "individual or entity."

(Comment 47) One comment recommended that proposed § 312.305(c)(2) (which states that an individual or entity that submits an

expanded access IND or protocol under subpart I is considered a sponsor for purposes of part 312) use the term "person" rather than "individual or entity." The comment pointed out that "person" is defined in the act and includes "individual, partnership, corporation, and association."

(Response) The term "individual or entity" is based on, and intended to be shorthand for, language in the definition of a "sponsor" in § 312.3(b) that states that a sponsor may be an "individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization." Because the term relates to an existing definition of sponsor in the IND regulations, and because in FDA's experience that definition has been clear and effective in describing who or what may be considered a sponsor for purposes of part 312, FDA prefers to retain the language in the proposed rule.

b. Sponsor and investigator responsibilities.

Proposed § 312.305(c)(5) provides that for all expanded access INDs, sponsors are responsible for submitting IND safety reports and annual reports (when the IND or protocol continues for 1 year or longer) to FDA as required by §§ 312.32 and 312.33, ensuring that licensed physicians are qualified to administer the investigational drug for expanded access use, providing licensed physicians with the information needed to minimize the risk and maximize the potential benefits of the investigational drug (e.g., providing the investigator's brochure if there is one), maintaining an effective IND for the expanded access use, and maintaining adequate drug disposition records and retaining records in a manner consistent with the requirements of § 312.57.

Proposed § 312.310(c)(3) further provides that FDA may also require sponsors to monitor an individual patient expanded access use if the use is for an extended duration. Proposed § 312.315(d)(2) states that the sponsor is responsible for monitoring the intermediate-size population expanded access protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators. Proposed § 312.320(c) states that the sponsor is responsible for monitoring the treatment protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators.

(Comment 48) One comment stated that making physicians investigators for purposes of part 312 will be daunting and extremely time-consuming and that the typical gastroenterologist not affiliated with a large teaching or

research hospital will not be able to satisfy these requirements.

(Response) FDA disagrees. For a licensed physician providing access under an individual patient IND, the responsibilities of an investigator closely parallel those necessary for providing routine patient care. For example, the information about a patient that a physician is required to submit to obtain an IND would usually be derived from the patient history and progress notes. In most cases, the remaining IND submission requirements would be largely satisfied by obtaining a right of reference to an IND maintained by a commercial sponsor, which is usually easily obtained. Any required monitoring of the course of treatment with the investigational drug would be similar to the type of monitoring provided as part of routine patient care. The patient outcomes information required to be submitted after treatment with the investigational drug would closely parallel the content of a typical discharge summary. Therefore, FDA believes that, in most cases, the IND obligations imposed on licensed physicians by this final rule would not be significantly more burdensome than the recordkeeping and patient evaluation required in the course of routine clinical care of a patient.

c. Adverse event reporting.

(Comment 49) One comment from a pharmaceutical company asked whether licensed physicians who obtain an investigational drug for expanded access use under their own INDs are required to report adverse events to both the pharmaceutical company supplying the drug and FDA. The comment maintained that it is important for the pharmaceutical company developing the drug to be informed of any adverse events observed in expanded access use.

(Response) Because the physician IND holder is both investigator and sponsor in this scenario, the physician is not required by the IND regulations to report adverse events to the drug manufacturer who provided the drug to the physician. The regulations require only that adverse events observed by the investigator (the physician) be reported to the sponsor, who is also the physician in this scenario. The physician, in his or her capacity as a sponsor, is required to report adverse events to FDA and other investigators (not relevant for individual patient access), including reporting of serious and unexpected adverse events in an expedited manner. However, although there is no regulatory provision that would require physicians to report adverse events to the drug

manufacturer/supplier, FDA sees no obstacle to the drug manufacturer/supplier requiring, as a condition of making the drug available to the physician, that the physician agree to provide the drug manufacturer/supplier with copies of all adverse event reports provided to FDA.

In addition, in the preamble to the proposed rule (71 FR 75147 at 75153), FDA expressed a strong preference for having commercial sponsors make investigational drugs available for treatment use under amendments to their INDs rather than requiring physicians to obtain their own INDs. In that scenario, the physician is required to report adverse events to the commercial sponsor under § 312.64.

(Comment 50) One comment suggested that adverse events for individual patient INDs should be addressed in a separate section of the NDA or biologics license application (BLA) instead of being included in the integrated summary of safety. The comment stated that this approach would help alleviate manufacturers' concerns that allowing individual patient INDs (typically involving especially sick patients) would exaggerate adverse events for the broader population.

(Response) FDA does not believe it is necessary or helpful to exclude adverse events information from individual patient INDs from the integrated summary of safety (ISS) in an NDA. The ISS is intended to evaluate adverse events information from the total population exposed to a drug. The analysis takes into account the relative strength of the data and the characteristics of subjects who experienced adverse events that may bear on causality. For example, data indicating that an adverse event occurred in multiple subjects in the drug treatment arm of a controlled trial is much more reliable than adverse events information from uncontrolled, individual patient expanded access exposures in patients who are very ill. The implication that inclusion of adverse events information from individual patient expanded access exposures over-emphasizes negative safety information is unfounded and plainly inconsistent with the methodology FDA uses to analyze drug safety.

(Comment 51) Two comments stated that, for investigational new molecular entities, adverse event reporting for expanded access use should be limited to serious adverse events and deaths unless there are specific adverse events that are identified a priori because they are related to an identified safety

concern that may affect the risk-benefit assessment.

(Response) FDA strongly disagrees. FDA believes that all adverse events identified in expanded access uses should be reported to FDA in the manner described in §§ 312.32 and 312.33. FDA's primary interest is the expedited reporting of serious and unexpected events as required by § 312.32(c). Data collected on nonserious or expected events from expanded access use, in particular from exposure of an individual patient or small number of patients to a drug, is not as useful as data collected from controlled trials that may identify differences in event rates across treatment groups (e.g., control group, across different doses). Nonetheless, information from expanded access exposures on these types of adverse events can still contribute to the safety assessment of a new molecular entity (e.g., corroborate observations in other settings). In general, FDA believes it is important that a drug's safety assessment consider adverse events observed in the entire population exposed to a drug.

(Comment 52) One comment inquired about how to report adverse events for approved drugs made available under an expanded access IND.

(Response) For an approved drug made available under an expanded access IND (e.g., in a circumstance in which an approved drug is subject to a restricted distribution agreement that limits prescribing to a certain disease or condition, and a patient is seeking access to the drug for another use), adverse events must be reported to FDA under the IND in accordance with § 312.305(c)(5).

d. Obtaining Informed Consent for Expanded Access Use.

(Comment 53) Many comments from individual consumers stated that it is particularly important for patients receiving investigational drugs in expanded access programs to receive full disclosure of the risks, and to fully understand the risks, associated with the investigational therapy. Two comments were very concerned that patients receiving investigational drugs for treatment use not be misled about the likelihood that the treatment will be beneficial. One comment stated that many patients are led to believe that access to an investigational intervention is their best hope, but often it is a false hope. Another comment stated that patients with immediately life-threatening conditions are extremely vulnerable and may not fully comprehend the information they are provided about a drug by health care

practitioners. Another comment recommended that FDA provide guidance on how to obtain informed consent from patients who are candidates to receive an investigational drug for treatment use.

(Response) FDA agrees that patients who are candidates to receive investigational drugs under expanded access programs, because they have serious or immediately life-threatening diseases or conditions and have exhausted other treatment options, are a particularly vulnerable population. Therefore, they should be afforded a rigorous informed consent process that effectively communicates the risks and potential benefits of any investigational therapy to be used for treatment use in a way that does not raise false expectations about a positive outcome from treatment and makes clear what is unknown about the drug. Because of the vulnerable nature of expanded access patients, FDA encourages submission of informed consent documents intended to be used for expanded access programs to FDA for review. FDA will also consider whether guidance on how to obtain informed consent from such patients is needed.

(Comment 54) One comment stated that because expanded access does not technically involve “research” or a “clinical investigation,” the requirements and principles for obtaining the informed consent of subjects participating in clinical investigations in part 50 may not adequately address the range of issues that would arise in obtaining the informed consent of patients receiving investigational drugs under expanded access programs. The comment recommended that the expanded access regulations include requirements concerning the specific information that must be included in informed consent documents for expanded access programs.

(Response) Again, because of the vulnerable nature of the typical patient or population to receive an investigational drug under an expanded access program, FDA agrees that patients in expanded access programs should be afforded a rigorous informed consent process tailored to the unique issues that arise in the expanded access context. FDA does not believe, however, that it is necessary to add specific informed consent requirements to the expanded access regulations or to amend the informed consent regulations to incorporate specific requirements for expanded access. FDA believes that existing informed consent regulations adequately address the range of issues relevant to informed consent for

expanded access problems, in particular issues concerning informed consent in vulnerable populations (see, e.g., parts 50 and 56).

(Comment 55) One comment stated that informed consent documents must reflect that patients cannot expect to personally benefit from the drug, but that the knowledge gained from the experiment will help other patients in the future.

(Response) FDA disagrees. The comment seems to misunderstand the overarching purpose of expanded access—to make investigational drugs available for treatment purposes to patients with serious or immediately life-threatening diseases or conditions and with no other treatment options because the investigational drugs could conceivably benefit these patients—not to systematically investigate the use of the drug for the disease or condition. Treatment use under an expanded access mechanism, in contrast to evaluation of an investigational drug in a clinical trial, is not intended primarily to develop data that could be used to benefit future patients. However, as FDA made clear in response to comment 54, patients receiving investigational drugs for treatment use should be afforded a rigorous informed consent process that is careful not to overstate the expected benefits of the investigational drug and is otherwise cognizant of the inherent vulnerabilities and information needs of patients seeking access to investigational drugs for treatment use.

(Comment 56) One comment recommended that before an IRB can be allowed to review expanded access programs, FDA should require the IRB to establish special criteria to ensure that physicians have discussed all treatment options with patients as part of the informed consent process and that patients and their families fully understand the experimental and investigational nature of a drug or other therapy, the types and degrees of unknown risks, and the potential positive and negative health outcomes.

(Response) Because patients seeking access to investigational drugs for treatment use are a particularly vulnerable group and the intent is treatment of a disease or condition, as opposed to a clinical investigation of the use, FDA believes it is important for IRB review to be particularly sensitive to the unique issues raised by use of investigational drugs in expanded access programs. FDA agrees that it would be useful for an IRB that is likely to review expanded access use to be familiar with the nature of expanded access protocols, the rules and processes

related to obtaining access, and the particular concerns related to obtaining informed consent from patients receiving investigational drugs for treatment use. FDA does not believe, however, that it is necessary to require in regulation that IRBs have special processes and procedures for reviewing expanded access protocols. Existing regulations already require IRBs to consider the vulnerable nature of the population that will receive an investigational drug and to ensure that risks are minimized (which would necessarily involve some consideration of whether there are any lower-risk treatment options), and § 50.25(a)(4) requires that an informed consent disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(Comment 57) One comment stated that a patient receiving expanded access should be competent to give informed consent.

(Response) While FDA agrees that valid informed consent is a necessary prerequisite to receiving an investigational product in an expanded access setting, FDA does not agree that access to investigational drugs under expanded access programs should be limited to only those who are competent to give their own informed consent, if that is the intended implication of the comment. FDA’s regulations concerning protection of human subjects informed consent (part 50) recognize that a subject may not be competent to give informed consent and that valid informed consent may be given by the subject’s legally authorized representative. Section 50.20 defines “legally authorized representative” as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. The same definition should apply to treatment with an investigational product under an expanded access program.

(Comment 58) One comment recommended requiring that IRBs establish criteria for the length and readability of informed consent documents.

(Response) This comment is beyond the scope of this rule. The rule does not address the requirements on IRBs and the comment raises a concern broader than expanded access.

e. IRB review of expanded access use.

(Comment 59) Some comments were concerned that the requirement for IRB review was a potential obstacle to making investigational drugs available

for treatment use under expanded access INDs, particularly for individual patient INDs. One comment maintained that the IRB review process is slow, tedious, cumbersome, and requires too much documentation, and that physicians are not familiar with the IRB process. The comment suggested that some type of centralized IRB may be needed for small- to medium-sized access programs. Another comment noted that in academic research settings, there is intensive IRB approval and oversight, and recommended that FDA explore standardizing expanded access program protocols so that some of the administrative work, in particular IRB submissions, can be lessened. One comment recommended that, for individual patient expanded access INDs, FDA reduce or limit the scope of the requirement for IRB review because of the time, difficulty, and, in some cases, the expense (e.g., when a commercial IRB must be used) of obtaining IRB review. The comment recommended that FDA permit review by a subset of the full IRB or waive IRB review if a drug has completed phase 1 safety testing (see response to comment 60 for discussion of why waiver of IRB review is not a viable option).

(Response) FDA recognizes that there are circumstances in which IRB review for an expanded access use, particularly an individual patient use, may be difficult to obtain because an institution's IRB cannot or will not provide a timely review or because the hospital or other clinical setting does not have an affiliated IRB. FDA recommends that IRBs affiliated with institutions that are likely to have patients seeking access to investigational drugs for treatment use under individual patient access INDs consider establishing processes or procedures to facilitate timely IRB review of these INDs. In addition, use of centralized IRB review and other cooperative arrangements could facilitate IRB review at these institutions as well as in settings that are not affiliated with IRBs. FDA fully supports centralized IRB review under appropriate circumstances and encourages sponsors to help make this option available where possible. FDA believes these mechanisms could ease the burdens associated with obtaining IRB review of individual patient INDs and limit the need to rely on commercial INDs. Therefore, FDA is not persuaded that obtaining IRB review is an excessive burden and potential obstacle to obtaining access to investigational therapies under expanded access INDs.

FDA does not believe that current regulations provide authority for IRB review of individual patient expanded access INDs by less than the full IRB. The IRB regulations provide for expedited review—under which an IRB review may be done by only one or a small number of IRB members—of new INDs or protocols only under minimal risk situations (§ 56.110(b)). Use of an investigational drug for treatment purposes would not be considered minimal risk and, therefore, does not meet the criteria for expedited review. Revising the IRB regulations to provide for a more limited IRB review of individual patient expanded access INDs involves significant human subject protections issues that were not considered in this rulemaking and, therefore, such revision is beyond the scope of this rulemaking.

(Comment 60) One comment stated that FDA should eliminate the proposed requirements for IRB review and obtaining informed consent for individual patient treatment use INDs. The comment maintained that the use of an investigational drug for treatment use is not part of a clinical investigation and therefore beyond the intended scope of parts 56 and 50. The comment further argued that these safeguards are unnecessary for individual patient treatment use because there is an established physician-patient relationship and, therefore, individual patient treatment use is analogous to the physician-patient relationship in a typical clinical setting in which such safeguards are unnecessary.

(Response) FDA does not agree that it lacks legal authority to require IRB review and informed consent for individual patient expanded access use or any other expanded access use. Expanded access use involves administration of unapproved products that have not yet been shown to be safe and effective, and raises sufficiently similar concerns to clinical research that informed consent and IRB review are warranted. Moreover, section 561 of the act contains numerous references to “conditions determined by the Secretary” and to protocol compliance with “regulations promulgated under section 505(i)” (which include informed consent and IRB regulations), indicating that Congress intended FDA to require conditions such as informed consent and IRB review, consistent with FDA's long-standing practice regarding treatment use with investigational products. In addition, FDA strongly believes that recipients of investigational products under any type of expanded access IND should be afforded the same human subject

protections provided clinical trial participants by the IRB review process. FDA equally strongly believes that all patients considering treatment with an investigational therapy under an expanded access IND should be fully informed about the risks and potential benefits of the experimental therapy, including disclosure that safety and effectiveness have not been established, and give their informed consent prior to being treated with an investigational therapy. Patients seeking access to investigational therapies under expanded access programs often are in somewhat dire clinical circumstances and thus are a particularly vulnerable population. Therefore, such patients are, arguably, even more in need of the human subjects protections provided by IRB review and informed consent than many clinical trial participants.

(Comment 61) One comment recommended the elimination of the requirements for prior IRB review and approval in accordance with part 56 and the requirement for written informed consent in accordance with part 50 for individual patient expanded access use (but recommended the retention of these requirements for intermediate-size population and treatment INDs). The comment argued that use of an investigational drug for the emergency treatment of individual patients is not part of a clinical investigation and thus is not consistent with the scope of parts 50 and 56. The comment stated that eliminating the requirement would solve problems and avoid confusion related to differences between FDA's IRB regulations and IRB regulations applicable to Federal agencies and grantees under 45 CFR part 46 (the so-called “Common Rule”). Current FDA regulations (§§ 56.104(c) and 50.23) allow for the emergency use of an investigational drug without prospective IRB review and approval and a waiver of the requirement for prospective informed consent of the involved patient-subject, but the Common Rule specifies that all research involving human subjects must be prospectively reviewed and approved by a convened IRB committee (with the exception of certain minimal risk categories of research, which do not include expanded access use). The comment maintained that the Common Rule applies unless the requested emergency use is considered “treatment” rather than “research” and thus is not subject to prior IRB review and approval under the Common Rule. The comment maintained that prior FDA review of individual patient expanded access would suffice to ensure patient safety

and compliance with the protocol and applicable regulations.

(Response) Although FDA agrees that it is accurate to characterize the use as “expanded access” or “treatment use” rather than a “clinical investigation” of the drug, which places individual patient INDs outside the scope of the Common Rule, FDA disagrees that prior FDA review, without additional review by a qualified third party, provides adequate safeguards. The types of patients that would typically be eligible to obtain investigational drugs under expanded access programs are vulnerable and have somewhat desperate clinical circumstances and, therefore, are in particular need of the protections afforded by IRB review and the informed consent process. FDA acknowledges that in emergency situations involving individual patient access, there is not always prospective IRB review. However, FDA believes that some type of retrospective IRB review is still important in most cases, especially if treatment with the investigational drug is ongoing. FDA also believes that informed consent is an important element of any treatment use, even in emergency situations. From a medical ethics perspective, the need for informed consent increases with the seriousness of the disease or condition and the exigency of the clinical situation, so it would be all the more important in emergency situations with individual patients. The purported advantages of eliminating any prospective third-party IRB review and informed consent are not enough to offset the potential harm.

f. Investigator reporting responsibilities for individual patient INDs.

Proposed § 312.310(c)(2) states that “at the conclusion of treatment, the licensed physician or sponsor must provide a summary of the results of the expanded access use, including unexpected adverse effects.”

(Comment 62) One comment recommended that the licensed physician be required to provide a summary of “all adverse effects possibly related to the investigational drug” rather than only “unexpected adverse effects.” The comment stated that it is likely that many private practice physicians requesting expanded access for the emergency treatment of their individual patients will not be familiar with all of the current information related to the adverse event profile of the investigational drug and/or FDA’s regulatory definition of “unexpected adverse effects.” The comment added that requiring physicians to report all adverse effects possibly related to the

investigational drug would be consistent with the investigator reporting requirements in § 312.64(b).

(Response) FDA agrees that the licensed physician may be unaware of what events are expected or unexpected and, therefore, should be required to include information on all observed adverse events. Therefore, section 312.310(c)(2) has been revised to state that at the conclusion of treatment, the licensed physician or sponsor must provide FDA with a written summary of the results of the expanded access use, including adverse effects.

(Comment 63) One comment stated that adverse event reporting for expanded access use should take advantage of technological modernization in adverse event reporting, such as by using a centralized electronic database. The comment stated that such a database could provide access to basic tabulation and analysis of the voluminous serious adverse event reports that, in their present form, are virtually useless to individual site investigators and site IRBs.

(Response) FDA has no plans to implement an electronic data capture and analysis system for adverse events that is devoted exclusively to adverse events observed during expanded access use. FDA is actively involved in efforts to develop and implement electronic data systems for adverse event reporting generally, for both pre- and postmarketing adverse event reporting. FDA believes these systems will also contribute to improved data collection and analysis of adverse events information obtained from exposure to investigational drugs in expanded access programs.

g. Qualifications of licensed physicians to participate in expanded access.

Proposed § 312.305(c)(5) requires, among other things, that sponsors ensure that licensed physicians participating in expanded access programs are qualified to administer the investigational drug for the expanded access use.

(Comment 64) One comment recommended that FDA revise § 312.305(c)(5) to state: “In general any licensed physician may participate in an expanded access protocol. Additional specific qualifications may be necessary in some situations.” The comment recommended that FDA clarify its expectations about investigator qualifications for expanded access programs to reduce the burden for sponsors and facilitate broader physician participation in expanded access programs.

(Response) FDA does not believe the recommended language is necessary or desirable. Section 312.305(c)(5) requires simply that sponsors assure themselves that the licensed physicians who will be participating in an expanded access program are qualified to administer the drug for the expanded access use. FDA believes the requirement concerning the qualifications of the licensed physician-investigator is narrowly focused on the most germane issue—whether the physician is qualified to administer the drug for the expanded access use. FDA believes the language proposed in the comment minimizes the qualifications of the licensed physician to too great an extent because it eliminates even the cursory inquiry as to whether the physician is qualified to administer the drug.

h. Investigator’s brochure.

Proposed § 312.305(c)(5) also requires the sponsor to provide the licensed physician with information needed to minimize the risk and maximize the potential benefits of the investigational drug, including “providing the investigator brochure, if there is one.”

(Comment 65) One comment requested that this language be revised to state that the sponsor provide the investigator’s brochure “if required under § 312.55 (Informing investigators).”

(Response) FDA does not agree with the proposed change because it would appear to narrow the circumstances in which a sponsor would be required to provide an investigator’s brochure. It could be interpreted as requiring that a sponsor make the investigator’s brochure available only if the treatment use is the same use as is being developed (i.e., the use for which the investigator’s brochure was written). FDA believes that the investigator’s brochure would typically contain information that would be important for any proposed use of the investigational drug (e.g., information about adverse events associated with use of the drug) and, therefore, should be made available by the sponsor to licensed physicians in an expanded access program whenever an investigator’s brochure exists. To more accurately express this intent, FDA has revised the provision in the final rule to state as follows: “In all expanded access cases, sponsors are responsible for * * * providing licensed physicians with the information needed to minimize the risk and maximize the potential benefits of the investigational drug (the investigator’s brochure must be provided if one exists for the drug)

* * *

i. *Monitoring of expanded access INDs.*

The proposed rule makes the sponsor responsible for monitoring of expanded access INDs or protocols. Proposed § 312.305(c)(2) states that an individual or entity that submits an expanded access protocol or IND is a sponsor for purposes of part 312 and, therefore, must comply with the responsibilities for sponsors concerning the oversight of clinical investigations in subpart D of part 312, including monitoring of ongoing protocols (§ 312.56). Proposed § 312.310(c)(3) provides that FDA may require sponsors to monitor an individual patient expanded access use if the use is for an extended duration.

(Comment 66) One comment maintained that the requirement that sponsors monitor the conduct of individual patient expanded access protocols is impractical and burdensome and should be eliminated. Another comment objected to the requirement to monitor individual expanded access when the use is for an extended duration. The comment stated that this provision inappropriately interfered with the patient-physician relationship and implied that the individual physician may be incapable of monitoring the patient for an extended duration.

(Response) FDA does not believe the provision that gives FDA the option to require monitoring for an individual patient access protocol of extended duration is overly burdensome or impractical. The provision is intended to provide the option to monitor for relatively long-term use, such as chronic open-ended use that is likely to continue for many months. In FDA's experience, the majority of individual patient treatment uses do not go on for an extended duration, so the number of instances in which FDA is likely to require monitoring is small. Moreover, uses that go on for an extended duration are likely to have greater potential risk and, therefore, warrant higher scrutiny. Also, the monitoring need not be resource-intensive. Guidance concerning acceptable monitoring practice in the International Conference on Harmonisation guidance document entitled "E6 Good Clinical Practice: Consolidated Guideline" provides that the sponsor should determine the extent and nature of monitoring needed based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. These factors are either absent from an extended duration individual patient treatment use or favor low-intensity monitoring (e.g., $n = 1$), so minimal monitoring would likely suffice (e.g.,

may not need onsite monitoring). Therefore, it is reasonable to require monitoring for individual patient protocols of extended duration and necessary for appropriate patient protection.

(Comment 67) Two comments questioned why an industry sponsor should be required to monitor an individual patient IND when the licensed physician holds the IND.

(Response) Where the licensed physician is the IND holder for an individual patient expanded access IND, as opposed to the entity that is providing the investigational drug for the expanded access use, the entity providing the drug is not a sponsor with respect to that IND and, therefore, has no sponsor responsibilities under part 312.

Proposed § 312.315(d)(2) provides that the sponsor is responsible for monitoring the conduct of an intermediate-size patient population access protocol to ensure that licensed physicians who are providing the drug to their patients are complying with the protocol and applicable regulations.

(Comment 68) One comment requested that FDA eliminate the requirement for sponsor monitoring of intermediate-size access programs. The comment urged FDA to replace the monitoring requirement with additional information about the criteria for selection of investigators, the method for data collection by investigators, the circumstances under which a commercial IRB might be used to provide IRB oversight for investigators who practice in a setting without an IRB (and also in settings that have an IRB), and the sponsor's prospective plan for demonstrating due diligence in obtaining data from investigators.

(Response) FDA does not believe that the provisions the comment suggests adding to the intermediate-size patient population IND submission are adequate to replace real-time monitoring intended to determine whether investigators are complying with the protocol and their investigator responsibilities. FDA believes such monitoring is important to ensure appropriate use of the investigational drug and patient safety.

6. *Issues Specific to Individual Patients, Including Emergency Use*

(Comment 69) One comment recommended that FDA change the name of this expanded access category from "individual patients, including for emergency use" to "individually identified patients for treatment use, including for emergency use" to make it clear that this expanded access category

is limited to the use of an investigational drug in an established physician-patient relationship.

(Response) FDA does not believe the name of the category needs to be changed. In FDA's experience, individual patient treatment use arises in the context of an established physician-patient relationship, so FDA does not think that point needs clarification. Moreover, FDA is uncertain how the recommended name change would clarify that issue.

Proposed § 312.310(a)(1) states that a licensed physician seeking to obtain an investigational drug for treatment use for a patient must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition. FDA must also determine that the potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition (proposed § 312.305(a)(2)).

(Comment 70) Some comments were concerned that the licensed physician would typically lack sufficient information about an investigational drug to make an informed decision about the risk to the patient from the investigational drug versus the risk from the disease or condition. One comment stated that the very nature of experimental drugs limits patients' and physicians' abilities to know and fully understand the risks and benefits of a particular drug. One comment maintained that it is also unlikely there would be any published literature or other sources of information available to physicians for drugs that are early in development. To address this problem, the comment requested that FDA revise the final rule to include a requirement that FDA provide information to the medical profession and patient advocacy organizations about the availability of investigational drugs for expanded access, including a full accounting of the scientific evidence supporting expanded access uses.

(Response) The requirement that the licensed physician determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition originates in Congress's mandate in FDAMA to expand access to investigational drugs for treatment use (section 561(b)(1) of the act) and is intended to provide greater autonomy to individual patients and their physicians in decisions about expanded access use. The underlying premise of the requirement is that physicians know more about the clinical situations of

their patients than does FDA and, therefore, should have considerable input into the assessment of risks and benefits. FDA acknowledges that there is often limited information available to physicians about the risks and benefits of an investigational drug and no practical way to provide the physician the information at FDA's disposal (information is typically proprietary and generally can only be disclosed to a member of the public on consent of the commercial sponsor).

That the physician will often have limited information does not, however, make access to investigational drugs for individual patients inherently dangerous. In these situations, in addition to the licensed physician's determination, FDA must determine that the potential benefit to the patient justifies the potential risks of the treatment use and that those potential risks are not unreasonable in the context of the disease or condition to be treated. FDA has access to considerably more information about the investigational drug and can evaluate the potential benefits and risks of the therapy in light of the information provided by the physician about risks and benefits in relation to the individual patient's condition. FDA believes that its knowledge of the drug combined with the licensed physician's knowledge of the patient's clinical condition will lead to expanded access decisions for individual patients that are in the best interests of those patients.

Proposed § 312.310(a)(2) states that FDA must determine that the individual patient for whom expanded access use is sought cannot obtain the drug under another type of IND or protocol.

(Comment 71) One comment recommended that the word "type" be deleted from the language in § 312.310(a)(2) that "FDA must determine that the patient cannot obtain the drug under another type of IND or protocol."

(Response) FDA agrees that the intent of § 312.310(a) is accurately conveyed when the words "type of" are omitted and has revised the provision accordingly.

Section 312.310(c)(1) of the proposed rule states: "Treatment is generally limited to a single course of therapy for a specified duration unless FDA expressly authorizes multiple courses or chronic therapy."

(Comment 72) One comment recommended that the final rule describe submission requirements and processes to extend the treatment use in those instances where the initial authorization was for a single course of

therapy, but additional courses are warranted.

(Response) FDA does not believe it is necessary to describe in the regulations specific requirements and processes for submissions to extend an expanded access treatment for an individual patient. FDA anticipates that, in most cases, the submission would require a minimal amount of information to demonstrate that the criteria for the expanded access use continue to be met and would focus primarily on the response to treatment to date, including any adverse events.

(Comment 73) One comment stated that the proposed rule's requirement that the duration of an individual patient treatment use generally be limited to a single course of therapy unless FDA expressly authorizes multiple courses or chronic therapy usurps the physician's role, restricts access, and therefore should be eliminated.

(Response) FDA disagrees. This rule provides for treatment use of an investigational drug in a vulnerable population, often on the basis of very little information about effectiveness and safety. To fairly weigh the risks and benefits of an investigational drug for use in this setting, FDA believes there has to be a clear understanding between the treating physician and FDA about the planned course of therapy. For example, to fairly evaluate the risks, it will usually be necessary to consider the planned dose and duration of therapy in relation to what is known about the occurrence of toxicity for that dose and duration of therapy. For the same reason, it will usually be necessary to consider the extent of prior exposure and the planned duration of subsequent therapy before authorizing additional courses of an investigational drug beyond the original treatment plan. Therefore, FDA does not believe it is reasonable or wise to authorize access of unspecified duration at the discretion of the treating physician. FDA also does not believe this provision unreasonably restricts access. FDA believes that subsequent courses of therapy will routinely be permitted where appropriate.

Proposed § 312.310(c)(2) requires, among other things, that "the licensed physician or sponsor must provide a written summary of the results of the expanded access use."

(Comment 74) One comment stated that the proposed rule should make clear to whom—presumably FDA—the written summary of the results of treatment use must be submitted.

(Response) FDA agrees. The written summary should be submitted to FDA,

specifically to the IND. FDA has revised the language to clarify who should receive this summary as follows: "At the conclusion of treatment, the licensed physician or sponsor must provide FDA with a written summary of the results of the expanded access use, including adverse effects."

Proposed § 312.310(c)(4) provides that when a significant number of similar individual patient expanded access requests have been submitted, FDA may ask the sponsor to submit an IND or protocol for the use under § 312.315 or § 312.320.

(Comment 75) One comment objected to this provision because it may increase the amount of time it takes for an individual to obtain access and, because there is a higher evidentiary standard for authorizing an intermediate-size population IND than for an individual patient IND, may make a drug less accessible for treatment use.

(Response) FDA does not believe that § 312.310(c)(4) will increase the amount of time it takes for an individual patient to obtain access. The intent of this provision is to make access more efficient at the point it becomes apparent that there will be more than a few isolated requests for expanded access by individual patients. By obtaining a submission for an expanded access IND that can enroll multiple patients, FDA believes this provision will decrease the amount of time needed to get an investigational drug to any patient seeking access under the multi-patient IND because it avoids the submission and review of many individual patient INDs. In addition, even at the point FDA believes it is appropriate to request a submission of a multi-patient access IND under § 312.315 or § 312.320, FDA does not intend to delay responding to individual patient submissions that are received during the time it takes a sponsor to prepare a submission for an intermediate-size population expanded access IND.

FDA agrees that the evidentiary requirement is somewhat higher as the size of the population to be treated under the access IND increases (e.g., from individual patient to intermediate-size population IND). However, FDA does not foresee that this will be an obstacle to obtaining access. FDA will not request submission of an expanded access IND that can enroll multiple patients until there has been some volume of experience under several individual patient INDs. Therefore, at the time FDA requests submission of a multi-patient expanded access IND under § 312.315 or § 312.320, FDA will have probably already concluded that

there is enough patient experience under individual patient INDs and other evidence to justify broader exposure under an IND that can enroll multiple patients (e.g., to permit treatment of 10 patients under an intermediate-size population IND).

(Comment 76) One comment pointed out an apparent discrepancy between the codified language in § 312.310(c)(4) of the proposed rule and the preamble discussion of the section. Section 312.310(c)(4) states that “* * * FDA may ask the sponsor to submit an IND or protocol for use under § 312.315 or § 312.320.” However, the preamble states that “* * * FDA will consider whether to request that a potential sponsor submit an intermediate-size patient population IND or protocol for the expanded access use and, possibly, conduct a clinical trial of the expanded access use.” The comment stated that it appears that the preamble goes beyond the language of the regulation and asks what is meant by “conduct a clinical trial of expanded access use” in the preamble.

(Response) FDA does not believe there is an inconsistency between the two statements in the preamble and proposed § 312.310(c)(4). If FDA asks the sponsor to submit an IND or protocol for use under § 312.315 for a drug being developed, that submission would have to address why the patients to be treated under the intermediate-size expanded access IND cannot be enrolled in a clinical trial and under what circumstances the sponsor would conduct a clinical trial in these patients. Based on the information submitted, FDA must conclude that enrollment in a clinical trial is not possible before the intermediate-size population expanded access protocol can begin. However, FDA might reasonably conclude, based on that information, that a clinical trial in the intended treatment population is possible and ask the sponsor to conduct a clinical trial of the treatment use, either in lieu of, or in addition to, an intermediate-size population expanded access IND.

Proposed § 312.310(d) sets out emergency procedures for expanded access for individual patients. If there is an emergency that requires a patient to be treated before a written submission can be made, FDA may authorize the use of the drug without a written submission. The proposed rule provides that emergency use can be authorized by telephone.

(Comment 77) One comment was concerned that emergency use might be too narrowly defined and thus unnecessarily restrict access in a true emergency.

(Response) FDA's intent in articulating criteria for when it is appropriate to consider authorizing access without a written submission is intended to differentiate true emergency situations in which treatment must occur within a fairly narrow time frame from situations in which there is sufficient time to make a written submission. The emergency process is, by its exigent nature, not as deliberative and thorough a consideration of the risks and benefits of a proposed treatment use in an individual patient as is afforded by a review of a written submission. Therefore, the emergency procedures may expose patients to somewhat higher risk than a more deliberative, non-time-sensitive review and, therefore, should be used only in true emergencies. FDA is confident, however, that the rule as proposed will permit evaluation of all true emergency treatment use requests using the emergency procedures.

(Comment 78) One comment noted that the proposed regulations on emergency INDs require that licensed physicians obtaining an IND take on responsibilities more commonly associated with commercial sponsors such as monitoring, reporting adverse events, and submitting annual reports (where applicable). The comment was concerned that these responsibilities may make physicians less willing to obtain investigational drugs for their patients.

(Response) The agency recognizes that the licensed physician who must obtain his or her own IND to make a drug available for treatment use to an individual patient, whether or not in an emergency situation, is subject to regulatory obligations usually applicable to commercial sponsors and with which the physician may not be familiar. However, the agency believes that for an individual patient IND, these obligations will not be too onerous because they closely parallel the type of monitoring and documentation that are routine in a clinical practice (e.g., routine patient care, progress notes, discharge summary) and, therefore, are not a substantial added burden. FDA also believes these obligations are essential elements of human subject protection. In addition, FDA can provide assistance to licensed physicians in complying with their expanded access IND regulatory requirements (e.g., FDA's Office of Special Health Issues is a good resource for physicians concerning expanded access (see <http://www.fda.gov/oashi/home.html>)).

Proposed § 312.310(d)(2) requires, as a condition for authorizing emergency use

without a written submission, that the licensed physician or sponsor explain how the expanded access use will meet the requirements of §§ 312.305(a) and 312.310(a) and, further, that the licensed physician or sponsor make a written submission that complies with the requirements of §§ 312.205(b) and 312.310(b) within 5 working days of the onset of the use.

(Comment 79) Two comments expressed concern about the requirement to make a written submission within 5 working days in situations in which a commercial sponsor has agreed to make the drug available under its own IND (as opposed to making the licensed physician obtain an IND). These comments stated that in these situations the commercial sponsor is dependent on the licensed physician to obtain the information needed to make a written submission and, in their experience, it takes approximately 30 days to obtain all the information needed to complete the written submission from the licensed physician. They ask that FDA provide a longer time period in which to make a submission.

(Response) FDA acknowledges that in situations in which a commercial sponsor makes an investigational drug available for treatment use under its own IND, it is dependent, to a certain extent, on the patient's physician to obtain the information needed to make the submission. Therefore, FDA agrees that the time to make a written submission should be extended. FDA believes that 15 working days should be sufficient time to obtain whatever information is needed to make a written submission. FDA is concerned that providing a longer period of time, such as 30 days, may reduce compliance with the written submission requirement and may negatively impact patient safety. FDA also believes it is inefficient and potentially confusing to have different time frames for making a written submission for a commercial sponsor who must obtain information from a patient's physician to complete a submission and a licensed physician who must complete his or her own IND submission. Therefore, 15 working days will be the time for making a written submission for each of these situations. Accordingly, the § 312.310(d)(2) has been revised to provide 15 working days for making a written submission following emergency authorization to treat an individual patient with an investigational drug.

(Comment 80) One comment stated that there were a number of administrative steps FDA should take to make expanded access for individual patients easier to obtain. The comment

stated that different divisions at FDA had different requirements concerning expanded access. The comment suggested that FDA make its internal requirements for individual patient expanded access consistent among the divisions. The comment also stated that FDA should post the name and contact information of the person in each division who is responsible for helping physicians submit individual patient expanded access requests.

(Response) One of the purposes that will be served by this final rule is to improve consistency in the way expanded access INDs are handled within FDA. FDA believes that including clear criteria and submission requirements in the regulations should help improve consistency in the individual patient expanded access process. In addition, FDA intends to educate reviewers and other review division staff on these new rules. FDA also plans to assess the implementation of these rules and will determine at a later time whether additional guidance is needed.

7. Issues Specific to Intermediate-Size Patient Populations

Proposed § 312.315 provides for expanded access use for multiple patients under a single IND or protocol for patient populations smaller than those typical in treatment INDs or treatment protocols, and sets forth the criteria, submission requirements, and safeguards specific to expanded access INDs for intermediate-size patient populations. The primary purpose of the intermediate-size patient population IND or protocol is to consolidate expanded access under a single IND to promote better monitoring, oversight, and ease of administration for an expanded access use compared to multiple individual patient INDs.

a. General comments.

(Comments 81) Several comments expressed approval for the creation of the intermediate-size patient population IND to formally bridge the gap between individual patient access and large population access under treatment INDs late in development. One comment agreed that this category would promote greater efficiency by aggregating various types of individual requests. Another comment stated that creation of this category might diminish the burdens of individual physicians in complying with the expanded access submission requirements for individual patient INDs, presumably because individual physicians would not have to make submissions once the individual patient INDs have been consolidated under an intermediate-size population IND.

(Response) FDA agrees that a potential advantage is to reduce the burdens of individual physicians trying to obtain access for individual patients. Ideally, only a limited number of physicians would make submissions for individual patients before patients receiving the investigational drug for the expanded access use could be consolidated under an intermediate-size population IND. That consolidation would ease the burden considerably for subsequent physicians seeking the drug for treatment use because they would not have to make their own IND submissions.

(Comment 82) One comment recommended that this expanded access category be renamed from “Intermediate-size patient populations” to “Limited patient populations for treatment use.” The comment maintained this change would clarify that the intent of this expanded access category is to provide “compassionate” treatment use of the investigational drug and involves only a limited number of prospective patients.

(Response) FDA does not believe it is necessary to further clarify the intent of this category of expanded access or of expanded access generally. Section 312.300(a) plainly describes the intent of expanded access. It states that “[t]his subpart contains the requirements for the use of investigational new drugs when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition.” Moreover, it is apparent throughout the various requirements set forth in this subpart that the intent is treatment rather than assessment of the safety and effectiveness of an investigational drug in a controlled setting. In addition, FDA believes the term “intermediate-size population” better reflects the intent to describe an expanded access category intended to accommodate populations in between individual patients and the large populations that are typical of access to investigational drugs under treatment INDs or treatment protocols.

(Comment 83) One comment stated that the proposed rule does not address the situation in which an investigational drug being made available under a treatment IND would no longer be available under a treatment IND because of new information about the drug, but could still be made available under an intermediate-size patient population IND. The comment was concerned that, in that situation, the evidentiary threshold for expanded access would actually be lower than for the treatment IND.

(Response) FDA agrees that the proposed rule was not specifically

intended to address a situation in which an investigational drug once available under a treatment IND would no longer be available under a treatment IND, but would then become available under an intermediate-size patient population expanded access IND. FDA believes this would be an unusual circumstance, but a foreseeable one, and that the rule as proposed could accommodate that circumstance. For example, clinical trials of an investigational drug available under a treatment IND might demonstrate lack of effectiveness on a primary endpoint that is compatible with the expanded access use under the treatment IND, but also provide preliminary evidence of effectiveness on secondary endpoints or in subset analyses, and such evidence could support a different expanded access use (e.g., a more narrowly defined population within a disease or a different indication) under an intermediate-size population expanded access IND. In this circumstance, some of the patients who were receiving the drug under the treatment IND might be eligible to receive the drug under the intermediate-size population IND on the basis of lesser evidence than supported the treatment IND. However, FDA does not see why this would be a problem (e.g., expose any patient to unreasonable risk), provided the evidence is adequate to support the size population to be treated under the intermediate-size population IND.

b. Number of patients.

The preamble to the proposed rule stated that FDA anticipates that the typical intermediate-size patient population treatment use IND or protocol will provide access to between 10 and 100 patients.

(Comments 84) Some comments were concerned that FDA’s estimated range for the number of patients that could be enrolled in an intermediate-size patient population IND was too narrow. One comment stated that FDA substantially underestimated the sizes of the potential populations that would need access to an investigational drug under an intermediate-size patient population, and that the estimated range (between 10 and 100 patients) leaves a significant gap between the intermediate-size population IND and the treatment IND. The comment recommended the creation of a fourth category of expanded access IND to bridge this gap. One comment asked FDA to clarify the difference in size of population between the intermediate category and larger populations under treatment INDs or protocols because FDA did not provide any estimate of the lower end of the range for a treatment IND. Two

comments stated that, although the proposed rule contemplated that § 312.315(a)(3)(i) and (a)(3)(ii) would be for an intermediate-size population of 10 to 100 patients, the situations described in these subsections could easily involve much larger numbers of patients.

(Response) The population range (10 to 100) for the intermediate-size patient population IND identified in the preamble to the proposed rule is simply an estimate and is not intended to exclude the possibility that more (or fewer) patients could be treated under an intermediate-size patient population IND. For a drug being developed, it is possible that more than 100 patients could be treated under an intermediate-size population IND. However, our experience suggests that programs substantially larger than this are best administered under a treatment IND. FDA expects that there would ordinarily be a seamless transition from intermediate-size population IND to treatment IND at the point when there was adequate evidence to support the treatment IND, adequate progress with drug development, a sponsor willing to make the drug available to a larger population under a treatment IND, and sufficient numbers of patients who need the drug to justify a treatment IND.

For a drug not being developed, there is also the possibility that greater than 100 patients will need access to an investigational drug under an intermediate-size patient population IND. Although FDA anticipates that a relatively small number of patients would be receiving access at any given point in time under such an IND, it is foreseeable that, for some drugs in this category, conditions will never be right for development, and over a period of years the IND will provide access to more than 100 patients. However, if substantially more than 100 patients seek or continue to need access under this category within a fairly narrow time frame, FDA believes there would likely be an adequate number of potential subjects to initiate a clinical trial and formal development of the drug.

When a drug has been withdrawn for safety reasons or in a drug shortage situation, it is also foreseeable that there will be greater than 100 patients who may need access to the drug—for patients in whom the benefits of the withdrawn drug continue to exceed the risks associated with the drug or patients who need to rely on a drug not approved for marketing in the United States to substitute for an approved drug in short supply. In those cases, the intermediate-size population IND could

be used to provide access to greater than 100 patients.

Because there is a need for flexibility to provide access to greater than 100 patients under an intermediate-size population IND in some circumstances, FDA has elected not to provide a specific estimate of the population range for this category in this final rule. FDA continues to believe that the population range identified in the proposed rule—10 to 100 patients—would accommodate most intermediate-size population INDs. However, FDA believes foremost that the size population that can be treated under an intermediate-size population IND should be dictated by the available evidence—the amount of exposure that the evidence will support—and the circumstances of a given case, rather than by a somewhat arbitrary estimate of the size of the upper bound of the population.

c. Sub-categories of intermediate-size patient population expanded access.

Proposed § 312.315 provides for access to an intermediate-size population in four situations:

- To provide a drug that is not being developed to patients who may benefit from the drug (typically patients with a rare disease or condition) (§ 312.315(a)(1))
- To make a drug that is being developed available to patients who cannot participate in clinical trials of the drug (§ 312.315(a)(2))
- To provide an approved drug that has been withdrawn for safety reasons, or cannot be marketed due to failure to meet the conditions of the approved application (usually a manufacturing problem) to a limited number of patients who are dependent on the drug (§ 312.315(a)(3)(i))
- To provide a drug that is related to an approved drug, but is not approved for marketing in the United States, in situations where there is a shortage of the approved drug or the approved drug is unavailable due to failure to meet the conditions of the approved application (§ 312.315(a)(3)(ii))

(Comment 85) One comment objected to the range of situations in this category, stating that the situations are too diverse to be accommodated in a single expanded access category.

(Response) FDA disagrees. Because the amount of evidence needed to make an investigational drug available under an intermediate-size population IND is based on the size of population anticipated to be treated under the IND, the category can accommodate situations with significant variations in the size of the treatment population (see also preceding comment response). FDA

believes, therefore, that the criteria set forth in § 312.315 are adequate to ensure that the risks associated with use of drugs made available in each of these four situations are minimized and the potential benefits maximized across a variety of different treatment use situations and size populations.

(Comment 86) One comment recommended deleting the option to make an investigational drug available under an intermediate-size population IND when the drug is not being developed. The comment argued that because the disease is so rare that it is not possible to recruit patients for a clinical trial, the sponsor would not ordinarily maintain an active IND, nor would the sponsor be manufacturing investigational drug supplies (so, presumably, there is no reason for the category). The comment stated that the proposed rule also implies that this situation may be an open-ended commitment to expanded access, which is likely to further deter commercial sponsors. One comment asked how FDA would determine that the drug is the only promising therapy for the people with a rare condition without clinical data to support the use. The comment stated that this provision of the proposed rule would further erode the possibility of conducting a controlled clinical trial in this situation.

(Response) This category of expanded access use is based on FDA's experience with situations in which there has been no alternative but to make a drug not being developed available under an IND to a small number of patients who could benefit from it. In FDA's experience, it has not been difficult to determine that a drug is the treatment of choice for a discrete group of patients with a particular rare disease or condition. For example, some antivenoms and drugs for tropical diseases are not commercially marketed in the United States because there is simply not a large enough market to develop the product for marketing, but these products are nonetheless needed on occasion by readily identifiable patients. FDA has made other products available to treat obscure conditions when the population is seemingly too small for even orphan drug development. For example, thalidomide was made available for a variety of conditions under several of these types of INDs before there was sufficient data to approve it. Currently, there are INDs for products not being actively developed that are ongoing, and FDA anticipates that it will encounter situations in the future in which this type of IND is needed. Because these types of INDs exist, and because one of FDA's goals with this rulemaking to

make the agency's various mechanisms for expanded access transparent and thereby make investigational drugs more widely available to those who might benefit, the agency believes it is important to describe this type of expanded access in the regulations.

FDA recognizes that a commercial sponsor might not be inclined to be a sponsor for this type of IND or to make a potentially open-ended commitment to manufacture products to provide to another sponsor under this type of IND. In FDA's experience, these types of INDs are not usually held by commercial sponsors. They are more commonly held by government agencies and academic institutions. So the fact that this type of IND is of little interest to a commercial sponsor is no reason to remove it from the expanded access regulations, particularly when it meets a demonstrated public health need.

FDA also recognizes that this type of access could potentially usurp the entire population that could possibly be enrolled in a clinical trial of a drug. However, FDA thinks this situation is not very likely because drugs are rarely developed (at least not in the United States) for the types of indications for which drugs are made available under this category. Nonetheless, where appropriate, FDA intends to make every effort to encourage potential sponsors to study such a drug in a clinical trial rather than provide it under an expanded access IND.

(Comment 87) One comment stated that there was no reason to have an intermediate-size population expanded access IND for a drug being developed. The comment stated that there is no justification for allowing access under such an IND for a disease different from the one being studied in the clinical trials. For the other situations in which a patient is unable to participate in the clinical trial (different disease stage, patient otherwise fails to meet enrollment criteria, enrollment is closed, or the trial site is not geographically accessible), the comment stated that the treatment IND would be the appropriate vehicle for expanded access.

(Response) FDA believes there is adequate justification for allowing expanded access under an intermediate-size patient population IND for a disease different from the one being studied in the clinical development program. For an oncology drug, for example, the characteristic of a cancer that is the target of a given chemotherapeutic agent (e.g., specific receptor or enzyme) may be present in other types of cancers. In that situation, it may be appropriate to make an investigational drug being

studied for one cancer available to treat patients with another type of cancer before there is definitive evidence of effectiveness in the other type of cancer. As discussed above, FDA also believes it is important to be able to provide access to multiple patients in a controlled manner under an intermediate-size patient population IND at a point in time in which the use for which the drug is being made available would not yet meet the criteria for a treatment IND. In FDA's experience, it has been helpful from an administrative, clinical safety, and monitoring perspective to provide for a multi-patient expanded access IND to bridge the gap between individual patient INDs and treatment INDs.

(Comment 88) One comment stated that it is not clear why patients should receive expanded access to a drug that is no longer marketed for safety reasons. The comment stated that a clinical trial is the appropriate setting to identify patients for whom the potential benefits of a drug outweigh the risks. One comment agreed that, when a drug is withdrawn from marketing because of safety reasons, there may be a subset of patients for whom the benefits of treatment would outweigh the risks. The comment also pointed out that by stating in the preamble to the proposed rule that those patients for whom the benefits of treatment are believed to outweigh the risks "could continue to receive the drug under an intermediate-size patient population IND," FDA implied that only patients who were already receiving the drug when marketing ceased could obtain the drug under such an IND. The comment asked FDA to clarify whether this provision is intended to make a drug available only to patients who were receiving the drug when it was withdrawn for safety reasons or if it would also be possible to provide the drug to patients who had not yet received it.

(Response) In FDA's experience, there are multiple examples of situations in which a drug has been withdrawn from the market for safety reasons and there has been a need to make the drug available to a subset of patients in whom the benefits of treatment outweigh the risks. Although those who receive the drug will ordinarily be those who were already receiving the drug at the time of withdrawal and appear to have benefited, it was not FDA's intent to absolutely foreclose the possibility that new patients could receive a drug that had been withdrawn from marketing for safety reasons. It is possible that a population in whom benefits continue to outweigh risks could be characterized in a way that

would permit access to patients who have not previously been treated with the drug, even though the drug is unsafe for marketing. However, a manufacturer may be reluctant to make an open-ended commitment to provide a drug that has been withdrawn for safety reasons to a subset of patients when there is no commercial benefit to the manufacturer. This reluctance could also affect whether new patients would be able to obtain the drug.

(Comment 89) One comment recommended that the final rule clarify that some situations in which a marketed drug is found to benefit only a subset of the population for which it was approved can be addressed through a restricted distribution program of the FDA-approved product in accordance with subpart H of part 314, rather than through withdrawal of the drug for safety reasons and use of an intermediate-size patient population IND to make the drug available to the subset population.

(Response) FDA agrees that, in situations in which a drug is found to be beneficial in only a subset of the population in which it was originally approved, it may be possible to allow continued marketing of the drug under a restricted distribution program (Lotronex was originally marketed without restrictions and is now marketed under a restricted distribution program). In these situations, there would usually be more compelling data to support the use in the subset population than would be needed for an expanded access IND (i.e., a more rigorously defined subset population). The appropriate mechanism for making a drug available to the subset of patients in whom the benefits continue to outweigh the risks would depend on the circumstances of the particular case. FDA is always willing to explore the full range of options with the manufacturer of such a drug.

d. Drug shortage.

(Comment 90) One comment stated that it is not clear that the expanded access rule would be the right mechanism for access in a drug shortage situation because the numbers of patients needing access could be well in excess of the 100 patients that the preamble suggests are the upper bound of the intermediate-size population IND category.

(Response) FDA is retracting a statement in the preamble to the proposed rule suggesting that there is a 100-patient upper bound on the population for an intermediate-size expanded access IND. FDA agrees that a drug shortage situation could result in a need for access in more than 100

patients and more patients than could reasonably be accommodated by an intermediate-size expanded access IND. In such situations, FDA would be more likely to exercise its enforcement discretion, the effect of which would be to permit marketing of a related product that did not meet the FDA approval requirements to substitute for the drug in short supply until supply issues for the FDA-approved product were resolved. FDA included the drug shortage provision in the expanded access regulations to address a situation in which there is a relatively small, discrete population affected by a drug shortage. Which mechanism would be appropriate to make a related drug available in a drug shortage situation—an intermediate-size population IND or enforcement discretion—would depend on the circumstances of that situation.

e. Good manufacturing practices (GMP) issues.

(Comment 91) One comment suggested that expanded access was not the appropriate vehicle for providing access to a drug that is approved but is not being manufactured in a manner consistent with the approval. The comment stated that because the drug is not investigational, access should be handled under a different mechanism. The comment added that there should be assurance of close oversight of the manufacturer to minimize harm to patients. Another comment asked how it would be determined that the risk due to manufacturing problems is acceptable. The comment pointed out that the IND would have to cross-reference the NDA for CMC information and also describe the good manufacturing practices (GMP) issues.

(Response) As in the case of a drug shortage, GMP issues for a product could create a need for access in a population too large to be accommodated under an intermediate-size expanded access IND. As with a drug shortage, in these situations FDA would be more likely to use enforcement discretion to make the drug available to a very large number of patients. FDA agrees that, whether enforcement discretion or an expanded access IND is used, there must be careful consideration of the safety implications of the manufacturing concerns, including possible monitoring mechanisms to ensure that patients are not being harmed by a product that has GMP concerns but is nonetheless being made available to patients.

8. Issues Specific to Treatment IND and Treatment Protocol

The proposed rule specifically solicited comment on FDA's decision to

continue to describe the type of expanded access for treatment use that makes investigational drugs available to large populations as the "treatment IND" or "treatment protocol."

(Comment 92) One comment expressed the view that, despite 20 years of use, these terms are confusing. The comment recommended that the terminology be changed to "large-size patient populations" to be consistent with the names of the other two categories of expanded access.

(Response) FDA continues to believe that it would be preferable to retain the terms "treatment IND" and "treatment protocol." Because these terms have been in use for more than 20 years, FDA believes they have become so strongly associated with making investigational drugs available to large populations that to replace the terms would generate needless confusion. FDA recognizes that the term "treatment use" is now widely used to refer generically to use of an investigational drug for treatment purposes outside of a clinical trial, and not just to use under a treatment IND or protocol. However, FDA believes the confusion that would result from changing the name of the treatment IND outweighs any potential confusion resulting from use of the word "treatment" in the title of the large population expanded access IND but not in the other expanded access categories.

(Comment 93) One comment noted that FDA's current regulation concerning the submission requirements for a treatment protocol (§ 312.35(a)(ii)) provides that a submission for a treatment protocol must explain why the use of the investigational drug is preferable to the use of available marketed treatments. The comment pointed out that § 312.305(b)(2)(ii) of the proposed rule provides that submissions for all expanded access uses must explain why the use of the investigational drug is preferable to the use of available therapeutic options. The comment interpreted this provision of the proposed rule as permitting expanded access for a treatment protocol only when the treatment protocol explains why the use of the investigational drug is preferable to any approved or unapproved therapies, not just preferable to any available marketed treatment. The comment contended that this provision could be interpreted to require companies to show that the product to be used for treatment use is better than both approved and unapproved therapies because the preamble states that "available therapy" includes not just FDA-approved products for that indication, but also includes (1) treatments not FDA-

regulated (e.g., surgery) and (2) off-label use (i.e., not labeled for use for the relevant condition or disease, but supported by compelling literature reference) (71 FR 75147 at 75151). To avoid this perceived problem, the comment suggested that FDA take one of three steps: (1) Put the definition of "available therapy" stated in FDA's guidance for industry entitled "Available Therapy" in a formally issued rule, (2) revert back to the requirement that the investigational new drug must only be measured against other FDA-approved marketed products, or (3) approve the unapproved therapy for the new indication so that its use becomes "on-label."

(Response) The Available Therapy guidance (p. 4) states that "available therapy (and the terms existing treatments and existing therapy) should be interpreted as therapy that is specified in the approved labeling of regulated products, with only rare exceptions." This guidance was intended to apply to the use of the term in § 312.34(b)(1)(ii) of FDA's current regulations concerning treatment INDs and treatment protocols. That regulation includes the criterion that "[t]here is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population." Section 312.34(b)(1)(ii) is intended to apply equally to the use of the term in new subpart I. FDA believes this guidance has effectively addressed confusion associated with use of the term "available therapy" in the varied contexts in which it is used in FDA's regulations. Therefore, FDA does not believe it is necessary at this time to promulgate a regulation defining the term or revise the guidance so that only approved therapies could be considered available therapy. Nor would it be appropriate to simply approve the unapproved therapy for the new indication for use, apparently without regard to the evidence supporting the use, so that its use becomes "on-label."

9. Clinical Holds of Expanded Access INDs

Proposed § 312.42(b)(3) specifies the conditions under which FDA may place an expanded access IND or protocol on clinical hold. Proposed § 312.42(b)(3)(i) allows FDA to place a proposed expanded access use on clinical hold if the pertinent criteria in subpart I for authorizing the use are not met (e.g., non-serious disease or condition, satisfactory or comparable therapies are available, insufficient evidence to support the use) or the IND does not comply with the pertinent submission

requirements in subpart I. Proposed § 312.42(b)(3)(ii) allows FDA to place an ongoing expanded access IND on clinical hold if the agency determines that the pertinent criteria in subpart I are no longer satisfied.

(Comment 94) One comment emphasized the importance of providing a high degree of clarity about the reasons for imposing a clinical hold on an access program to assure that other studies of the investigational drug are not unintentionally affected. The comment stated that lack of clarity could shut down an entire development program and suggested that in the final rule, FDA cite specific reasons for imposing a clinical hold on an access program. The comment asserted that FDA should apply the same level of rigor for imposing holds on access programs as is applied to clinical holds of clinical trials. Another comment suggested that FDA propose an approach for supplying drugs to patients who are clearly benefiting from treatment and are participating in an expanded access program that is put on clinical hold.

(Response) FDA does not believe it is necessary or desirable to cite in the regulations specific potential reasons for a clinical hold of an expanded access IND. Section 312.42(b)(3) makes clear that failure to meet any of the criteria or submission requirements pertinent to authorizing any of the expanded access IND categories may be a basis for a clinical hold. It also makes clear that if any of the criteria that were the basis for authorizing an expanded access IND are no longer satisfied, FDA may place an ongoing expanded access IND on clinical hold. If FDA were to cite specific potential reasons for a hold, it could give the misimpression that failure to meet criteria or submission requirements not expressly mentioned would not be a basis for a hold.

FDA anticipates that clinical holds for expanded access INDs will be handled in the same manner as for INDs for clinical trials. That is, the clinical hold letter will cite the relevant regulation and explain in detail how the criteria that are the basis for the hold are not met. FDA further anticipates that, in the event that the basis for a clinical hold is relevant only to an expanded access IND and not to the clinical development program, the relevant clinical hold documentation will make this abundantly clear.

In addition, in situations in which an ongoing expanded access IND is placed on hold, FDA will carefully consider the needs of patients already receiving the drug. FDA will not hesitate to use a partial clinical hold (which permits

patients already being treated with a drug to continue treatment) where appropriate.

10. Comments on Analysis of Impacts

(Comment 95) Three comments from pharmaceutical companies and a trade association stated that the rule would likely increase sponsors' administrative, medical, and regulatory burdens associated with expanded access. The comments specifically mentioned the costs of providing the investigational drug, conducting clinical laboratory tests, and monitoring, collecting, processing, analyzing, and summarizing data.

(Response) Based on our analysis, we conclude that the final rule will not have a substantial economic impact. The final rule clarifies and expands on regulations in place since 1986 but does not substantially change those regulations; therefore, the overall economic impact should be small. Treatment use of investigational drugs is relatively uncommon and a particular sponsor would be expected to submit a treatment use request only infrequently. Therefore any additional regulatory burden is expected to be small and widely dispersed among affected entities. Most treatment use requests are for individuals or single patients for which the drug, clinical laboratory testing, monitoring, data processing, and reporting costs are expected to be small. The proposed rule does not require sponsors to make investigational drugs available for treatment use. Such a decision is the sponsor's alone and will presumably be based on a number of factors, including cost. If the sponsor can demonstrate that the clinical trial could not be conducted unless the sponsor is able to charge for the investigational drug, the sponsor may request permission to charge patients and recover the direct costs associated with the treatment use.

(Comment 96) A comment from an insurance company provided an estimate of the costs to enrollees in commercial private health plans associated with the expanded access rule that indicates the costs to be much larger than those stated in the proposed rule. The comment assumed that physicians would request access to investigational drugs only when available therapies have failed or when conventional therapies do not exist. Additional information related to the comment and submitted to the docket at FDA's request indicated that " * * * the grand total number of patients projected to utilize INDs under these proposals each year is approximately 67,500." The comment also stated its belief that

investigational drugs will be used as first-line therapy, second-line therapy, monotherapy, and combined therapy with FDA-approved medications. The comment stated that the aggregate additive cost per year to all U.S. private-sector payers would be \$273,600,000. The comment maintained that these estimates actually understate the burden to private-sector payers because they exclude potential annual costs to Medicare Advantage plans.

(Response) Based on our analysis, we concluded that the costs of this final rule should be small. The cost estimate provided in the comment appears to include costs for investigational drugs under provisions of the charging final rule published elsewhere in this issue of the **Federal Register**. In response to the comment, we have included estimates of the number of individual patients with access to investigational drugs under current rules and the number of additional patients we expect to gain expanded access to investigational drugs under this final rule. FDA's estimates indicate that, on average, as many as 53,159 patients per year have access to investigational drugs under current rules. In addition, we estimate that as many as 3,095 additional patients will gain expanded access to investigational drugs under this final rule. These estimates are based on assumptions used in our Analysis of Impacts for the proposed rule that were not substantively challenged in any comments received. It appears that the estimate of 67,500 patients per year in the comment draws no distinction between patients receiving investigational drugs under current rules and the additional patients who will have expanded access under this final rule. In assessing the impact of the final rule, it is the incremental effect, or additional patients that will gain expanded access, that must be considered. Patients with access to investigational drugs under current rules are not relevant to an analysis of impacts for this final rule. The only direct costs that are relevant to this final rule are the costs to drug sponsors to prepare and submit expanded access requests. The comment did not provide an estimate of these costs.

(Comment 97) A comment from a capital fund disagreed with the proposed rule's assertion that the rule would not have a significant economic impact on a substantial number of small entities. The comment stated that FDA had overlooked the extensive role of small biotech companies in developing novel kinds of investigational drugs that are often the most sought-after therapies for expanded access. The comment also

stated that small biotech companies severely lack funding and also face special difficulties in getting their therapies to the stage where they are able to obtain significant partnering arrangements. The comment stated that such companies could be substantially helped by expanded access programs by permitting them to reach larger numbers of patients sooner and to generate larger amounts of supporting data sooner. The comment stated that the most powerful boost for small biotech companies and the patients seeking their new therapies would come from combining expanded access programs with policies allowing cost recovery and reimbursement (the subject of the charging proposed rule). The comment also advocated minimal efficacy requirements for expanded access and stated that such a policy would not impose substantial costs on society or the healthcare system because sponsors would be paying for the costs of producing and supplying the therapy in most expanded access programs. The comment added that if such programs enable a product to reach marketing approval sooner than otherwise, that would greatly reduce the costs that sponsors must recoup in pricing products for commercial sale.

(Response) The comment suggests that investigational drugs produced by small biotech companies are often the most sought-after therapies for expanded access, but provides no examples. While small biotech companies may face a number of difficulties—including a lack of funding and partnering opportunities—such obstacles are neither the subject of this final rule nor the responsibility of FDA. The purpose of the proposed expanded access rule is not to help sponsors reach larger numbers of patients and generate larger amounts of supporting data sooner. The agency believes that these goals are best pursued through the normal drug development process. FDA believes that cost recovery for expanded access—the subject of the charging proposed rule—is appropriate only in limited circumstances. Further, the agency has determined that the amount to be charged should be limited to the direct costs of providing the investigational drug for the treatment use. Cost recovery through charging is not intended as a mechanism through which sponsors may generate funds to support drug development generally. The agency agrees with the comment that the proposed rule would not impose substantial costs on society or the healthcare system.

(Comment 98) One comment stated that the estimates of increased expanded use in the Analysis of Impacts appeared

overly optimistic because **Federal Register** notices are not the best way of disseminating information to the lay public or their physicians and the proposed rule did not mention any additional efforts to disseminate information about expanded access.

(Response) Issuance of the final rule is not the only way FDA plans to disseminate information on expanded access programs to the lay public and physicians. FDA intends to develop and engage in a broad range of publicity and educational efforts in a variety of forums and media to increase awareness of the mechanisms for obtaining investigational drugs for treatment use.

IV. Legal Authority

The agency believes it has the authority to impose requirements regarding expanded access to investigational drugs under various sections of the act, including sections 505(i), 561, 701(a) (21 U.S.C. 371(a)), and 505–1(f)(6).

Section 505(i) of the act directs the agency¹ to issue regulations exempting from the operation of the new drug approval requirements drugs intended solely for investigational use by experts qualified by scientific training and expertise to investigate the safety and effectiveness of drugs. The final rule explains procedures for obtaining FDA authorization for expanded access uses of investigational drugs and factors relevant to making necessary determinations.

Section 561 of the act, added by FDAMA, provides significant additional authority for this final rule. Section 561(a) of the act states that FDA may, under appropriate conditions determined by the agency, authorize the shipment of investigational drugs for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations. This final rule sets forth factors that the agency will consider in determining whether to authorize shipment of investigational drugs in emergency situations.

Section 561(b) of the act allows any person, acting through a physician licensed in accordance with State law, to request from a manufacturer or distributor an investigational drug for the diagnosis, monitoring, or treatment of a serious disease or condition if four conditions are met: (1) The physician must determine that the person has no comparable or satisfactory alternative

therapy available and the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition; (2) FDA must determine that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug in the particular case; (3) FDA must determine that provision of the investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and (4) the sponsor or clinical investigator of the investigational drug must submit a clinical protocol consistent with the provisions of section 505 of the act (21 U.S.C. 355) describing the use of the investigational drug in a single patient or a small group of patients. The final rule sets forth factors that FDA will consider in making the necessary determinations and explains the procedures and criteria for physicians, sponsors, and/or investigators to make the necessary representations and submissions to FDA.

Section 561(c) of the act specifically authorizes expanded access under a treatment IND if FDA makes the following determinations: (1) Under the treatment IND, the investigational drug is intended for use in diagnosing, monitoring, or treating a serious or immediately life-threatening disease or condition; (2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of the disease or condition in the population of patients to which the investigational drug is intended to be administered; (3) the investigational drug is already under investigation in a controlled clinical trial for the same use under an IND under section 505(i) of the act, or all clinical trials necessary for approval of that use of the investigational drug have been completed; (4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug, with due diligence, for the same intended use; (5) provision of the investigational drug will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) of the act; (6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the intended use; and (7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug may be effective for its intended use and will not expose patients to an unreasonable and significant risk of illness and injury. The

¹ In light of section 903(d) of the act (21 U.S.C. 393(d)) and the Secretary's delegations to the Commissioner of Food and Drugs, statutory references to "the Secretary" in the discussion of legal authority have been changed to "FDA" or "the agency."

final rule sets forth factors that FDA will consider in making the necessary determinations.

Section 561 of the act further requires that protocols submitted under section 561 be subject to section 505(i) of the act including regulations issued under section 505(i). Section 561(d) of the act permits the agency to terminate expanded access for failure to comply with the requirements of section 561 of the act. The final rule sets forth the conditions under which FDA will place an expanded access use on clinical hold.

This final rule establishes three categories of expanded access. While authority for individual patient access is based on section 561(b) of the act, and authority for treatment INDs and treatment protocols is based on section 561(c) of the act, there is also authority in the statute for FDA to issue regulations for intermediate-size patient populations. Section 561(b)(4) of the act requires submission of a protocol for the expanded access use that is consistent with the requirements of the IND regulations describing the use of the investigational drug in a single patient or a small group of patients. The provisions of the final rule concerning expanded access for intermediate-size patient populations address the use of the investigational drug in the small groups of patients mentioned in the statute.

Section 701(a) of the act provides general authority to issue regulations for the efficient enforcement of the act. By clarifying the criteria and procedures relating to expanded access to investigational products, this final rule is expected to aid in the efficient enforcement of the act.

Finally, section 505–1(f)(6) of the act, added by FDAAA, states that “[t]he mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this subsection.” FDA “shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.” Because the expanded access mechanisms in this final rule may be used by patients seeking access to a drug that is subject to elements to assure safe use, this rule fulfills the FDAAA requirement.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VI. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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). The agency believes that this final rule is not an economically significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Our economic analysis for the proposed rule did not indicate any significant new regulatory burden, and we did not receive any comments that would cause us to reconsider this determination. Therefore, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

The agency estimates that the total costs to drug sponsors and physicians to submit the additional expanded access submissions expected under this final rule will be between \$1.5 million and \$3.0 million per year. Because a typical sponsor will submit an expanded access use request only infrequently, these costs are expected to be widely dispersed among affected entities. The benefits of the final rule are expected to

result from increased patient access to investigational drugs generally and from expanded access being made available for a broader variety of disease conditions and treatment settings. Private benefits will accrue to individual patients receiving drugs for expanded access use, whereas social benefits will accrue if information obtained contributes to the development of new therapies generally. Due to uncertainty with respect to the potential magnitude of such benefits, and a lack of necessary data, FDA did not generate quantitative estimates of expected benefits.

A. Objectives of the Final Action

FDA is proposing this action to describe in greater detail all of the ways patients may obtain expanded access to investigational drugs for treatment use. Specifically, the final rule establishes eligibility criteria, submission requirements, and safeguards for the expanded access use of investigational drugs by individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment IND. The proposal is also intended to increase public knowledge and awareness of expanded access and, thus, to make investigational drugs more widely available. In addition, by establishing clear eligibility criteria and submission requirements, the final rule will ease administrative burdens on physicians seeking investigational drugs for their patients and on sponsors who are willing to make promising unapproved therapies available for treatment use.

B. Nature of the Problem Being Addressed

The fundamental problem addressed by the final rule is one of incomplete information. In some circumstances, a lack of clearly defined eligibility criteria and submission requirements has created inefficiencies that limit patient access to potentially beneficial investigational drugs. The final rule is also intended to address concerns that, historically, cancer and Acquired Immunodeficiency Syndrome (AIDS) patients have had better access to investigational drugs than patients with other serious diseases or conditions, and that patients under the care of physicians based in academic medical centers are more likely to obtain such access than patients whose physicians practice outside such centers. In addition, the lack of clearly defined eligibility criteria and submission requirements has led some physicians and drug sponsors to devote more

resources than necessary to the preparation of expanded access submissions. Through this final rule, the agency seeks to correct these shortcomings.

The final rule establishes general eligibility criteria, submission requirements, and safeguards for the expanded access use of investigational drugs. The requirements that apply to all types of expanded access use are discussed in section III.C.3 of this document. The final rule also describes more specific eligibility criteria, submission requirements, and safeguards for three specific categories of expanded access: (1) Expanded access for individual patients, (2) expanded access for intermediate-size patient populations, and (3) expanded access

under a treatment protocol or treatment IND.

C. Baseline for the Analysis

During the period 1997 through 2005, FDA received an average of 2,046.6 INDs per year. Of this number, on average, approximately 659, or 32.2 percent ($0.322 = 659 / 2,046.6$) were individual patient or emergency INDs. In addition, FDA received approximately 4.6 treatment IND or treatment protocol submissions per year during this time period. Thus, treatment IND or treatment protocol submissions represent about 0.2 percent ($0.0022 = 4.6 / 2,046.6$) of all INDs received by the agency each year. Because expanded access for intermediate-size patient populations is not currently established in the regulations, FDA does not have a

record of the number of submissions in this category. However, based on an internal survey of drug review divisions, FDA estimates that approximately 55 other expanded access submissions were received each year between 2000 and 2002. While it is not possible to determine the precise number that will be considered intermediate-size patient population expanded access submissions, FDA experts believe that most of the 55 other submissions each year will fall under this category.

Thus, approximately 2.7 percent ($0.0269 = 55 / 2,046.6$) of all INDs received by FDA each year may be associated with intermediate-size patient population expanded access requests. The information presented previously is summarized in table 1 of this document.

TABLE 1.—BASELINE DATA FOR THE NO. OF INDs AND EXPANDED ACCESS REQUESTS BY CATEGORY

Category	Total INDs	Individual Patient or Emergency IND	Treatment IND or Protocol	Other
Number	2046.6	659	4.6	55
Percent of all INDs	100	32.2	0.2	2.7

One comment submitted in response to the proposed rule provided an estimate of the number of patients that might be affected by this rule. As part of our response, we have generated estimates of the number receiving investigational drugs under current expanded access programs, in place since 1986.

Based on the information presented previously, FDA currently receives an average of 659 individual patient or emergency INDs per year. Thus, approximately 659 individuals per year currently receive investigational drugs

under single patient or emergency INDs. FDA believes that it is reasonable to assume that a typical expanded access submission for an intermediate-size patient population will affect between 10 and 100 individuals. Given that FDA currently receives an average of 55 such submissions per year, we estimate that between 550 and 5,500 individuals currently receive investigational drugs under intermediate-size patient population or other expanded access programs. A treatment IND or protocol can vary significantly in size and may include between 100 and 10,000

patients. Thus, an average of 4.6 treatment IND or protocol submissions could affect between 460 and 46,000 individuals. Based on this information, FDA estimates that between 1,669 and 52,159 individuals currently receive investigational drugs through expanded access programs. The wide range of these estimates reflects significant variation in the number of patients in intermediate-size patient populations, and treatment INDs or protocols. These estimates are summarized in table 2 of this document.

TABLE 2.—APPROXIMATE NO. OF INDIVIDUALS AFFECTED BY EXPANDED ACCESS PROGRAMS IN PLACE SINCE 1986

Category	Average No. of Submissions	No. of Patients	Minimum No. of Individuals	Maximum No. of Individuals
Individual Patient or Emergency IND	659	1	659	659
Small Patient Population/Other	55	10 to 100	550	5,500
Treatment IND or Protocol	4.6	100 to 10,000	460	46,000
Total			1,669	52,159

D. Nature of the Impact

The final rule will affect patients who lack effective therapeutic alternatives and may benefit from access to investigational drugs, physicians attempting to obtain investigational drugs for their patients, drug sponsors who make investigational drugs

available to patients, and FDA in its oversight role in the process for making investigational drugs available for expanded access use. As discussed in the preamble of the proposed rule (71 FR 75147 at 75149 to 75150), a major purpose of this rule is to expand access to investigational drugs for patients with

serious and immediately life-threatening conditions who lack satisfactory therapeutic alternatives. Therefore, FDA anticipates that the final rule will increase the number of patients who obtain access to investigational drugs for treatment use. This increase in volume will lead to more expanded access

submissions from sponsors and physicians seeking investigational drugs for their patients and, as a consequence, will require FDA to review more submissions. Given the relatively small burden associated with expanded access use submissions under the previous regulations (although such submissions are approximately one-third of all IND submissions, the vast majority of those are for individual patients and do not typically require substantial agency resources to review), and the small additional burden associated with the expanded access provisions in this final rule, FDA expects that the economic impact of the final rule will be small.

The final rule also attempts to minimize the potential administrative burdens for physicians, sponsors, and FDA that will result from an increased volume of patients obtaining investigational drugs for expanded access use. The final rule encourages the consolidation of multiple individual patient INDs or protocols for a given use under an intermediate-size patient population IND or protocol. By reducing the total volume of submissions that will have been prepared if all patients were to obtain a drug under individual patient INDs or protocols, consolidation will limit the additional administrative burdens from increased patient access. In addition, by explicitly clarifying the eligibility criteria and submission requirements for expanded access, the final rule should make the process of obtaining access to investigational drugs more efficient for all affected parties.

It is expected that any increase in the volume of submissions will result primarily from greater numbers of

patients obtaining investigational drugs under expanded access INDs or protocols for individual patients and intermediate-size patient populations. Because this final rule does not significantly change the existing regulations concerning treatment INDs or treatment protocols, the number of patients receiving investigational drugs under these mechanisms should be largely unaffected.

1. Individual Patient Expanded Access Submissions

By increasing awareness of the ways individual patients can obtain expanded access to investigational drugs for treatment use, and decreasing the perceived difficulty of obtaining such access, the final rule should increase the number of individual patients seeking access to investigational drugs. FDA anticipates that this increase in individual patient expanded access submissions will be greatest in the years immediately following implementation of the final rule and will at some point level off or possibly even decline. This leveling off or decline will occur when a significant volume of individual patient expanded access has accumulated for a variety of drugs, and the individual patient expanded access INDs or protocols for those drugs are then replaced with intermediate-size patient population INDs or protocols that enroll multiple subjects. Making the transition from multiple individual patient INDs or protocols to a single intermediate-size patient population IND or protocol should reduce the overall administrative burden associated with making a particular investigational drug available for treatment use.

From 1997 to 2005, FDA received, on average, approximately 659 individual patient and emergency IND submissions per year. Although FDA is confident this final rule will increase this volume, it is difficult to predict with precision the extent of the increase. There is uncertainty concerning the extent to which patients who desire expanded access to investigational drugs are unable to obtain them; the extent to which better information about the mechanisms and processes for obtaining access to investigational drugs will stimulate more patients, or their physicians, to seek investigational drugs for expanded access use; and the extent to which drug manufacturers will be willing to make investigational drugs more broadly available for expanded access use. Although FDA is confident there will be an increase in the volume of individual patient expanded access use following issuance of this final rule, because of these uncertainties the agency can provide only an estimate of the range of potential increase. FDA believes that, after publication of the final rule, it is reasonable to anticipate a 40 to 60 percent increase in the volume of individual patient expanded access submissions by year 3. As discussed previously in this document, we anticipate that growth will be most rapid in the years immediately following publication of the final rule and will eventually plateau or possibly even decline. The implications of these assumptions for the total number of individual patient expanded access submissions are summarized in table 3 of this document.

TABLE 3.—EXPECTED PERCENT INCREASE AND ESTIMATED NO. OF INDIVIDUAL PATIENT EXPANDED ACCESS SUBMISSIONS

Year After Implementation of Final Rule	Expected Percent Increase in Individual Patient Submissions	Expected No. of Individual Patient Submissions ¹
1	20 to 40	791 to 923
2	30 to 50	857 to 988
3	40 to 60	923 to 1054
4	0	923 to 1054
5	0	923 to 1054

¹ Based on the current average of 659 individual patient treatment use submissions per year and the estimated percent increases in column 2.

2. Intermediate-Size Patient Population Expanded Access Submissions

Although intermediate-size patient population expanded access has not previously been described in the regulations, this general type of mechanism has been used informally to make investigational drugs available for

treatment use. Based on an internal survey of review divisions, FDA estimates that for the period 2000 through 2002 it received approximately 55 submissions per year that would be considered intermediate-size patient population expanded access submissions under the final rule. The

agency anticipates that this final rule will increase the number of such submissions. Because this previously informal mechanism will be described in the regulations for the first time, there will be greater awareness, which is likely to stimulate submissions. In addition, the anticipated increase in

volume of individual patient expanded access submissions discussed previously in this document is expected to increase the number of intermediate-size patient population expanded access submissions because the final rule encourages the consolidation of multiple individual patient INDs or protocols for a given expanded access use.

The extent to which submissions for expanded access for intermediate-size patient populations will increase is uncertain. Section 312.315 of the final rule concerns expanded access for intermediate-size patient populations. This section provides that FDA may ask a sponsor to consolidate expanded access under this section when the agency has received a significant number of requests for individual patient expanded access to an investigational drug for the same use. FDA does not have historical information that will permit us to accurately predict what portion of

individual patient expanded access submissions are likely to be appropriate for consolidation.

Based on our experience, we believe that many of the individual patient expanded access submissions we receive will be appropriate for consolidation. However, some individual patient expanded access submissions will be for expanded access uses that are sufficiently rare that it is unlikely that there will be enough similar uses to consolidate them under an intermediate-size patient population IND or protocol. There is also uncertainty about the extent to which sponsors will be willing to make investigational drugs available for expanded access use under intermediate-size patient population INDs or protocols. Although FDA is confident that there will be growth in the volume of intermediate-size patient population expanded access INDs or protocols, because of the uncertainties identified, we can provide only an

estimate of the range of potential increase. FDA believes it is reasonable to anticipate a 25 to 50 percent growth in the volume of submissions for intermediate-size population expanded access INDs or protocols over a 5-year period.

Compared with the growth in individual patient expanded access submissions, this increase is likely to be more gradual in the years immediately following implementation of a final rule, and will increase more sharply after 2 to 3 years as some of the increase in volume of individual patient expanded access submissions is shifted to intermediate-size population INDs or protocols. As in the case of expanded access for individual patients, growth in the number of submissions is expected to plateau or even decline after a few years. The implications of these assumptions for the number of individual patient expanded access submissions are summarized in table 4 of this document.

TABLE 4.—EXPECTED PERCENT INCREASE AND ESTIMATED NO. OF INTERMEDIATE-SIZE PATIENT POPULATION EXPANDED ACCESS SUBMISSIONS

Year After Implementation of Final Rule	Expected Percent Increase in Intermediate-Size Patient Population Submissions	Expected No. of Intermediate-Size Patient Population Submissions ¹
1	5 to 10	58 to 61
2	10 to 20	61 to 66
3	20 to 40	66 to 77
4	25 to 50	69 to 82
5	0	69 to 82

¹ Based on the current average of 55 intermediate-size patient population submissions per year and the estimated percent increases in column 2.

3. Expanded Access under Treatment INDs and Treatment Protocols

The number of treatment INDs and treatment protocols should be largely unaffected by the final rule. The concept of large access programs is well established and most drugs that meet an unmet medical need for a serious or immediately life-threatening condition have had some kind of large access program late in their development. Therefore, the number of large access programs is primarily a function of the number of new drugs to treat serious and immediately life-threatening conditions that reach the latter stages of drug development (e.g., become NDA submissions). This rule is unlikely to influence that number.

As stated in the preamble of the proposed rule (71 FR 75147 at 75155), sponsors have instituted large expanded access programs under treatment INDs

or treatment protocols or under less formal open-label (also referred to as open-access) protocols. The agency intends to be more vigilant in ensuring that a use of an investigational drug that has the characteristics of a treatment IND or treatment protocol is submitted and authorized as such, rather than as an open-label protocol. While this increased vigilance may increase the number of treatment INDs or treatment protocols, any increase will be primarily attributable to reclassifying open-label safety studies as treatment INDs or treatment protocols rather than a net increase in the overall number of large access programs. This reclassification should also improve safety monitoring of large access programs without significantly increasing administrative costs, because the costs for a treatment IND or treatment protocol and an open-label protocol are similar.

Reclassification of an open-label protocol as a treatment IND or treatment protocol may also increase publicity for, and awareness of, the access program. Sponsors of treatment INDs or treatment protocols may, in certain circumstances, be required to list those programs at <http://www.clinicaltrials.gov>, a Web site maintained by the NIH as a resource for patients seeking to enroll in clinical trials or obtain access to investigational drugs for treatment use. The additional exposure generated by this site may attract more patients than will have had access under an open-label protocol. As a result, any given treatment IND or treatment protocol may be somewhat more costly than a less-publicized open-label protocol due to the volume of patients enrolled. FDA is not able to predict the impact on patient volume as a result of reclassifying open-label or open-access protocols as treatment INDs or treatment protocols. However, FDA

anticipates that there will be some economies of scale, so that the incremental costs will be relatively small on a per-patient basis. FDA believes any added costs will be justified by the potentially greater number of patients who will benefit from access to investigational drugs.

E. Benefits of the Final Rule

Because FDA currently has no data that will allow us to predict the extent to which the amendments to existing IND regulations will generate direct benefits for consumers, it is not possible to accurately quantify the magnitude of any expected incremental benefits at this time. The number of patients obtaining expanded access to investigational drugs is expected to increase. However, because eligible patients will have serious or immediately life-threatening conditions that have failed to respond to available therapies, and because the investigational drugs are unproven, FDA cannot predict the extent to which individual patients will benefit from access to these drugs. Thus, the following discussion describes, in general terms, the nature of the potential benefits associated with the final rule.

The benefits of the final rule are expected to result from improved patient access to investigational drugs generally and from expanded access being made available for a broader variety of disease conditions and treatment settings. In particular, the clarification of eligibility criteria and submission requirements will enhance patient access by easing the administrative burdens on individual physicians seeking investigational drugs for their patients and on sponsors who make investigational drugs available for expanded access use. Expanded access to investigational drugs may generate both private and social benefits. Private benefits will accrue to individual patients receiving drugs for expanded access use, whereas social benefits will accrue if these private benefits are also valued by society at large, or if any information obtained contributes to the development of new therapies generally.

The final rule is also designed to address concerns that many physicians and their patients, particularly those outside of academic medical centers, are unaware of the availability of investigational drugs for expanded access use. In FDAMA, Congress included language in section 561(c) of the act to authorize the Secretary to inform medical associations, medical societies, and other appropriate persons of the availability of investigational drugs under treatment INDs or treatment

protocols. FDA believes that this action, along with detailed eligibility criteria and submission requirements established in the final rule, will improve access to investigational drugs and result in making expanded access use more widely available to patients regardless of treatment setting.

In formulating the final rule, FDA considered its statutory mandate and the interests of individuals and special patient populations, drug sponsors, and the general public. The agency found that in many situations, individuals or special patient populations have benefited from increased access to a drug that has not yet been approved for marketing (e.g., in the case of cancer or HIV therapies). These individuals or patient groups generally have serious or immediately life-threatening conditions and have not responded to available therapies or cannot participate in ongoing clinical trials for some reason.

On the other hand, unrestricted access to investigational drugs for treatment use could reduce the patient population available for enrollment in the clinical trials required to demonstrate safety and efficacy in support of new drug marketing applications. If expanded access to investigational drugs were to adversely affect the marketing approval process, the general population will experience diminished social benefits due to the reduced or delayed availability of new therapies approved for marketing by FDA.

The final rule addresses these competing interests by allowing investigational drugs to be made available for expanded access use only if providing the drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval, or otherwise compromise the potential development of the expanded access use. In this way, the final rule effectively balances the interests of those patient populations who will benefit from having greater access to investigational drugs with the broader interests of society in having safe and effective new therapies approved for marketing and widely available.

The agency is also aware that allowing expanded access to investigational drugs before they are fully evaluated for safety may have adverse consequences for the seriously ill patients who receive them. The safeguards in the final rule are also designed with this concern in mind. Authorization of a particular expanded access use is generally contingent upon a number of factors, including some evidence of the drug's safety and

effectiveness, obtaining the informed consent of the patient, approval of an IRB, and a careful assessment of the potential risks and benefits to the patient. In addition, the final rule will place limits on the scope and duration of certain types of expanded access use, require that sponsors of such INDs or protocols monitor the expanded access use and comply with safety and annual reporting requirements for INDs, and subject ongoing INDs or protocols to periodic reassessment. The agency believes these safeguards will adequately protect the safety and welfare of patients who will seek, and may benefit from, expanded access to investigational drugs.

F. Costs of the Final Rule

To the extent that the final rule results in an increase in the number of expanded access submissions, drug sponsors and physicians requesting investigational drugs on behalf of their patients will incur some additional costs. Because the final rule does not include any new, mandatory reporting requirements, the agency believes that the one-time costs associated with this rule will be negligible. Thus, the incremental burden imposed by this final rule will be in the form of additional annual or recurring costs associated with the increased number of expanded access submissions estimated previously in this document.

The agency estimates that preparation and submission of an individual patient expanded access submission will require a total of approximately 8 hours. This time burden will be divided among physicians (approximately 15 percent or 1.2 hours) and nurses, nurse practitioners, or medical administrators (approximately 85 percent or 6.8 hours). According to the U.S. Department of Labor, Bureau of Labor Statistics,² total employer costs per hour worked for employee compensation for registered nurses in the health care and social assistance sector was \$44.21 as of March 2008. Thus, the cost of the estimated 6.8 hours of nurse time required to prepare and submit an individual patient expanded access submission will be approximately \$301 (\$300.62 = \$44.21 per hour x 6.8 hours).

Historically, most of the treatment use requests submitted to the agency have been prepared by physicians in the hematology/oncology specialty category. Data available on the Internet indicate

² See <http://www.bls.gov/news.release/ecec.toc.htm>, last viewed July 11, 2008. (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**.)

that the median expected total compensation for a physician in the hematology/oncology specialty category was \$387,739 as of March 2008.³ This median total compensation figure corresponds to approximately \$186 per hour (\$186.41 = \$387,739 / 2,080 hours). Thus the cost for the 1.2 hours of

physician time required to prepare and submit an individual patient expanded access submission is about \$224 (\$223.69 = \$186.41 per hour x 1.2 hours). Therefore, the agency estimates that the total cost to prepare and submit an individual patient expanded access submission will be about \$525 (\$525 =

\$301 + \$224). Applying this cost figure to the number of additional individual patient expanded access submissions estimated previously in this document suggests the pattern of incremental annual costs summarized in table 5 of this document.

TABLE 5.—NO. OF ADDITIONAL INDIVIDUAL PATIENT EXPANDED ACCESS SUBMISSIONS AND ESTIMATED ANNUAL COSTS

Year After Implementation of Final Rule	Expected Increase in the No. of Individual Patient Submissions ¹	Expected Cost of Additional Individual Patient Submissions ²
1	132–264	\$69,300 to \$138,600
2	198–329	\$103,950 to \$172,725
3	264–395	\$138,600 to \$207,375
4	264–395	\$138,600 to \$207,375
5	264–395	\$138,600 to \$207,375

¹ Based on increases in the number of individual patient expanded access submissions implied by the estimates presented in table 2 of this document.

² Based on an estimated cost of \$525 per individual patient expanded access submission.

Preparation and submission of an intermediate-size patient population expanded access IND or protocol is expected to require a total of about 120 hours of staff time. This time burden will be divided between a Medical Director or Director of Clinical Research, typically a medical doctor (approximately 50 percent or 60 hours), a Regulatory Affairs Director (approximately 20 percent or 24 hours), and a Clinical Research Associate (approximately 30 percent or 36 hours).

Information available on the Internet suggests that the median total compensation for a physician serving as a Medical Director is about \$316,134 per year.⁴ This translates into an estimated hourly total compensation figure of about \$152 (\$151.98 = \$316,134 / 2,080 hours). Thus, the cost associated with the 60 hours of Medical Director time required to prepare and submit an

intermediate-size patient population expanded access submission is approximately \$9,120 (\$9,120 = 60 hours x \$152).

Information available on the Internet also indicates that the median total compensation for a Regulatory Affairs Director is approximately \$235,149 per year.⁵ This translates into an estimated hourly total compensation figure of about \$113 (\$113.05 = \$235,149 / 2,080 hours). Thus, the cost associated with the 24 hours of Regulatory Affairs Director time required to prepare and submit an intermediate-size patient population expanded access submission is approximately \$2,712 (\$2,712 = 24 hours x \$113).

Finally, information available on the Internet indicates that the median total compensation for a Clinical Research Associate is approximately \$86,890 per year.⁶ This translates into an estimated

hourly total compensation figure of about \$42 (\$41.77 = \$86,890 / 2,080 hours). Thus, the cost associated with the 36 hours of Clinical Research Associate time required to prepare and submit an intermediate-size patient population expanded access submission is approximately \$1,512 (\$1,512 = 36 hours x \$42).

Based on the information presented, the agency estimates that the total cost to prepare and submit an intermediate-size patient population expanded access submission will be approximately \$13,350 (\$13,344 = \$9,120 + \$2,712 + \$1,512). Applying this figure to the increases in the number of intermediate-size patient population expanded access submissions estimated previously in this document suggests the pattern of annual cost increases summarized in table 6 of this document.

TABLE 6.—NO. OF ADDITIONAL INTERMEDIATE-SIZE PATIENT POPULATION EXPANDED ACCESS SUBMISSIONS AND ESTIMATED ANNUAL COSTS

Year After Implementation After Final Rule	Expected Increase in the No. of Intermediate-Size Patient Population Submissions ¹	Expected Cost of Additional Intermediate-Size Patient Population Submissions ²
1	3 to 6	\$40,050 to \$80,100
2	5 to 11	\$66,750 to \$146,850
3	11 to 22	\$146,850 to \$293,700

³ See http://swz.salary.com/salarywizard/layouts/scripts/swzl_newsearch.asp, last viewed July 11, 2008. (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**).

⁴ See http://swz.salary.com/salarywizard/layouts/scripts/swzl_newsearch.asp, last viewed July 11, 2008. (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**.)

⁵ See footnote 4 of this document.

⁶ See footnote 4 of this document.

TABLE 6.—NO. OF ADDITIONAL INTERMEDIATE-SIZE PATIENT POPULATION EXPANDED ACCESS SUBMISSIONS AND ESTIMATED ANNUAL COSTS—Continued

Year After Implementation After Final Rule	Expected Increase in the No. of Intermediate-Size Patient Population Submissions ¹	Expected Cost of Additional Intermediate-Size Patient Population Submissions ²
4	14 to 27	\$186,900 to \$360,450
5	14 to 27	\$186,900 to \$360,450

¹ Based on increases in the number of intermediate-size patient population expanded access submissions implied by the estimates presented in table 3 of this document
² Based on an estimated cost of \$11,000 per intermediate-size patient population expanded access submission.

For reasons discussed previously in this document, the agency does not expect that the final rule will have an impact on the overall number of treatment INDs or treatment protocols.

Therefore, FDA does not expect the provisions of this final rule regarding treatment INDs or treatment protocols to impose any incremental cost burden. The total estimated variable and annual

cost burdens associated with this final rule are summarized in table 7 of this document.

TABLE 7.—COST SUMMARY

Year After Implementation of Final Rule	One-Time Fixed Cost	Variable Cost	Annual Cost ¹
1	\$0	\$109,350 to \$218,700	\$109,350 to \$218,700
2	\$0	\$170,700 to \$319,575	\$170,700 to \$319,575
3	\$0	\$285,450 to \$501,075	\$285,450 to \$501,075
4	\$0	\$325,500 to \$567,825	\$325,500 to \$567,825
5	\$0	\$325,500 to \$567,825	\$325,500 to \$567,825

¹ Since estimated one-time fixed costs are negligible, annual costs equal variable costs.

For reasons discussed previously in this document, the agency expects that the total one-time costs of the final rule will be negligible. FDA expects that the annual costs of this final rule will range from a low of about \$109,000 to \$219,000 in the first year following publication of the final rule, to a high of about \$325,000 to \$568,000 in the fourth and fifth years. These estimates suggest total annual costs for the final rule of between \$1.2 and \$2.2 million for the 5-year period following implementation of the final rule.

The agency expects that the estimated incremental cost burdens associated with this final rule are likely to be widely dispersed among affected entities for several reasons. First, given the historical volume of various types of treatment use submissions, the agency believes that a particular drug sponsor—or a physician acting on behalf of a patient—will submit a request for expanded access to investigational drugs fairly infrequently. Second, as noted previously, the final rule encourages the consolidation of multiple expanded access INDs or protocols for individual patients for a particular expanded access use under an intermediate-size patient population expanded access IND or protocol. Such

consolidation should, to some extent, offset incremental administrative burdens caused by increased patient access. Making the transition from multiple individual patient expanded access INDs or protocols to a single IND or protocol for an intermediate-size patient population should reduce for sponsors the administrative burdens associated with making a drug available for expanded access use. In addition, provisions of the final rule are designed to minimize the amount of information and paperwork required to support a particular expanded access request. Physicians and drug sponsors will need to review the rule to become familiar with its provisions and to gather the evidence and information necessary to support an expanded access submission. However, in instances where a current IND already exists, a sponsor need only submit an amendment describing the information relevant to the expanded access protocol. Also, another sponsor or individual physician acting on behalf of a patient may, with the written permission of the original sponsor, reference information in the current IND already on file. The agency believes that a majority of expanded access submissions will have such a right of reference, either because the sponsor is

also the drug developer or the developer will generally be willing to grant the request. To the extent that these provisions minimize the informational burden on potential sponsors or physicians, the final rule will enhance both efficiency and cost effectiveness.

One comment submitted in response to the proposed rule provided an estimate of the number of patients that might be affected by this final rule. As part of our response, we have generated estimates of the number additional individuals that will gain access to investigational drugs as a result of the final rule.

Information presented in table 5 of this document indicates that FDA expects this final rule to generate between 132 and 395 additional individual patient or emergency INDs per year. Thus, we estimate that between 132 and 395 additional individuals per year will have expanded access to investigational drugs under single patient or emergency INDs as a result of this final rule. Information presented in table 6 of this document indicates that FDA expects this final rule to generate between 3 and 27 additional expanded access submissions for intermediate-size patient populations. As discussed previously,

we believe that an intermediate-size patient population or other expanded access program will generally include between 10 and 100 individuals. Therefore, we estimate that between 30 ($30 = 3 \times 10$) and 2,700 ($2,700 = 27 \times 100$) additional individuals per year will have expanded access to investigational drugs under intermediate-size patient

populations. Finally, because FDA expects this final rule to have no impact on the number of treatment INDs or protocols, the number of patients with access to investigational drugs will be unaffected. Based on this information, FDA estimates that between 162 ($162 = 132 + 30$) and 3,095 ($3,095 = 395 + 2,700$) additional individuals will

receive investigational drugs through expanded access programs as a result of this final rule. The range of these estimates reflects significant variation in the number of patients in intermediate-size patient populations. These estimates are summarized in table 8 of this document.

TABLE 8.—APPROXIMATE NO. OF ADDITIONAL INDIVIDUALS AFFECTED BY EXPANDED ACCESS PROGRAMS UNDER THE FINAL RULE

Category	Expected No. of Additional Submissions	No. of Patients	Minimum No. of Additional Individuals	Maximum No. of Additional Individuals
Individual Patient or Emergency IND	132 to 395	1	132	395
Small Patient Population/Other	3 to 27	10 to 100	30	2,700
Treatment IND or Protocol	0	100 to 10,000	0	0
Total			162	3,095

G. Minimizing the Impact on Small Entities

The agency does not believe the final rule will have a significant economic impact on a substantial number of small entities. Nevertheless, in the proposed rule, we recognized our uncertainty regarding the number and size distribution of affected entities, as well as the economic impact of the final rule on those entities, and requested detailed comment on these important issues. We received no comments that would cause us to change our determination that the final rule will not have a significant economic impact on a substantial number of small entities.

Agency records indicate that the majority of submissions for treatment use of investigational drugs (about 78 percent) are submitted by commercial drug sponsors. Other entities making treatment use submissions include government agencies (approximately 14 percent), individual physicians (7 percent), and academic institutions (1 percent). Thus, the agency believes that the vast majority (92 percent) of sponsors of expanded access INDs or protocols (consisting of commercial drug sponsors or government agencies) will not be considered small entities. The remaining 8 percent of treatment use submissions are made by individual physicians and academic institutions that the agency believes will meet Small Business Administration small business criteria.

Of the average of 659 individual patient treatment use submissions submitted annually, very few are associated with commercial sponsors. The vast majority are submitted by individual physicians and various other

unidentified sponsors for research purposes. Because nearly all individual patient treatment use submissions are made by various types of entities for research purposes, the agency believes that most of these entities will be classified as small entities.

Because there is currently no formal mechanism in place for tracking the other types of expanded access (e.g., intermediate-size patient population submissions), no data exist that will allow the agency to identify the number of sponsors in this category that will qualify as small entities.

Thus, while highly uncertain, the agency believes that at least some of the entities submitting expanded access requests will qualify as small entities. As discussed in section VI.F of this document, the agency expects that any incremental burden associated with the final rule will be small and widely dispersed among affected entities.

H. Alternatives

FDA considered several alternatives to the final rule. They are discussed in the following paragraphs.

1. Do Not Propose Implementing Regulations for the Expanded Access Provisions of FDAMA

FDAMA revised the act to specifically authorize the use of investigational new drugs by licensed physicians to diagnose, monitor, or treat individual patients who have a serious disease or condition if, among other things, the physician determines that the person has no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition, and that the probable risk from the investigational drug is not greater than

the probable risk from the disease or condition; and FDA determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug. FDAMA also largely incorporated into the act FDA's current regulation concerning treatment INDs or treatment protocols under which large populations currently receive investigational drugs for treatment use. Because FDAMA did not require that FDA adopt implementing regulations, the agency could have chosen not to do so.

However, the agency believes that implementing regulations will further improve expanded access to investigational drugs for treatment use. One of the major criticisms about access to investigational drugs is that the criteria for authorizing access are unclear and that there is not broad knowledge among affected, or potentially affected, parties about the mechanisms or procedures to obtain access. FDA believes the final regulations are needed to address these concerns. The regulations provide to sponsors, patients, and licensed physicians who will be seeking investigational drugs for their patients clear direction about the criteria for authorizing expanded access and what information must be submitted to the agency to enable it to evaluate a proposed expanded access submission. Clearer direction and greater knowledge of the mechanisms and procedures for obtaining investigational drugs for expanded access use should reduce barriers to access.

2. Propose a Regulation Describing Only Individual Patient Expanded Access and the Treatment IND or Treatment Protocol

As discussed in the previous paragraphs, FDAMA specifically authorized the use of investigational new drugs by licensed physicians to diagnose, monitor, or treat individual patients in certain circumstances. FDAMA also essentially repeated FDA's current regulation concerning treatment INDs or treatment protocols under which large populations currently receive investigational drugs for treatment use.

FDA could have chosen to adopt regulations that described only these two categories of expanded access. However, FDA has had a long history of using an informal mechanism to make investigational drugs available to intermediate-size patient populations. This mechanism has been used in situations in which both: (1) The expanded access use did not meet the criteria for a treatment IND under the previous regulation and (2) it would have been excessively burdensome for sponsors and FDA to require large numbers of individual patient INDs for the same use. The agency concluded that, consistent with the terminology of section 561(b)(4) of the act, it is preferable to establish an intermediate category for expanded access, with additional criteria and monitoring requirements, that will be used for more than an individual patient, but fewer than the large numbers of patients in treatment INDs or treatment protocols.

In FDA's experience, there is often a need for a middle ground between an individual patient IND or protocol and a treatment IND or treatment protocol. For some drugs in development, there is considerable demand for expanded access before the use meets the criteria for a treatment IND or treatment protocol. There are also situations in which investigational drugs that are not being actively developed are the best available therapy for a significant number of patients and should be made available to patients under an expanded access process. In these situations, making the drug available under a series of individual patient expanded access INDs or protocols is burdensome on physicians, sponsors, and FDA, and makes it difficult to monitor the expanded access use to identify significant safety concerns such as serious adverse events.

Describing this intermediate category in the regulations is also consistent with FDA's goal of maximizing awareness of expanded access programs by being

more transparent about the processes for making drugs available for expanded access. As stated previously, FDA has used this intermediate category informally in the past and believes it will have reason to use this category in the future. Therefore, FDA believes it is appropriate to formalize and fully describe in the regulations the intermediate expanded access category, as well as the two other categories of expanded access.

3. Propose a Regulation Describing More Than Three Expanded Access Categories

FDA also considered proposing a rule that will include more than three expanded access categories, but rejected this alternative. In internal discussions, FDA found that the distinctions between the proposed categories and the additional categories it considered were unclear. FDA was concerned that the additional categories would create confusion rather than provide the clarity that is the goal of the final regulations. FDA concluded that the additional categories could be merged into the three proposed categories and that these categories will be able to provide access to investigational drugs in all situations FDA is likely to encounter.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that 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 PRA). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Expanded Access to Investigational Drugs for Treatment Use

Description: The final rule clarifies existing regulations and revises them by adding new types of expanded access for treatment use. Under the final rule, expanded access to investigational drugs will be available to individual patients, including in emergencies; to intermediate-size patient populations; and to larger populations under a treatment protocol or IND. The final rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and may benefit from such therapies.

A. The Final Rule

1. Submission Requirements for All Expanded Access Uses

Section 312.305(b) describes the submission requirements applicable to all types of expanded access.

Section 312.305(b)(1) states that an expanded access submission is required for each type of expanded access. The submission may be a new IND or a protocol amendment to an existing IND. Information required for a submission may be supplied by referring to pertinent information contained in an existing IND if the sponsor of the existing IND grants a right of reference to the IND.

Section 312.305(b)(2) describes the expanded access submission requirements. The following items must be included:

- A cover sheet (Form FDA 1571) meeting the requirements of § 312.23(a);
- The rationale for the intended use of the drug, including a list of available therapeutic options that will ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options;
- The criteria for patient selection; or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments used for the disease or condition;
- The method of administration of the drug, dose, and duration of therapy;
- A description of the facility where the drug will be manufactured;
- Chemistry, manufacturing, and controls information adequate to ensure the proper identification, quality, purity, and strength of the investigational drug;
- Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration for expanded access use (ordinarily, information that will be adequate to permit clinical testing of the drug in a population of the size expected to be treated); and
- A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

2. Individual Patient Expanded Access

Section 312.310(b) contains additional submission requirements that apply to use of an investigational drug for the treatment of an individual patient by a licensed physician. The expanded access submission must include information adequate to satisfy

FDA that the criteria for all expanded access uses and those specific to individual patient expanded access have been met. The individual patient expanded access criteria are:

- The physician must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition, and
- FDA must determine that the patient cannot obtain the drug under another type of IND.

Section 312.310(b)(1) states that if the drug is the subject of an existing IND, the expanded access submission may be made by a commercial sponsor or by a licensed physician.

Section 312.310(b)(2) states that a sponsor may satisfy the submission requirements by amending its existing IND to include an individual patient expanded access protocol.

Section 312.310(b)(3) states that a licensed physician may satisfy the submission requirements by obtaining a right of reference to pertinent information in the IND and providing any other required information not contained in the IND (usually only the information specific to the individual patient).

3. Intermediate-Size Patient Populations

Section 312.315(c) states that an expanded access submission for an intermediate-size patient population must include information adequate to satisfy FDA that the criteria for all expanded access uses and those specific to intermediate-size patient populations have been met. The intermediate-size patient population criteria are: (1) There is enough evidence that the drug is safe at the dose and duration proposed for treatment use to justify a clinical trial of the drug in the approximate number of patients expected to receive the drug for treatment use; and (2) there is at least preliminary clinical evidence of effectiveness of the drug or of a plausible pharmacologic effect of the drug to make expanded access use a reasonable therapeutic option in the anticipated patient population. Section 312.315(c) contains additional submission requirements that apply to use of an investigational drug for intermediate-size patient populations. The expanded access submission must state whether the drug is being developed or is not being developed and describe the patient population to be treated. If the drug is not being actively developed, the sponsor must explain why the drug cannot currently be developed for the expanded access use and under what circumstances the drug could be developed. If the drug is being

studied in a clinical trial, the sponsor must explain why the patients to be treated cannot be enrolled in the clinical trial and under what circumstances the sponsor will conduct a clinical trial in these patients.

4. Treatment IND or Protocol

Section 312.320 describes the treatment IND or treatment protocol currently codified in §§ 312.34 and 312.35. Section 312.320(b) states that the expanded access submission must include information adequate to satisfy FDA that the criteria for all expanded access uses and those specific to the treatment IND or protocol have been met. The criteria specific to a treatment IND or treatment protocol are: (1) The drug is being investigated in a controlled clinical trial designed to support a marketing application for the expanded access use or all clinical trials of the drug have been completed, (2) the sponsor is pursuing marketing approval of the drug for the expanded access use with due diligence, and (3) there is sufficient clinical evidence of safety and effectiveness to support the treatment use. Such evidence will ordinarily consist of data from phase 3 trials, but could consist of compelling data from completed phase 2 trials. When the expanded access use is for an immediately life-threatening disease or condition, the available scientific evidence, taken as a whole, could provide a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and will not expose patients to an unreasonable and significant risk of illness or injury. This evidence will ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence.

B. Estimates of Reporting Burden

Our estimate of the amount of time required to complete an expanded access submission is based on the assumption that either the submission will be made by the drug developer or the submitter will have obtained a right of reference from the drug developer. We expect an increase in the number of submissions for expanded access for individual patients and for intermediate-size patient populations as a result of this final rule.

1. Individual Patient Expanded Access

From 1997 to 2005, we received on average approximately 659 submissions for the treatment use of investigational drugs by individual patients per year. This estimate is based on our records of the number of individual patient IND

submissions (primarily from physicians) and a survey of our review divisions on the prevalence of individual patient protocol exception submissions received from commercial drug sponsors. As indicated in the table below, we expect an increase in the number of individual patient expanded access submissions because the final rule will increase awareness of the option for individual patients to gain access to investigational drugs and decrease the perceived difficulty of obtaining such access. We anticipate that the increase in individual patient expanded access INDs or protocols will be greatest in the years immediately following implementation of the final rule and will at some point level off or possibly even decline. This leveling off or decline will occur when a significant volume of individual patient expanded access INDs or protocols have accumulated for a variety of drugs, and the individual patient expanded access INDs or protocols for those drugs are then replaced with intermediate-size patient population expanded access INDs or protocols that enroll multiple subjects.

We estimate that preparation and submission of an individual patient expanded access IND or protocol submission will require a total of approximately 8 hours.

2. Intermediate-Size Patient Population Expanded Access

Although intermediate-size patient population expanded access INDs or protocols have not previously been described in regulation, investigational drugs have been made available informally for treatment use to such populations. Based on an internal survey of our review divisions, we estimate that, for the period 2000 through 2002, we received approximately 55 submissions per year that we consider expanded access for an intermediate-size patient population under the final rule. As indicated in table 9, we anticipate that this number will increase under the final rule because there will be greater awareness of this option. In addition, the anticipated increase in volume of submissions for expanded access for individual patients discussed previously is expected to increase the number of submissions for expanded access for intermediate-size patient populations because the final rule encourages the consolidation of multiple individual patient INDs or protocols for a given expanded access use.

Information provided by our review divisions indicates that preparation and

submission of an intermediate-size patient population IND will require a total of approximately 120 hours.

3. Treatment IND or Treatment Protocol

We do not expect the final rule to have an impact on the overall number of treatment INDs or treatment protocols because this type of expanded access is already established in FDA regulations at §§ 312.34 and 312.35. Therefore, we

do not expect the provisions of this final rule regarding treatment INDs or treatment protocols to impose any increased paperwork burden. The burden for these submissions, as currently required under § 312.35, is already approved by OMB under OMB control number 0910–0014.

Description of Respondents: Licensed physicians and manufacturers, including small business manufacturers.

Table 9 of this document presents the annualized reporting burden for the total number of expanded access submissions by type of expanded access use. The estimates in the table are based on data from section VI of this document and are calculated by averaging the projected number of submissions for the first 3 years after implementation of this final rule.

TABLE 9.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
§§ 312.305 and 312.310(b)	988	1	988	8	7,904
§§ 312.305(b) and 312.315(c)	68	1	68	120	8,160
Total					16,064

¹ There are no capital costs or operating and maintenance costs associated with this collection.

The information collection provisions in this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has tentatively determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 316

Administrative practice and procedure, Drugs, Investigations,

Medical research, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 316 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

- 1. The authority citation for 21 CFR part 312 is revised to read as follows:
- Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.
- 2. Section 312.30 is amended by revising paragraph (c) to read as follows:

§ 312.30 Protocol amendments.

(c) *New investigator.* A sponsor shall submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol, except that a protocol amendment is not required when a licensed practitioner is added in the case of a treatment protocol under § 312.315 or § 312.320. Once the investigator is added to the study, the investigational drug may be shipped to the investigator and the investigator may begin participating in the study. The sponsor shall notify FDA of the new investigator within 30 days of the investigator being added.

§ 312.34 [Removed]

- 3. Section 312.34 is removed.

§ 312.35 [Removed]

- 4. Section 312.35 is removed.

§ 312.36 [Removed]

- 5. Section 312.36 is removed.

- 6. Section 312.42 is amended by revising paragraph (b)(3) to read as follows:

§ 312.42 Clinical holds and requests for modification.

(b) * * *

(3) *Clinical hold of an expanded access IND or expanded access protocol.* FDA may place an expanded access IND or expanded access protocol on clinical hold under the following conditions:

- (i) *Final use.* FDA may place a proposed expanded access IND or treatment use protocol on clinical hold if it is determined that:
- (A) The pertinent criteria in subpart I of this part for permitting the expanded access use to begin are not satisfied; or
- (B) The expanded access IND or expanded access protocol does not comply with the requirements for expanded access submissions in subpart I of this part.
- (ii) *Ongoing use.* FDA may place an ongoing expanded access IND or expanded access protocol on clinical hold if it is determined that the pertinent criteria in subpart I of this part for permitting the expanded access are no longer satisfied.

- 7. Part 312 is amended by adding and reserving subpart H, and by adding subpart I, consisting of §§ 312.300 through 312.320, to read as follows:

Subpart H—[Reserved]

Subpart I—Expanded Access to Investigational Drugs for Treatment Use

Sec.
312.300 General.

- 312.305 Requirements for all expanded access uses.
- 312.310 Individual patients, including for emergency use.
- 312.315 Intermediate-size patient populations.
- 312.320 Treatment IND or treatment protocol.

Subpart I—Expanded Access to Investigational Drugs for Treatment Use

§ 312.300 General.

(a) *Scope.* This subpart contains the requirements for the use of investigational new drugs and approved drugs where availability is limited by a risk evaluation and mitigation strategy (REMS) when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The aim of this subpart is to facilitate the availability of such drugs to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition.

(b) *Definitions.* The following definitions of terms apply to this subpart:

Immediately life-threatening disease or condition means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

Serious disease or condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

§ 312.305 Requirements for all expanded access uses.

The criteria, submission requirements, safeguards, and beginning treatment information set out in this section apply to all expanded access uses described in this subpart. Additional criteria, submission requirements, and safeguards that apply to specific types of expanded access are described in §§ 312.310 through 312.320.

(a) *Criteria.* FDA must determine that:

(1) The patient or patients to be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or

satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;

(2) The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated; and

(3) Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

(b) *Submission.* (1) An expanded access submission is required for each type of expanded access described in this subpart. The submission may be a new IND or a protocol amendment to an existing IND. Information required for a submission may be supplied by referring to pertinent information contained in an existing IND if the sponsor of the existing IND grants a right of reference to the IND.

(2) The expanded access submission must include:

(i) A cover sheet (Form FDA 1571) meeting the requirements of § 312.23(a);

(ii) The rationale for the intended use of the drug, including a list of available therapeutic options that would ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options;

(iii) The criteria for patient selection or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;

(iv) The method of administration of the drug, dose, and duration of therapy;

(v) A description of the facility where the drug will be manufactured;

(vi) Chemistry, manufacturing, and controls information adequate to ensure the proper identification, quality, purity, and strength of the investigational drug;

(vii) Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration proposed for expanded access use (ordinarily, information that would be adequate to permit clinical testing of the drug in a population of the size expected to be treated); and

(viii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

(3) The expanded access submission and its mailing cover must be plainly marked "EXPANDED ACCESS SUBMISSION." If the expanded access submission is for a treatment IND or treatment protocol, the applicable box on Form FDA 1571 must be checked.

(c) *Safeguards.* The responsibilities of sponsors and investigators set forth in subpart D of this part are applicable to expanded access use under this subpart as described in this paragraph.

(1) A licensed physician under whose immediate direction an investigational drug is administered or dispensed for an expanded access use under this subpart is considered an *investigator*, for purposes of this part, and must comply with the responsibilities for investigators set forth in subpart D of this part to the extent they are applicable to the expanded access use.

(2) An individual or entity that submits an expanded access IND or protocol under this subpart is considered a *sponsor*, for purposes of this part, and must comply with the responsibilities for sponsors set forth in subpart D of this part to the extent they are applicable to the expanded access use.

(3) A licensed physician under whose immediate direction an investigational drug is administered or dispensed, and who submits an IND for expanded access use under this subpart is considered a *sponsor-investigator*, for purposes of this part, and must comply with the responsibilities for sponsors and investigators set forth in subpart D of this part to the extent they are applicable to the expanded access use.

(4) *Investigators.* In all cases of expanded access, investigators are responsible for reporting adverse drug events to the sponsor, ensuring that the informed consent requirements of part 50 of this chapter are met, ensuring that IRB review of the expanded access use is obtained in a manner consistent with the requirements of part 56 of this chapter, and maintaining accurate case histories and drug disposition records and retaining records in a manner consistent with the requirements of § 312.62. Depending on the type of expanded access, other investigator responsibilities under subpart D may also apply.

(5) *Sponsors.* In all cases of expanded access, sponsors are responsible for submitting IND safety reports and annual reports (when the IND or protocol continues for 1 year or longer) to FDA as required by §§ 312.32 and 312.33, ensuring that licensed physicians are qualified to administer the investigational drug for the expanded access use, providing licensed

physicians with the information needed to minimize the risk and maximize the potential benefits of the investigational drug (the investigator's brochure must be provided if one exists for the drug), maintaining an effective IND for the expanded access use, and maintaining adequate drug disposition records and retaining records in a manner consistent with the requirements of § 312.57.

Depending on the type of expanded access, other sponsor responsibilities under subpart D may also apply.

(d) *Beginning treatment*—(1) *INDs*. An expanded access IND goes into effect 30 days after FDA receives the IND or on earlier notification by FDA that the expanded access use may begin.

(2) *Protocols*. With the following exceptions, expanded access use under a protocol submitted under an existing IND may begin as described in § 312.30(a).

(i) Expanded access use under the emergency procedures described in § 312.310(d) may begin when the use is authorized by the FDA reviewing official.

(ii) Expanded access use under § 312.320 may begin 30 days after FDA receives the protocol or upon earlier notification by FDA that use may begin.

(3) *Clinical holds*. FDA may place any expanded access IND or protocol on clinical hold as described in § 312.42.

§ 312.310 Individual patients, including for emergency use.

Under this section, FDA may permit an investigational drug to be used for the treatment of an individual patient by a licensed physician.

(a) *Criteria*. The criteria in § 312.305(a) must be met; and the following determinations must be made:

(1) The physician must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition; and

(2) FDA must determine that the patient cannot obtain the drug under another IND or protocol.

(b) *Submission*. The expanded access submission must include information adequate to demonstrate that the criteria in § 312.305(a) and paragraph (a) of this section have been met. The expanded access submission must meet the requirements of § 312.305(b).

(1) If the drug is the subject of an existing IND, the expanded access submission may be made by the sponsor or by a licensed physician.

(2) A sponsor may satisfy the submission requirements by amending its existing IND to include a protocol for individual patient expanded access.

(3) A licensed physician may satisfy the submission requirements by

obtaining from the sponsor permission for FDA to refer to any information in the IND that would be needed to support the expanded access request (right of reference) and by providing any other required information not contained in the IND (usually only the information specific to the individual patient).

(c) *Safeguards*. (1) Treatment is generally limited to a single course of therapy for a specified duration unless FDA expressly authorizes multiple courses or chronic therapy.

(2) At the conclusion of treatment, the licensed physician or sponsor must provide FDA with a written summary of the results of the expanded access use, including adverse effects.

(3) FDA may require sponsors to monitor an individual patient expanded access use if the use is for an extended duration.

(4) When a significant number of similar individual patient expanded access requests have been submitted, FDA may ask the sponsor to submit an IND or protocol for the use under § 312.315 or § 312.320.

(d) *Emergency procedures*. If there is an emergency that requires the patient to be treated before a written submission can be made, FDA may authorize the expanded access use to begin without a written submission. The FDA reviewing official may authorize the emergency use by telephone.

(1) Emergency expanded access use may be requested by telephone, facsimile, or other means of electronic communications. For investigational biological drug products regulated by the Center for Biologics Evaluation and Research, the request should be directed to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 301–827–1800 or 1–800–835–4709, e-mail: ocod@fda.hhs.gov. For all other investigational drugs, the request for authorization should be directed to the Division of Drug Information, Center for Drug Evaluation and Research, 301–796–3400, e-mail: druginfo@fda.hhs.gov. After normal working hours, the request should be directed to the FDA Office of Emergency Operations, 301–443–1240, e-mail: emergency.operations@fda.hhs.gov.

(2) The licensed physician or sponsor must explain how the expanded access use will meet the requirements of §§ 312.305 and 312.310 and must agree to submit an expanded access submission within 15 working days of FDA's authorization of the use.

§ 312.315 Intermediate-size patient populations.

Under this section, FDA may permit an investigational drug to be used for the treatment of a patient population smaller than that typical of a treatment IND or treatment protocol. FDA may ask a sponsor to consolidate expanded access under this section when the agency has received a significant number of requests for individual patient expanded access to an investigational drug for the same use.

(a) *Need for expanded access*.

Expanded access under this section may be needed in the following situations:

(1) *Drug not being developed*. The drug is not being developed, for example, because the disease or condition is so rare that the sponsor is unable to recruit patients for a clinical trial.

(2) *Drug being developed*. The drug is being studied in a clinical trial, but patients requesting the drug for expanded access use are unable to participate in the trial. For example, patients may not be able to participate in the trial because they have a different disease or stage of disease than the one being studied or otherwise do not meet the enrollment criteria, because enrollment in the trial is closed, or because the trial site is not geographically accessible.

(3) *Approved or related drug*. (i) The drug is an approved drug product that is no longer marketed for safety reasons or is unavailable through marketing due to failure to meet the conditions of the approved application, or

(ii) The drug contains the same active moiety as an approved drug product that is unavailable through marketing due to failure to meet the conditions of the approved application or a drug shortage.

(b) *Criteria*. The criteria in § 312.305(a) must be met; and FDA must determine that:

(1) There is enough evidence that the drug is safe at the dose and duration proposed for expanded access use to justify a clinical trial of the drug in the approximate number of patients expected to receive the drug under expanded access; and

(2) There is at least preliminary clinical evidence of effectiveness of the drug, or of a plausible pharmacologic effect of the drug to make expanded access use a reasonable therapeutic option in the anticipated patient population.

(c) *Submission*. The expanded access submission must include information adequate to satisfy FDA that the criteria in § 312.305(a) and paragraph (b) of this section have been met. The expanded

access submission must meet the requirements of § 312.305(b). In addition:

(1) The expanded access submission must state whether the drug is being developed or is not being developed and describe the patient population to be treated.

(2) If the drug is not being actively developed, the sponsor must explain why the drug cannot currently be developed for the expanded access use and under what circumstances the drug could be developed.

(3) If the drug is being studied in a clinical trial, the sponsor must explain why the patients to be treated cannot be enrolled in the clinical trial and under what circumstances the sponsor would conduct a clinical trial in these patients.

(d) *Safeguards.* (1) Upon review of the IND annual report, FDA will determine whether it is appropriate for the expanded access to continue under this section.

(i) If the drug is not being actively developed or if the expanded access use is not being developed (but another use is being developed), FDA will consider whether it is possible to conduct a clinical study of the expanded access use.

(ii) If the drug is being actively developed, FDA will consider whether providing the investigational drug for expanded access use is interfering with the clinical development of the drug.

(iii) As the number of patients enrolled increases, FDA may ask the sponsor to submit an IND or protocol for the use under § 312.320.

(2) The sponsor is responsible for monitoring the expanded access protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators.

§ 312.320 Treatment IND or treatment protocol.

Under this section, FDA may permit an investigational drug to be used for widespread treatment use.

(a) *Criteria.* The criteria in § 312.305(a) must be met, and FDA must determine that:

(1) *Trial status.* (i) The drug is being investigated in a controlled clinical trial under an IND designed to support a marketing application for the expanded access use, or

(ii) All clinical trials of the drug have been completed; and

(2) *Marketing status.* The sponsor is actively pursuing marketing approval of the drug for the expanded access use with due diligence; and

(3) *Evidence.* (i) When the expanded access use is for a serious disease or condition, there is sufficient clinical evidence of safety and effectiveness to support the expanded access use. Such evidence would ordinarily consist of data from phase 3 trials, but could consist of compelling data from completed phase 2 trials; or

(ii) When the expanded access use is for an immediately life-threatening disease or condition, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an

unreasonable and significant risk of illness or injury. This evidence would ordinarily consist of clinical data from phase 3 or phase 2 trials, but could be based on more preliminary clinical evidence.

(b) *Submission.* The expanded access submission must include information adequate to satisfy FDA that the criteria in § 312.305(a) and paragraph (a) of this section have been met. The expanded access submission must meet the requirements of § 312.305(b).

(c) *Safeguard.* The sponsor is responsible for monitoring the treatment protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators.

PART 316—ORPHAN DRUGS

■ 8. The authority citation for 21 CFR part 316 continues to read as follows:

Authority: 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

■ 9. Section 316.40 is revised to read as follows:

§ 316.40 Treatment use of a designated orphan drug.

Prospective investigators seeking to obtain treatment use of designated orphan drugs may do so as provided in subpart I of this chapter.

Dated: July 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-19005 Filed 8-12-09; 8:45 am]

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Federal Register

**Thursday,
August 13, 2009**

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 409, 424, 484, and 489
Medicare Program; Home Health
Prospective Payment System Rate Update
for Calendar Year 2010; Proposed Rule;
Republication**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, and 489

[CMS–1560–P]

RIN 0938–AP20

Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2010

Editorial Note: Federal Register proposed rule document E9–18587, originally published at pages 39436 to 39496 in the issue of Thursday, August 6, 2009, included incorrect tables from pages 39471 to 39496. This document, along with the correct tables, is being republished in its entirety.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth an update to the Home Health Prospective Payment System (HH PPS) rates; the national standardized 60-day episode rates, the national per-visit rates, the non-routine medical supply (NRS) conversion factor, and the low utilization payment amount (LUPA) add-on payment amount, under the Medicare prospective payment system for home health agencies effective January 1, 2010. In addition, this rule proposes a change to the HH PPS outlier policy and proposes to require the submission of OASIS data as a condition for payment under the HH PPS. Also, this rule proposes payment safeguards that would improve our enrollment process, improve the quality of care that Medicare beneficiaries receive from HHAs, and reduce the Medicare program's vulnerability to fraud. This rule also proposes clarifying language to the "skilled services" section and Condition of Participation (CoP) section of our regulations. This proposed rule also clarifies the coverage of routine medical supplies under the HH PPS. We are also soliciting comments on: Physician/patient interaction associated with the home health plan of care (POC); a Consumer Assessment of Healthcare Providers and Systems (CAHPS) Home Health Care Survey; the Outcome and Assessment Information Set (OASIS), Version C, effective January 1, 2010; proposed pay for reporting measures for use in CY 2011; and a number of minor payment-related issues. We are also responding to comments received as a result of our solicitation in the CY 2008 HH PPS final rule with comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 28, 2009.

ADDRESSES: In commenting, please refer to file code CMS–1560–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1560–P, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1560–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

FOR FURTHER INFORMATION CONTACT:

Randy Thronset, (410)786–0131 (overall HH PPS). Sharon Ventura, (410) 786–1985 (for information related to payment rates and wage indexes). James Bossenmeyer, (410) 786–9317 (for information related to payment safeguards). Doug Brown, (410) 786–0028 (for quality issues). Kathleen Walch, (410) 786–7970 (for skilled services requirements and clinical issues).

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I. Background

A. Requirements of the Balanced Budget Act of 1997 for Establishing the Prospective Payment System for Home Health Services

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) enacted on August 5, 1997, significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the home health prospective payment system (HH PPS). Until the implementation of a HH PPS on October 1, 2000, home health agencies (HHAs) received payment under a cost-based reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Social Security Act (the Act), entitled “Prospective Payment For Home Health Services”. Section 1895(b)(1) of the Act requires the Secretary to establish a HH

PPS for all costs of home health services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires that: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase.

Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor that adjusts for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Pursuant to 1895(b)(4)(c), the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Total outlier payments in a given fiscal year (FY) or year may not exceed 5 percent of total payments projected or estimated.

In accordance with the statute, we published a final rule (65 FR 41128) in the **Federal Register** on July 3, 2000, to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999 (Pub. L. 105–277), enacted on October 21, 1998; and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113),

enacted on November 29, 1999. The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

B. Deficit Reduction Act of 2005

On February 8, 2006, the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) was enacted. Section 5201 of the DRA requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to payment. This requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase will be reduced 2 percentage points. In accordance with the statute, we published a final rule (71 FR 65884, 65935) in the **Federal Register** on November 9, 2006 to implement the pay-for-reporting requirement of the DRA, codified at 42 CFR 484.225(h) and (i).

C. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine medical supplies (NRS), is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section III.C.4.e). Durable medical equipment covered under the home health benefit is paid for outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument.

For episodes with four or fewer visits, Medicare pays on the basis of a national

per-visit rate by discipline; an episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

D. Corrections

We published a final rule with comment period in the **Federal Register** on August 29, 2007 (72 FR 49762) that set forth a refinement and rate update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for home health services for CY 2008. In this final rule with comment period, in Table 10B (72 FR 49854), the short description for ICD-9-CM code 250.8x & 707.10-707.9 should read "PRIMARY DIAGNOSIS = 250.8x AND FIRST OTHER DIAGNOSIS=707.10-707.9". Instead of a formal correction notice, we are notifying the public of this correction in this proposed rule, and subsequent final rule.

E. Updates to the HH PPS

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**.

We published a notice in the **Federal Register** on November 3, 2008 (73 FR 65351) that set forth the update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for home health services for CY 2009.

II. Analysis of and Responses to Comments on the HH PPS Refinement and Rate Update for CY 2008

Our August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the Medicare prospective payment system for HHAs for CY 2008. For that final rule, analysis performed on home health claims data, from CY 2005, indicated a 12.78 percent increase in the observed case-mix since 2000. The case-mix represented the variations in conditions of the patient population served by the HHAs. We then performed a more detailed analysis on the 12.78 percent increase in case-mix to see if any portion of that increase was associated with a real change in the actual clinical condition of home health patients. CMS examined data on demographics, family

support, pre-admission location, clinical severity, and non-home health Part A Medicare expenditure data to predict the average case-mix weight for 2005. As a result of that analysis, CMS recognized that an 11.75 percent increase in case-mix was due to changes in coding practices and documentation rather than to treatment of more resource-intensive patients.

To account for the changes in case-mix that were not related to an underlying change in patient health status, CMS implemented a reduction over 4 years in the national standardized 60-day episode payment rates and the NRS conversion factor. That reduction was to be taken at 2.75 percent per year for three years beginning in CY 2008 and at 2.71 percent for the fourth year in CY 2011. CMS indicated that it would continue to monitor for any further increase in case-mix that was not related to a change in patient status, and would adjust the percentage reductions and/or implement further case-mix change adjustments in the future.

The CY 2008 HH PPS final rule with comment period specifically solicited comments on the 2.71 percent reduction that is scheduled to occur in 2011. In response, we received approximately 44 items of correspondence from the public. Comments originated from trade associations, HHAs, hospitals, and health care professionals such as physicians, nurses, social workers, and physical and occupational therapists. In the HH PPS Rate Update for CY 2009, we stated that we would delay our responses to these comments until future rulemaking, enabling us to respond more comprehensively as more current data became available. The following discussion, arranged by subject area, includes our responses to the comments.

A. Payment Reductions in the 4th Year (2011)

Comment: Commenters requested that CMS release the Abt technical report so that the industry could review the data and information within it. Without the Abt report, the commenters stated the industry would be unable to offer meaningful comments on the case-mix reductions.

Response: The Abt Technical Report was posted online and made available to the public on April 30, 2008 at: http://www.cms.hhs.gov/Reports/downloads/Coleman_Final_April_2008.pdf. Although we posted the report later than anticipated, we believe that the CY 2008 HH PPS final rule with comment period adequately presented

information, documentation and evidence describing the Abt case-mix study and CMS' rationale for the reductions. Accordingly, we believe we have provided sufficient time and information to the public to fully review and comment upon the rate reductions that will take effect in CY 2011.

Comment: A commenter suggested that the 4th year cut of 2.71 percent be eliminated or indefinitely deferred until better data are available. Some commenters stated that an additional year of rate cuts will place a financial burden on HHAs, and will result in limited access to home care, especially in rural areas. These commenters further state that limited access may result in more hospitalizations and/or care being provided in more costly settings. Commenters also stated that imposing a 4th year reduction on HHAs would be detrimental and unduly harsh, as many HHAs are already struggling to meet the rising costs of providing care, and that the reductions will cause HHAs to operate at negative margins and likely close.

Several commenters suggested alternatives to CMS' approach to adjusting for nominal case-mix. For example, one commenter suggested spreading the total cuts across a 6-year period rather than a 4-year period, enabling CMS to better monitor the impact of the CY 2008 HH PPS refinements and CY 2008 and 2009 reductions prior to imposing additional reductions.

Another commenter suggested that CMS withdraw its decision to reduce the payment rates until CMS could design and implement a better method to analyze changes in the case-mix, based on adjusted final claims data that would utilize patient characteristics in the model, as well as changes in per-patient annual expenditures, patient clinical, functional, and service utilization data, and dynamic factors in the Medicare system that impact on the nature of patients served with home health care.

Response: Our continued analysis shows that Medicare nominal case-mix continues to increase. Therefore, we continue to believe it necessary to reduce rates through 2011 to counterbalance the Medicare expenditure effects of this nominal increase. We also continue to believe that phasing in the reductions over a four year period provides fair and ample time for HHAs to prepare for the reductions.

As more current data become available, we will continue to update our case-mix analysis. As discussed in Section III.B. of this proposed rule,

based on analysis of data through 2007, nominal case-mix has further increased. We now estimate that the nominal case-mix has grown by an estimated 13.56 percent between FY 1999 (the Interim Payment System (IPS) baseline period) and 2007, an additional 1.81 percentage points above the previously recognized increase. If we were to account for the entire 13.56 percent increase in nominal case-mix in one year (taking into account that we have already imposed 2.75 percentage reductions in CY 2008 and CY 2009), we estimate that the percentage reduction in the national standardized 60-day episode payment rates and the NRS conversion factor would be 6.89 percent in CY 2010. If we were to account for the entire 13.56 percent increase in nominal case-mix over two years (taking into account that we have already imposed 2.75 percentage reductions in CY 2008 and CY 2009), we estimate that the percentage reduction in the national standardized 60-day episode payment rates and the NRS conversion factor for each of the remaining two years (2010 and 2011) would be 3.51 percent per year. As discussed in Section II.C. of this proposed rule, we currently plan to move forward with the CY 2010 reduction of 2.75 percent, as set forth in the CY 2008 final rule. However, we note that, in light of, among other things, new policy developments, more recent information, or changed circumstances from the time the CY 2008 rule was published, the Secretary is also considering making additional changes in the final rule to account for the residual increase in nominal case-mix discussed above. In such an instance, we would consider accounting for the residual increase in nominal case-mix in one year in the final rule, which we estimate would result in a 6.89 percent reduction to the national standardized 60-day episode payment rates and the NRS conversion factor for CY 2010. We are seeking comments on the full range of potential nominal case-mix reduction percentages.

With high projected HH margins and continued growth in the number of new HH agencies, we do not believe that the 2.71 percent reduction for 2011 will result in decreased access to home health care for Medicare beneficiaries. The Medicare Payment Advisory Commission's (MedPAC) March 2009 Annual Report states that the home health industry margin for 2007 was 16.6 percent and projects that average margins for 2009, which considers the 2.75 reduction, will be 12.2 percent. MedPAC also analyzed the average rate of HH cost growth and found that in

most years, the rate of actual cost growth in HHAs has been lower than the rate of inflation indicated by the home health market basket. MedPAC reports that payments for HHAs have exceeded costs for all of the period under PPS by a wide margin.

Also, in their March 2009 report, MedPAC reports a 32 percent growth in the number of HH agencies since 2003, stating that the supply of agencies continues to increase faster than the growth in the overall number of Medicare beneficiaries. We believe that new home health providers continue to enter the home health industry because Medicare payment levels give them adequate incentive to do so.

In response to commenters who suggested that we consider alternative methods to identify nominal case-mix before we impose the CY 2011 reductions, we continue to believe that the Abt model adequately identifies nominal case-mix. As we described in our August 2007 final rule, our enhanced model included variables such as changes in the age structure of the home health user population, changes in the types of patients being admitted to home health, utilization of Medicare Part A services in the 120 days leading up to home health, the type of preadmission acute care stays when the patient last had such a stay and variables describing living situations. Many of these model enhancements addressed suggestions made by the industry in their proposed rule comments.

B. General Case-Mix Comments

Our August 29, 2007 final rule with comment period solicited comments only on the 2.71 percent fourth year reduction (72 FR 49762). Nevertheless, we received several comments unrelated to the fourth year reduction. Because such comments (including comments on outliers, LUPAs (Low Utilization Payment Adjustments), OASIS, wage index, operational issues, diagnosis coding, HHRGs, and wound care payment) are out of the scope of this rulemaking, we are not responding to these comments in this proposed rule. However, we are responding to comments on case-mix measurement methodology, as we believe such comments are tangentially related to the reduction for CY 2011, and because we wish to fully address this issue.

Comment: A commenter stated that the August 27, 2007 final rule with comment period was not a "logical outgrowth" of the May 4, 2007 proposed rule. The commenter stated that CMS used a different methodology for evaluating case-mix weight scores and

changes in patient characteristics than had been used in the proposed rule. The commenter recommended that CMS engage in another cycle of rulemaking in order to provide further opportunity to comment.

Response: The policy adopted in the August 2007 final rule was a policy that adjusted payments in order to account for increases in nominal case-mix. This policy was both proposed and finalized. The commenter is addressing not the policy of adjusting payments for nominal case-mix increases, but rather, how CMS implements this policy; that is, the methodology CMS uses for determining the level of nominal case-mix increase. While we do not believe we are required to subject our exact, final calculations regarding the increase to public comment, it is also important to note that our final methodology clearly was an outgrowth of the proposed rule. The proposed rule included a detailed analysis of various kinds of data, such as an extensive review of the content of changes in OASIS instructions, a review of changes in the frequencies of severity levels of the case-mix system, and a detailed presentation of how OASIS items other than those used for case-mix frequently changed little, if at all. We also discussed the pattern of change in functional items, showing that for a number of items, some changes occurred at the high-functioning end, while the worst-functioning levels didn't increase in the population. There was a similar analysis of wound item changes. Our interpretation of the totality of the data was that real case-mix did not materially change since the IPS baseline. We also identified a large increase in post-surgical patients with their traditionally lower case-mix index. However, we made an adjustment to our estimate of case-mix change to account for the change in the composition of the home health industry on account of the exit of some hospital-owned agencies. These details enabled the home health industry to analyze our proposed methodology and provide comments suggesting specific types of changes in patient acuity that could help to explain identified changes in home health case-mix. For the final rule, we enhanced our formal estimate of case-mix change, which we had statistically adjusted to account for change in the presence of hospital-owned agencies in the industry, with a methodology that statistically adjusted for multiple factors, including the types of factors mentioned by commenters. Application of this model allowed us to simultaneously "subtract" from the

growth in the national case-mix index the effects of a multitude of factors besides the change in hospital-owned agencies. Additionally, in the May 4, 2007 proposed rule (72 FR 25395) we indicated that our analysis for the final rule would be updated to include 2005 data.

Specifically, for the final rule, we updated the case-mix index and some of the statistical data (e.g., average resources per episode) to include 2005 data. We also added analyses focusing on certain types of patients, including those mentioned in public comments on the proposal (e.g., knee replacement patients). Further, as just discussed in the paragraph above, we added results from a multivariate model of case-mix that isolated real case-mix change between the HH IPS baseline and 2005. The newly added data and the model responded to comments that cited circumstances of particular types of patients and/or sought additional types of evidence. These added data and analyses were made in response to the proposed rule comments. The data and information added for the final rule, along with the entire array of evidence we presented in the proposed and the final rule are the bases for the identification of nominal case-mix change.

Comment: Some commenters focused on the finding that only 8 percent of the case-mix change from 2000 to 2005 was real. These commenters recommended that CMS start with the assumption that all case-mix change is real, and only consider the amount that could be estimated as nominal to be unjustified.

Another commenter pointed to CMS' assertion that "real" case-mix increased prior to implementation of the HH PPS (prior to September 2000) and argued that this fact demonstrates that it was unreasonable for CMS to assume that none of the change after that point was real.

Commenters suggested that case-mix has increased due to several factors, including earlier discharges from general acute hospitals, PPS changes that provided incentives to treat higher-acuity patients, and other post-acute care regulations issued by CMS (such as the inpatient rehabilitation "75% Rule"), which diverts more medically complex patients to homecare. One commenter urged CMS to defer any adjustment for case-mix change and to perform an analysis that accounted for these factors.

Response: The predictive model isolated 8.03 percent of the overall 12.78 percent increase in case-mix as real, resulting in an 11.75 percent nominal increase in case-mix. We relied on those

results to arrive at the nominal case-mix reductions – 2.75 percent for 3 years and – 2.71 percent for the fourth year of the phase-in. (Refer to Section III.B. of this proposed rule for an update based on analysis of data through 2007.) Thus, our model allowed and presumed some real case-mix change. The model data relied on claims data instead of OASIS data (with the exception of one variable, which described the patient's living situation), to avoid reliance on data which we knew were subject to coding changes such as those resulting from educational improvements, changes in OASIS instructions, and financial incentives. The model takes into account the total change between the baseline and the follow-up year (2005) in the sources of patients (hospital, inpatient rehabilitation facility, and skilled nursing facility). It also takes into account total change in the types of acute hospital problems and hospital-recorded comorbidities experienced by patients before they entered home health care, total change in living situation, and total change in patients' Part A expenditures incurred in the 120 days leading up to the beginning of each episode (expenditures were adjusted for price increases). Length of stay is also accounted for by summing the number of inpatient days of various types. Additionally, we added analyses focusing on certain types of patients, including those mentioned in public comments on the proposal (e.g., knee replacement patients).

Every predictive model has its limitations; however, we believe the model and data we used were the best available for the purposes of measuring case-mix in an unbiased manner. For example, we relied on hospital claims data instead of OASIS data (with the exception of one OASIS variable), and enhanced our calculation method to include a multivariate approach to case-mix measurement. For those patients who were hospitalized before home care, the model included whether the hospitalization was surgical or medical, and in many cases the model identified the particular, detailed conditions that were responsible for that hospital stay. These additions to the model were suggested by the industry in comments on the proposed rule.

Moreover, we again note that the Abt model was not the sole basis for the final regulation provision on nominal case-mix change. The basis for the final provision was the entire array of evidence we presented in the proposed and the final rules. In addition, in the May 4, 2007, proposed rule (72 FR 25362–25366) we noted data as well as commentary from observers indicating

that therapy treatment plans were sometimes "padded" to reach the ten-visit therapy threshold; we consider this behavior a component of nominal case-mix change, because therapy visits help to determine the case-mix group.

In response to the comment that CMS should have started with the assumption that all case-mix growth was real, and then calculate what portion, if any, was nominal, the model did assess real case-mix using a variety of Part A claims. We then compared the model's prediction of real case-mix with the actual billed case-mix, determining the calculated difference to be nominal. The May 4, 2007, proposed rule put the case-mix of the Medicare home health population in historical perspective. It described the changes affecting the home health benefit since the Balanced Budget Act of 1997 and cited MedPAC, GAO and other literature findings that the HH IPS had a strong impact on the types of patients served. We compared the case-mix index from the Abt Associates study sample with the case-mix index of the HH IPS baseline (1999–2000), a comparison that suggested that changes in real case-mix did occur as a result of the HH IPS. Literature findings (GAO, "Medicare Home Health Benefit: Impact of Interim Payment System and Agency Closures on Access to Services," September 1998, GAO/HEHS–98–238) describe an HH IPS incentive to admit many different patients with short-term or rehabilitation needs instead of lengthy low skilled care needs. We did not rule out that some of the change during that period was nominal, in part because the HH PPS proposed rule of 1999 probably affected provider behavior.

Moreover, our analysis of changes in resource use showed that resource use stayed below the resource use level of the HH IPS period for much of the succeeding five years, casting doubt on the commenters' assertion that patient acuity increased. Specifically, after the IPS was implemented, we saw a decline in visit use from 73 visits per person in 1997 to 42 visits per person in 1999. The number of visits further decreased under the HH PPS, decreasing to 37 in 2000, and 31 for each year 2001 through 2004.

Comment: A commenter believes that CMS's decision to implement these payment reductions is unjustified and flawed for two basic reasons: (1) There have been actual changes in the home health population; and (2) providers have improved the accuracy of OASIS coding. The commenter refers to recently released data by Outcome Concept Systems citing the average 2005 adjusted case-mix weight nationally and

in New York was approximately 1.15, not 1.2361, as CMS asserts.

The commenter believes that the average case-mix weight has changed because CMS fails to consider therapy as a patient characteristic and because patients' clinical severity has increased. Furthermore, the commenter believes that the increase in patients' clinical needs is largely due to an inpatient hospital payment system that has created incentives for early discharge of patients who require more care. The result is a home health population with higher acuity and more intense resource needs. The commenter also states that growth in Medicare Advantage plans has shifted lower acuity patients out of traditional Medicare, leaving higher need and higher cost beneficiaries within the traditional Medicare program.

A commenter stated that current OASIS data show that HHAs are admitting increased numbers of beneficiaries with: (1) Comorbidities such as diabetes and obesity; (2) abnormalities of gait; (3) wound infections; (4) urinary incontinence; and (5) increased cognitive function deficits. The accumulative effect of these admissions has necessitated increased therapy services which have resulted in higher clinical and functional scores in case-mix weights. In addition, the commenter believes that physical therapy services were underutilized during the HH IPS and at the onset of the HH PPS because of lack of clinical knowledge and understanding of best practice standards. The delivery of medical services in the home has improved over recent years. This is evident by implementation of quality measures and outcomes data. Several commenters believe that the increase in average case-mix can be attributed fully to an improvement in each agency's ability to correctly answer OASIS items and increased emphasis on OASIS validity by Quality Improvement Organizations (QIO). Another commenter stated that their agency has experienced a change in the percentage of orthopedic patients due to changes in regulations for rehabilitation hospitals.

Response: In the May 4, 2007 HH PPS proposed rule, we indicated that the analysis of national case-mix would be updated using 2005 data in that year's HH PPS final rule, and that the annual adjustments for nominal case-mix change would be modified accordingly.

As we have noted elsewhere, improvements in coding do not represent real case-mix changes, which means that the Medicare program arguably may have overpaid for some of the services which were provided after

improvements in OASIS coding were implemented. CMS subsequently adjusted the standardized payment amount to compensate for the nominal change in case-mix used to pay claims in the years following the introduction of the PPS.

We acknowledge that therapy treatment services were used as a case-mix characteristic in the case-mix model, in the absence of sufficient explanatory power from OASIS data items to model resource use by themselves. However, we found a dramatic change in the distribution of episodes according to the number of therapy visits between the HH IPS baseline period and the early years of the HH PPS period, and the new distribution has persisted. We continue to believe that the change in this short period is an indication of behavioral change on the part of home health agencies, and is not necessarily related to real case-mix change. Moreover, the distributional shift occurred in the absence of convincing evidence from various OASIS items that patients were actually more impaired and sickly. Furthermore, when we took account of patient characteristics in the model of real case-mix change, the results did not support a large difference in patient acuity.

We also note that the reporting of more comorbidities by HHAs is not clear evidence of change in patient status, as it could be a result of improvements in coding training alone. In addition, changes in regulations affecting rehabilitation hospitals are represented in the case-mix change model by the variables that measure the source of admission.

To the extent that the home health industry has accomplished improvements in patient function without adding significant resources to the provision of care in home health episodes, we understand this is likely attributable to shifts in the service mix provided within the episode, as well as improved care practices. Again, however, the situation does not necessarily indicate a real change in case-mix.

Without more detailed information about their analysis, we are unable to comment on the implication in the statistic from Outcome Concept Systems in New York State (as reported by the commenter) that the average case-mix rose only 1.15 as compared to 1.2361 in CMS's analysis. The average case-mix is computed from an extremely large representative sample of national home health claims data. The commenter does not provide information about the method of adjustment, the conditions of

data-gathering, or the quality or source of the data sources used by Outcome Concept Systems.

Comment: A commenter stated that CMS' review of 20 percent of claims (OASIS for 2004–2005) does not reflect the patient characteristics in 2007, and it certainly does not reflect those receiving services in 2010 and 2011.

Response: We based our proposals on the latest statistically representative data available, and those data were from 2005 at the time of the preparation of the final regulation. We will continue to update the data as they become available.

Comment: A commenter stated that CMS should look more closely at specific agencies it suspects may be upcoding and then seek financial restitution from those that are ultimately deemed to be following this practice. Across-the-board cuts of this magnitude are unwarranted at a time when the home health industry should be receiving additional support to serve an expanding older population.

Response: As we stated in the CY 2008 HH PPS final rule (72 FR at 49837), we believe that it is more appropriate to implement a nationwide approach to the issue of a case-mix change adjustment. An individual agency approach would be administratively burdensome and difficult to implement. Policies to address the identity of agencies in light of changes to organizational structures and configurations would need to be developed. Furthermore, smaller agencies might have difficulty in providing accurate measures of real case-mix changes because of their small caseloads. Because the nominal increase in case-mix grew significantly from 2003 to 2005 (8.7 percent to 11.75 percent), we spread out the schedule of adjustments from 3 years to 4 years in order to ameliorate the impact that would have been felt by HHAs had we decided to account for the entire 11.75 percent increase in case-mix over 3 years.

Comment: A commenter is concerned that CMS has not correctly addressed factors measuring the apparent "creep". Additionally, the commenter states that it was useful to have CMS clarify that they had excluded LUPAs from the two measurement bases utilized and that fact raises an issue that CMS did not address in the rule. When the original HH PPS was proposed (October 1999) and finalized (July 2000), CMS asserted that it expected LUPA incidence, as estimated by its actuaries, would be five percent. Actual incidence has, since implementation, averaged sixteen percent of total reimbursements. Using

just a five percent rate of occurrence resulted in every original HHRRG assigned a lower value than if CMS had used, say, a fifteen percent rate of incidence. Accordingly, the commenter argues that home health agencies were under-compensated by approximately 11 percent for LUPA savings.

Response: While this comment is outside the scope of the topic (the 4th year reductions) which we solicited comments on, we will briefly respond. In the July 2000 final rule (65 FR 41162), we stated that the estimate of the percentage of LUPA episodes was an actuarial estimate, as were the estimates of incidence of SCICs, PEPs, and outliers. Our base episode payment rates are derived using the best data available at that time. The commenter is correct that the actual number of LUPA episodes is higher than our original estimate. However, while it is true that 16 percent of episodes from the 1998 pre-PPS data analysis were shown to be LUPA-type episodes (65 FR 41186), we also provided reasoning in that discussion as to why we believed actual LUPA incidence under the HH PPS would be lower. Granted, the incidence of LUPAs did not drop to the level of 5 percent of the total number of episodes as was originally estimated, however the average actual incidence of LUPAs is, and has always been considerably lower than the 16 percent suggested by the commenter. In fact, data analysis shows us that the incidence of LUPA episodes was first measured at approximately 15.2 percent of the total number of episodes and has continued to decrease under the HH PPS. Specifically, recent analysis of home health claims shows that LUPA episodes made up approximately 10.6 percent of the total number HH PPS episodes in CY 2007.

Another important fact that should not be lost, as part of this discussion, is that while the incidence of LUPAs is less than originally estimated, we note that the average number of home health visits provided per episode for non-LUPAs episodes is also lower than what we originally estimated (65 FR 41171) when we built the base payment rates (21.16 vs 25.5 home health visits). Hence, the national standardized 60-day episode payment is currently based on the delivery of significantly more home health visits per episode (25.5) than is currently being delivered (21.16).

It is also worth noting that the manner in which the commenter appears to arrive at their under-compensation of payment percentage is by subtracting the original estimate for LUPA episodes of 5 percent from their inaccurate estimate of 16 percent incidence of

LUPA episodes. In addition to the commenters 16 percent being inaccurate (as mentioned above), it is important to point out that even in doing the math, an inaccurate 16 percent minus 5 percent actually reflects that there is an 11 percentage point difference between the two, not an 11 percent under-compensation in payment as the commenter suggests. Because the incidence of LUPAs is considerably lower than the 16 percent that the commenter suggests, and the average number of home health visits per episode is far less than originally estimated, HHAs have not been under-compensated by 11 percent, as the commenter suggests.

Since the inception of the HH PPS, we have monitored home health utilization in preparing the refinements to the HH PPS. We have always contended that it would not be appropriate to address single aspects of the system, as the many pieces/aspects of the system interact and there are causes and effects that each has on one another. Consequently, we have addressed those issues for which we believed we had adequate information, as a result of our analysis in the CY 2008 HH PPS proposed and final rules. In doing so, as is generally done in a prospective payment system, we decided not to make retroactive adjustments for actual utilization that differed from estimates.

III. Provisions of the Proposed Rule

A. Outlier Policy

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the regular 60-day case-mix and wage-adjusted episode payment amount in the case of episodes that incur unusually high costs due to patient home health care needs. This section further stipulates that total outlier payments in a given year may not exceed 5 percent of total projected or estimated HH PPS payments. Section 1895(b)(3)(C) of the Act stipulates that the standard episode payment be reduced by such a proportion to account for the aggregate increase in payments resulting from outlier payments.

In the July 2000 final rule (65 FR 41189), we described and subsequently implemented an HH PPS outlier policy under which we reduce the standard episode payment by 5 percent, and target up to 5 percent of total projected estimated HH PPS payments to be paid as outlier payments. The July 2000 final rule described a methodology for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated cost

exceeds a threshold amount. The episode's estimated cost is the sum of the national wage-adjusted per-visit rate amounts for all visits delivered during the episode. The outlier threshold is defined as the national standardized 60-day episode payment rate for that case-mix group plus a fixed dollar loss (FDL) amount. Both components of the outlier threshold are wage-adjusted. The wage-adjusted FDL amount represents the amount of loss that an agency must experience before an episode becomes eligible for outlier payments. The wage-adjusted FDL amount is computed by multiplying the national standardized 60-day episode payment amount by the FDL ratio, and wage-adjusting that amount. That wage-adjusted FDL amount is added to the HH PPS payment amount to arrive at the wage-adjusted outlier threshold amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated costs beyond the wage-adjusted outlier threshold amount. The proportion of additional costs paid as outlier payments is referred to as the loss-sharing ratio. The FDL ratio and the loss-sharing ratio were selected so that the estimated total outlier payments would not exceed the 5 percent level. We chose a value of 0.80 for the loss-sharing ratio, which is relatively high, but preserves incentives for agencies to attempt to provide care efficiently for outlier cases. A loss-sharing ratio of 0.80 means that Medicare pays 80 percent of the additional costs above the wage-adjusted outlier threshold amount. A loss-sharing ratio of 0.80 is also consistent with the loss-sharing ratios used in other Medicare PPS outlier policies, such as inpatient hospital, inpatient rehabilitation, long-term hospital, and inpatient psychiatric payment systems. In CY 2000, we estimated that a FDL ratio of 1.13 would yield estimated total outlier payments that were projected to be no more than 5 percent of total HH PPS payments. As discussed in the October 1999 proposed rule (64 FR 58169) and the July 2000 final rule (65 FR 41189), the percentage constraint on total outlier payments creates a tradeoff between the values selected for the FDL amount and the loss-sharing ratio. For a given level of outlier payments, a higher fixed dollar loss amount reduces the number of cases that receive outlier payments, but makes it possible to select a higher loss-sharing ratio and therefore increase outlier payments per episode. Alternatively, a lower fixed dollar loss amount means that more episodes qualify for outlier payments but outlier payments per episode must be lower.

Therefore, setting these two parameters involves policy choices about the number of outlier cases and their rate of payment.

When the data became available, we performed an analysis of CY 2001 home health claims data. This analysis revealed that outlier episodes represented approximately 3 percent of total episodes and 3 percent of total HH PPS payments. Additionally, we performed the same analysis on CY 2002 and CY 2003 home health claims data and found the number of outlier episodes and payments held at approximately 3 percent of total episodes and total HH PPS payments, respectively. Based on these analyses and comments we received, we decided that an update to the FDL ratio would be appropriate.

To that end, for the October 22, 2004 HH PPS rate update for the CY 2005 final rule, we performed data analysis on CY 2003 HH PPS claims data. The results of that analysis indicated that a FDL ratio of 0.70 was consistent with the existing loss-sharing ratio of 0.80 and a projected target percentage of estimated outlier payments of no more than 5 percent. Consequently, we updated the FDL ratio from the initial ratio of 1.13 to an FDL ratio of 0.70. Our analysis showed that reducing the FDL ratio from 1.13 to 0.70 would increase the percentage of episodes that qualified for outlier payments from 3.0 percent to approximately 5.9 percent. A FDL ratio of 0.70 also better met the estimated 5 percent target of outlier payments to total HH PPS payments. We believed that this updated FDL ratio of 0.70 preserved a reasonable degree of cost sharing, while allowing a greater number of episodes to qualify for outlier payments.

Our CY 2006 update to the HH PPS rates (70 FR 68132) updated the FDL ratio from 0.70 to 0.65 to allow even more home health episodes to qualify for outlier payments and to better meet the estimated 5 percent target of outlier payments to total HH PPS payments. For the CY 2006 update, we used CY 2004 home health claims data.

In our CY 2007 update to the HH PPS rates (71 FR 65884) we again updated the FDL ratio from 0.65 to 0.67 to better meet the estimated 5 percent target of outlier payments to total HH PPS payments. For the CY 2007 update, we used CY 2005 home health claims data.

In the CY 2008 final rule with comment period, in the interest of using the latest data and best analysis available, we performed supplemental analysis on the most recent data available in order to best estimate the

FDL ratio. That analysis derived a final FDL ratio of 0.89 for CY 2008.

In order to determine the appropriate value for the FDL ratio for the CY 2009 rate update, in the November 3, 2008 HH PPS Rate Update for CY 2009 notice (73 FR 65351), we performed an analysis using the most recent, complete available data at the time (CY 2006), applying a methodology similar to that which we used to update the FDL ratio in the CY 2008 HH PPS final rule. That updated analysis projected that in CY 2009 we would expend an estimated 10.26 percent of total estimated HH PPS payments in outlier payments, more than twice our 5 percent statutory limit. Our analysis also revealed that this growth in outlier payments was primarily the result of excessive growth in outlier payments in a few discrete areas of the country. We noticed statistical anomalies in outlier payments in terms of both high outlier dollars and as a percentage of total HH PPS payments, in areas such as Miami-Dade Florida, where outlier payments to providers far exceed the national average and the 5 percent target for outlier payments. Using similar analysis to what was performed for the CY 2008 final rule with comment, we estimated that we would need to raise our FDL ratio from 0.89 to 2.71 for CY 2009 in order for estimated outlier payments to be no more than 5 percent of total HH PPS payments. In addition, the size of these statistical anomalies raised concerns about the medical necessity of the outlier episodes in some areas. However, in our CY 2009 payment update, we did not raise the FDL ratio to 2.71, given the statistical outlier data anomalies that we identified in certain targeted areas, because program integrity efforts, such as payment suspensions for suspect HHAs, were underway to address excessive, suspect outlier payments that were occurring in these areas. Instead, we maintained the then-current (CY 2008) FDL ratio of 0.89 in CY 2009 while actions to remedy any inappropriate outlier payments in these target areas of the country were effectuated.

2. Proposed Change To Target Outlier Payment Percentage

For CY 2010 rulemaking, we have expanded our outlier analysis. In addition to assessing what FDL ratio would most accurately achieve the 5 percent target of outlier payments as a percentage of total HH PPS payments, we also performed analyses to assess the appropriateness of adopting a lower target percentage of outlier payments to total HH PPS payments. Some commenters to our CY 2008 proposed

rule suggested that CMS should consider targeting a lower percentage in outlier payments to total estimated HH PPS payments.

Commenters suggested that by lowering the target outlier percentage to total estimated HH payments, CMS could then return to the national standardized 60-day episode payment rate, a portion of that 5 percent which was originally withheld from the rates to fund the 5 percent of total estimated HH PPS outlier payments. In our response to the CY 2008 comments, we described our concern that reducing the target outlier percentage could risk access to home care for high needs patients. However, recent analysis of more current data, specifically CY 2007 and CY 2008 data, suggests that a target around that of 2.5 percent in outlier payments to total estimated HH PPS payments may be a more appropriate target than 5 percent, while not risking access to care for high needs patients. Section 1895(b)(5) of the Act states that the Secretary "may" provide for an addition or adjustment to the payment amount otherwise made in the case of outliers. It goes on to say that if the Secretary decides to provide such a payment, that the total amount of the additional payments or payment adjustments may not exceed 5 percent of the total payment projected or estimated to be made under the payment system. Consequently, providing an addition or adjustment to the payment amount for outliers is optional and not statutorily required. We performed an analysis of all providers who receive outlier payments, focusing our analysis on total HH PPS payments, total outlier payments, number of episodes, number of outlier episodes, and location of provider. As discussed below under "Proposed Outlier Cap Policy", our analysis incorporates a proposed 10 percent cap on outliers and looks at outlier payments as a percentage of total HH PPS payments with that 10 percent cap in place. In our analysis of 2007 data, after implementing the 10 percent cap, outlier dollars accounted for approximately 2.1 percent of total HH PPS payments.

Additionally, we performed a separate analysis on a major association of home health agencies who claim to be safety-net providers, serving sicker, more costly patients. The average outlier payment to these agencies is also under 2 percent. Therefore, we believe a target of less than 5 percent for outlier dollars as a percentage of total estimated HH PPS payments is appropriate. However, past years' data trends show us that outlier payments will likely continue to

grow. Consequently, we propose to change our target percentage of outlier payments from 5 percent to approximately 2.5 percent of total estimated HH PPS payments.

Currently, we reduce the national standardized 60-day episode payment rates, the national per-visit rates, the LUPA add-on amount, and the NRS conversion factor by 5 percent in order to create an outlier pool that accommodates estimated outlier payments of 5 percent of total HH PPS payments. Targeting the percentage of outlier payments at approximately 2.5 percent will allow us to create a smaller outlier pool and return the remaining 2.5 percent to the HH PPS rates. We would retain a 2.5 percent reduction to the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor to fund the proposed target of approximately 2.5 percent of total estimated HH PPS payments in outlier payments, adhering to the statutory requirement in Section 1895(b)(3) of the Act.

3. Proposed Outlier Cap Policy

Although program integrity efforts associated with excessive outlier payments continue in targeted areas of the country, we continue to be at risk of exceeding the 5 percent statutory limit on estimated outlier expenditures. Therefore, our recent analysis also focused on whether a broader policy change to our outlier payment policy might also be warranted, to mitigate possible billing vulnerabilities associated with excessive outlier payments, and to adhere to our statutory limit on outlier payments.

We also considered eliminating outlier payments altogether and restoring the 5 percent, originally taken out of the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor to pay for the existing outlier policy, back into the HH PPS rates. Eliminating outlier payments would simplify payments to HHAs and remove the vulnerability associated with inappropriate outlier payments. However, we are concerned that eliminating outlier payments to HHAs could result in denying added protection to HHAs that historically treat sicker, more costly patients.

In attempts to better estimate outlier payments as a percentage of total HH PPS payments and to mitigate vulnerabilities associated with inappropriate outlier payments, we also looked into options that would impose

an outlier cap, at the agency level, such that in any given year, an individual HHA would receive no more than a set percentage of its total HH PPS payments in outlier payments. We performed extensive analyses to model the impact to HHAs of a variety of percent caps in outlier payments. A primary focus of this analysis was to identify HHAs which would be representative of the types of agencies we are most concerned about disadvantaging with an outlier policy that included an outlier cap at the agency level. Our analysis revealed that a 10 percent agency cap in outlier payments would mitigate potential inappropriate outlier billing vulnerabilities while minimizing the access to care risk for high needs patients.

We used CY 2007 claims data to perform a detailed impact analysis. We identified 1137 HH agencies whose outlier payments exceeded 10 percent of their total HH PPS payments in CY 2007. However, we excluded 700 of these agencies from the impact analysis, because these agencies received sizeable outlier payments (totaling at least around \$100,000), had high percentages (at least around 30 percent) of outlier payments to total HH PPS payments, and were located in the counties in FL, TX and CA where we believe possible program integrity issues had been identified.

We targeted our in-depth impact analysis to the remaining 437 agencies, about 5 percent of all Medicare home health agencies. We analyzed these agencies as a group and individually. Our analysis focused on total HH PPS payments, total outlier payments, number of episodes, number of outlier episodes, percentage reductions in payments if a 10 percent outlier cap were imposed, and location. Analyzing CY 2007 data, these 437 agencies would have experienced about a 10 percent decrease in their total HH payments if an outlier cap of 10 percent, at the agency level, were imposed. As we looked closely at the individual 437 agencies, we excluded additional agencies for a number of reasons. Specifically, we excluded 70 agencies that had fewer than 20 Medicare HH episodes, believing that Medicare beneficiaries account for such a small part of their business that they are not representative of the types of agencies we are most concerned about disadvantaging with an outlier cap policy.

We excluded an additional 197 agencies because they are also located in the counties identified as experiencing program integrity problems. While these 197 agencies did not receive exorbitant

outlier payments, their relatively high outlier payment percentages to total agency HH PPS payments led us to suspect inappropriate payments. We believe that the remaining 170 agencies, representing less than 2 percent of all Medicare home health agencies, are representative of the types of agencies we are most concerned about disadvantaging with an outlier policy that included a 10 percent cap at the agency level.

This analysis showed that almost all of the 170 agencies are in urban areas, with only 16 agencies in rural areas. The total number of episodes that resulted in outlier payments is 4,497, about 15 percent of their total episodes. The total HH PPS payments for these agencies equaled about \$85 million in CY 2007. The total outlier payments for these agencies equaled \$14.4 million, representing an average of about 17 percent of their total HH PPS payments. The total amount of payments that would be lost by these providers due to a 10 percent cap would be \$6.6 million, representing an average of approximately 7.9 percent of their total HH PPS payments. However, because most affected agencies are in urban areas, and there is not an access problem with regard to receiving home health services in urban areas, we do not expect that an outlier cap of 10 percent at the agency level would result in any access to care issues.

Additionally, we also performed a separate analysis of the major home health agency association which claims to service a sicker, more costly population. In 2007, only one of these agencies exceeded 10 percent of its total episode payments in outlier payments, receiving approximately 15 percent of its total HH PPS payments in outlier payments.

Finally, we performed an analysis of the impact that imposing an outlier cap of 10 percent at the agency level would have on total outlier payments as a percentage of total HH PPS payments. The FDL ratio for CY 2007 was 0.67. In simulating for 2010 using 2007 data, imposing an outlier cap of 10 percent at the agency level, we estimate that we would pay approximately 2.32 percent of total HH PPS payments in outlier payments.

Therefore, to mitigate possible billing vulnerabilities associated with excessive outlier payments, and to adhere to our statutory limit on outlier payments, we propose to implement an agency level outlier cap such that in any given calendar year, an individual HHA would receive no more than 10 percent of its total HH PPS payments in outlier payments. Additionally, we propose to

reduce the FDL ratio to 0.67 for CY 2010. This combination of a 10 percent agency level outlier cap, and reduced FDL ratio of 0.67, and allowing for future growth in outlier payments, results in a projected target outlier payment outlay of approximately 2.5 percent of total HH PPS payments in outlier payments.

Our analysis demonstrates that approximately 2 percent of HH agencies may experience an average 7.9 percent decrease in payments. This decrease will be mitigated by a 2.5 percent increase in the HH PPS rates, as a result of lowering the outlier pool from 5 percent to 2.5 percent. However, these impacts are averages. Some agencies that legitimately serve a sicker population may experience a larger decrease. Because MedPAC reported in their January 2009 public meeting (<http://www.medpac.gov/transcripts/0108-0109MedPAC.final.pdf>) that Medicare beneficiaries have access to an adequate number of HHAs, we do not believe this policy will result in access to home care issues for high needs patients.

As discussed in the CY 2009 HH PPS Update notice (73 FR 65357), past experience has shown that outlier payments have been increasing as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007. Analysis at the time of the above notice indicated that we could expect outlier payments as a percentage of total HH PPS payments to be approximately 8.1 percent of total payments in CY 2008, and increase to approximately 10.26 percent in CY 2009. Given that predicted trend in outlier payments, we estimated that we would have had to raise our FDL ratio from 0.89 to 2.71 for CY2009 in order to ensure that estimated outlier payments would be no more than 5 percent of total HH PPS payments. We believe that it is the high suspect outlier payments in suspect areas of the country that cause existing data analysis to seemingly require such a high FDL ratio in order to meet the target 5 percent of total HH PPS payments.

Because outlier payments continue to grow, and those outlier payments as a percentage of total HH PPS payments already exceed the statutory limit, absent our proposed outlier cap of 10 percent at the agency level, we would be required to raise the FDL ratio to a level much higher than either the current 0.89 or the proposed 0.67, and doing so would deleteriously affect agencies providing legitimate care to home health beneficiaries. We do not believe that raising the FDL ratio to such a high

level, making it even harder for legitimate episodes to qualify for outlier payments, is the appropriate policy, especially given the fact that we believe it is these high suspect outlier payments in suspect areas of the country that are causing outlier payments as a percentage of total HH PPS payments to continue to increase to levels beyond the existing 5 percent target. Conversely, we believe that our proposed outlier policy that includes a 10 percent cap on outlier payments at the agency level, in concert with a new 2.5 percent outlier pool (as opposed to the existing 5 percent outlier pool), and returning 2.5 percent back into the national standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor, with a 0.67 FDL ratio, would be the appropriate policy at this time. We expect the new outlier policy to curtail approximately \$340 million, in CY 2010, in what we believe to be inappropriate outlier payments.

Finally, CMS will continue to monitor the trends in outlier payments and these policy effects. Specifically, CMS plans to analyze overall national spending on outlier payments relative to the new 2.5 percent outlier pool by geographic area and provider type. CMS also plans on looking at outlier payments, per HHA, relative to the proposed 10 percent cap on outlier payments at the agency level by geographic area and provider type. So far as activities related to high suspect outlier payments, CMS is continuing with program integrity efforts including possible payment suspensions for suspect agencies. If we are unable to see measurable improvements with respect to suspected fraudulent billing practices as they relate to HHA outlier payments, CMS may consider eliminating the outlier policy entirely in future rulemaking.

Proposed implementation approach to a 10 percent agency level outlier cap.

CMS envisions the proposed 10 percent cap on outlier payments at the agency level would be managed by the claims processing system. For each HH provider, for a given calendar year, the claims processing system would maintain a running tally of YTD total HH PPS payments and YTD actual outlier payments. The claims processing system would ensure that each time a claim for a provider was processed; YTD outlier payments for that calendar year could never exceed 10 percent of YTD total HH PPS payments for that provider for that calendar year. As a provider's claims (RAPs and final claims) were processed and YTD HH PPS payments for that calendar year increased throughout the course of the year, the

claims processing system would be triggered to pay outlier payments, adjusting prior final claims by paying previously unpaid outlier payments, as the YTD total HH PPS payments for that calendar year allowed, never exceeding 10 percent of total YTD HH payments for that calendar year. In cases where a provider submitted a claim with an outlier payment early in the year when YTD total HH PPS payments for that calendar year were low, outlier payments would be delayed until YTD total HH PPS payments for that calendar year reached a level to pay the outlier payment.

More specifically, instead of a given claim being readjusted several times as total HH PPS payments increase, but not enough to pay an entire outlier payment on a given claim, we are considering a process by which an outlier payment on a previous claim would not be adjusted until total HH PPS payments for that calendar year were such that the entire outlier payment could be made without exceeding 10 percent of total HH PPS payments for a particular HHA for that calendar year. Doing so would avoid not only the cost of possible multiple adjustments to a given claim, but would also simplify the process making adjustments easier to track and understand. We solicit comments on these proposed outlier policy changes.

B. Case-Mix Measurement Analysis

In the CY 2008 HH PPS final rule with comment period, we stated that we would continue to monitor case-mix changes in the HH PPS and to update our analysis to measure change in case-mix, both nominal and real. We have continued to monitor case-mix changes and our latest analysis supports the payment adjustments which we implemented in the CY 2008 HH PPS.

We have updated our examination of five conditions that commenters on our case mix change adjustment suggested indicate a real case mix change. This analysis was originally summarized as Table 8 in the August 29, 2007, final rule. The updated results (see Table 1 below) show that the shares of episodes preceded by a hospital discharge for hip fracture, congestive heart failure, and cerebrovascular accident have continued to decline since the IPS baseline. The percent share for hip and knee replacements rose and then began to decline slightly around the middle of the time series shown. (**Note:** Data since 2005 for joint replacements differ slightly from the original Table regarding the five conditions published in the August 29, 2007, Final Rule because we changed our methodology to recognize several ICD-9 procedure code

changes that affected joint replacements). The increase in joint replacements as a proportion of all episodes was not sustained at the 2004–2005 level by the end of the period, perhaps because whatever mechanism operated to cause the growth lost some of its strength, or perhaps because even faster growth occurred in other types of episodes (such as outlier episodes and/or later episodes).

Our interpretation of these trends in the Aug. 29, 2007, Final Rule was that, with the possible exception of knee replacements, the trends observed at that time were not clearly indicative of a more-severe case mix. If anything, the sustained downward trend for hip fracture, CHF, and CVA suggests that the burden of these diseases on home health providers is lighter now than it used to be. For hip replacement, the share appears to have ended up (thus far) below the share of such patients during the IPS period. For knee

replacements, it appears that shares may have ceased climbing. Our interpretation of the knee replacement trend in the August 29, 2007, final rule was that this category constituted a small share, that the Abt case mix change model took account of it, and that based on the model results the knee replacement change apparently was not enough to move the estimate of real case mix change very much. The updated data now suggest that knee replacements leveled off as a share of total episodes since around 2005. As a result, we have not changed our interpretation of the trends in episode shares for these five conditions.

Our estimates of average number of days from hospital discharge to entrance into home health was an attempt to examine the hypothesis that patients were entering home health in a more sickly condition. We did not see any evidence of that for the three medical conditions; the number of days prior to

entering home health exhibits no clear trend. For joint replacements, as in the earlier analysis, we saw a continuing decline in the average number of days prior to entering home health. These patients may present in a more sickly condition than was the case under IPS, but they are no longer a growing share of the HH caseload and represent slightly less than 4% of the episodes. Combined with the downward or stabilizing trends in the shares for all five conditions, the shortening of the time period to admission for the two joint replacement conditions does not suggest an overall more-acute case mix, at least as indicated by these five conditions. As we noted in the CY 2008 final rule, the Abt Associates model simultaneously takes account of all of the kinds of patients incurring home health episodes, including the five conditions detailed here.

TABLE 1

		FY2000	CY2001	CY2002	CY2003	CY2004	CY2005	CY2006	CY2007	CY2008 *
Hip fracture	pct share	0.82	0.83	0.75	0.73	0.70	0.62	0.56	0.50	0.48
	days prior to entering	7.19	7.12	7.17	7.21	7.30	7.10	7.08	7.20	7.00
Congestive heart failure.	pct share	3.31	3.06	2.96	2.89	2.72	2.45	2.23	1.95	2.06
	days prior to entering	3.38	3.28	3.35	3.33	3.36	3.40	3.40	3.53	3.55
Cerebrovascular accident.	pct share	1.52	1.45	1.40	1.29	1.15	1.03	0.92	0.85	0.82
	days prior to entering	4.32	4.23	4.21	4.29	4.20	4.32	4.31	4.42	4.59
Hip replacement	pct share	1.47	1.65	1.64	1.59	1.63	1.49	1.38	1.33	1.27
	days prior to entering	6.45	6.32	6.26	6.29	5.92	5.56	5.30	5.01	4.78
Knee replacement	pct share	1.89	2.20	2.31	2.44	2.59	2.74	2.62	2.49	2.64
	days prior to entering	5.40	5.30	5.42	5.19	4.93	4.60	4.25	3.99	3.71

Note: Based on a 10% beneficiary HH user sample.

* CY 2008 data for first quarter of the year only.

In the course of updating the estimate of real case-mix change, our analysis contractor, Abt Associates, discovered a number of errors in data handling for the case-mix change model. The analysis files included relatively small numbers of records that should have been excluded, and relatively small numbers that were dropped but that should have been included. Another error was in the handling of missing data for one of the key variables in the regression model (patient's living situation); data were not recognized as missing and were therefore miscoded. Methodologically, an improvement was implemented to ensure that the observation period for the IPS baseline sample was consistent with the observation period for the PPS sample (2005).

Abt Associates made corrections in response to each problem identified. The only significant change in results

came from correcting the handling of missing data. Correcting this error (by imputing values for cases with missing data) caused an increase in the estimated real change in case-mix. Our original estimate, published in the CY 2008 HH PPS final rule (72 FR 49842), was that about 8.03 percent of the increase in case-mix between the IPS baseline (1999–2000) and 2005 was due to actual changes in patient characteristics (*i.e.*, “real”). After this correction, the real case-mix change estimate for the same period increased by several percentage points. Had the data corrections and improvements been implemented in the CY 2008 HH PPS final rule, our estimate of real case-mix change, as a percentage of total case-mix change, would have been approximately 14.15 percent as opposed to 8.03 percent (73 FR 49833, 49842). Updating that analysis, using PPS data from 2006, our best estimate of real case-mix

change, as a percentage of total case-mix change, is slightly lower (11.45 percent). This is due to the combination of continued strong annual growth between 2005 and 2006 in the average case-mix weight, along with little change between 2005 and 2006 in patient characteristics.

We have further updated our case-mix analysis, for this rule, using PPS data from 2007. That analysis indicated a 15.03 percent increase in the overall observed case-mix since 2000. We next determined what portion of that increase was associated with a real change in the actual clinical condition of home health patients. As was done for the CY 2008 final rule, using Abt Associates' 6-phase model, we examined data on demographics, family support, pre-admission location, clinical severity, and non-home health Part A Medicare expenditure data to predict the average case-mix weight for 2007.

As such, our best estimate is that approximately 9.77 percent of the 15.03 percent increase in the overall observed case-mix between the IPS baseline and 2007 is real, that is, due to actual changes in patient characteristics.

The estimate of real case-mix change continues to decrease for a number of reasons: First, because the nominal change in case-mix continues to grow, real case-mix as a percentage of the total change/increase in case-mix becomes less. With each successive sample, beginning with 2005 data (in the CY 2008 final rule), the predicted average national case-mix weight is moving very little because the variables in the model used to predict case-mix are not changing much. At the same time, the actual average case-mix continues to grow steadily. Thus, the gap between the predicted case-mix value, which is based on information external to the OASIS, and the actual case-mix value, grows with each successive sample. Consequently, as a result of this analysis, CMS recognizes that a 13.56 percent nominal increase $((15.03 - (15.03 \times 0.0977))$ in case-mix is due to changes in coding practices and documentation rather than to treatment of more resource-intensive patients.

To compensate for this growth over four years, an increase of this magnitude (13.56 percent), had it existed when the CY 2008 final rule was published, would have implied reductions in the rates of 3.13 percent per year for 4 years (CY 2008–CY 2011). We stated in our CY 2008 HH PPS proposed and final rules that we might find it necessary to adjust the offsets as new data became available. Given that we have adjusted the rates for two consecutive years by -2.75 percent in each year, based on 2007 data available for this proposed rule, if we were to account for the residual increase in nominal case-mix over the next two years, maintain our existing policy of a -2.75 percent case-mix change in 2010, and account for the residual increase in nominal case-mix in 2011, we estimate that the percentage reduction in the rates for nominal case-mix change in 2011 would be 4.26 percent. If we were to account (in the final rule) for the full residual increase in nominal case-mix in CY 2010, we estimate that the percentage reduction to the national standardized 60-day episode rates and the NRS conversion factor would be 6.89 percent. Similarly, if we were to account (in the final rule) for the full residual increase in nominal case-mix in two years, we estimate that the percentage reduction to the national standardized 60-day episode payment rates and the NRS conversion factor would be 3.51 percent, per year, in CY

2010 and CY 2011. We are planning to move forward with our existing policy, as implemented in the August 22, 2007 HH PPS Refinement and Rate Update for CY 2008 final rule with comment, of imposing a 2.75 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor for CY 2010. We are accepting comments on the reduction percentages. We will continue to monitor any future changes in case-mix as more current data become available. Given the continued growth in nominal case-mix, we expect to revise, upward, the 2.71 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor for CY 2011 in next year's rule. Analysis in next year's rule will update the measure of the nominal increase in case-mix and compute the appropriate percent reduction to the national standardized 60-day episode rates and the NRS conversion factor to account for that increase.

We may update the above-mentioned analysis for the final rule in a number of ways. We have been assembling data to enhance the Abt model to take into account factors that might have been unmeasured in the original model. We plan to introduce diagnostic summaries created from a broader sweep of the patient's claims history, including Part B claims. Specifically, we may add information from the Medicare Hierarchical Coexisting Condition (HCC) data file to identify diagnoses for home health users and their impact on the predicted real case-mix weight. The HCC system is used for risk adjustment in Part C of the Medicare program. CMS annually produces an HCC record containing diagnosis flags and an HCC "score" for every beneficiary. The diagnoses used for HCC risk adjustment come from hospital inpatient claims (primary and secondary diagnoses) (including rehabilitation, long-term, and psychiatric hospitals), hospital outpatient department claims, physician claims, and claims from clinically trained nonphysicians such as podiatrists, psychologists, and physical therapists. Until now, diagnostic information for the Abt model came from Part A inpatient claims only.

Commenters have suggested that we take into account changes in the role of managed care in the Medicare program. These commenters stated that growth in managed care enrollment implies a generally sicker population remaining in the fee-for-service program; a change in home health users' general health status might be reflected in OASIS items that determine the episode's HHRG. Medicare managed care began to grow modestly in 2004, but growth

accelerated in 2006. Therefore, another enhancement that we may test is a variable measuring managed care penetration in the beneficiary's area; this variable is intended to capture any possible effects of attrition from FFS Medicare due to growing enrollment in Medicare Advantage plans. Attrition might result in the exit of relatively healthy beneficiaries from the FFS program, leaving a population in FFS whose average health status worsens over time. It is only the FFS population that is at risk for home health benefit use in the HH PPS.

C. Proposed CY 2010 Rate Update

1. The Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires for CY 2010 that the standard prospective payment amounts be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary.

The proposed HH PPS market basket update for CY 2010 is 2.2 percent. This is based on Global Insight Inc.'s first quarter 2009 forecast, utilizing historical data through the fourth quarter 2008. A detailed description of how we derive the HHA market basket is available in the CY 2008 Home Health PPS proposed rule (72 FR 25356, 25435).

2. Home Health Care Quality Improvement

Section 1895(b)(3)(B)(v)(II) of the Act requires that "each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause." In addition, section 1895(b)(3)(B)(v)(I) of the Act dictates that "for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points." This requirement has been codified in regulations at § 484.225.

CMS published information about the quality measures in the **Federal Register** as a proposed rule on May 4, 2007 (72 FR 25449, 25452) and as a final rule with comment period on August 29, 2007 (72 FR 49861, 49864). We proposed and made final the decision to use a subset of OASIS data that is

publicly reported on Home Health Compare as the appropriate measure of home health quality.

Reporting these quality data has also required the development of several supporting mechanisms such as the HAVEN software, used to encode and transmit data using a CMS standard electronic record layout, edit specifications, and data dictionary. The HAVEN software includes the required OASIS data set that has become a standard part of HHA operations. These early investments in data infrastructure and supporting software that CMS and HHAs have made over the past several years in order to create this quality reporting structure have been successful in making quality reporting and measurement an integral component of the HHA industry.

Development and selection of home health quality measures is a constant and dynamic process based on the characteristics and needs of the population served. A total of 54 quality measures are currently reported to home health agencies for use in their Outcomes Based Quality Improvement (OBQI) activities. Every three years a selection of Home Health quality measures are submitted to the National Quality Forum (NQF) for consideration and endorsement through their consensus process. A subset of measures are chosen by CMS for public reporting on the Home Health Compare Web site. The following twelve measures are currently publicly reported:

- Improvement in ambulation/locomotion,
- Improvement in bathing,
- Improvement in transferring,
- Improvement in management of oral medications,
- Improvement in pain interfering with activity,
- Acute care hospitalization,
- Emergent care,
- Discharge to community,
- Improvement in dyspnea,
- Improvement in urinary incontinence,
- Improvement in status of surgical wounds, and
- Emergent care for wound infections, deteriorating wound status.

Accordingly, for CY 2010, we propose to continue to use submission of OASIS data and the quality measures that are publicly reported on Home Health Compare to meet the requirement that the HHA submit data appropriate for the measurement of health care quality. Continuing to use the specified measures from the OASIS instrument for purposes of measuring health care quality ensures that providers will not have an additional burden of reporting

through a separate mechanism, and that the costs associated with the development and testing of a new reporting mechanism can be avoided.

We are proposing for CY 2010 to consider OASIS assessments submitted by HHAs to CMS in compliance with HHA conditions of participation for episodes beginning on or after July 1, 2008 and before July 1, 2009 as fulfilling the quality reporting requirement for CY 2010. This time period would allow 12 full months of data collection and would provide us the time necessary to analyze and make any necessary payment adjustments to the payment rates in CY 2010 and each year thereafter. We propose to reconcile the OASIS submissions with claims data in order to verify full compliance with the quality reporting requirements in CY 2010 and each year thereafter on an annual cycle July 1 through June 30 as described above.

As set forth in the CY 2008 final rule with comment period (72 FR 49863), agencies do not need to submit quality measures for reporting purposes for those patients who are excluded from the OASIS submission requirements under the Home Health Conditions of Participation (CoP). The conditions of participation (42 CFR 484.200–484.265) that require submission also provide for exclusions from this requirement if:

- Those patients are receiving only non-skilled services,
- Neither Medicare nor Medicaid is paying for home health care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement),
- Those patients are receiving pre- or post-partum services, or
- Those patients are under the age of 18 years.

As set forth in the CY 2008 final rule with comment period (72 FR 49863), agencies that certify on or after May 31 of the preceding year involved are excluded from any payment penalty for quality reporting purposes for the following CY. Therefore, HHAs that are certified on or after May 1, 2009 are excluded from the quality reporting requirement for CY 2010 payments since data submission and analysis will not be possible for an agency certified this late in the reporting time period. At the earliest time possible after obtaining the CMS Certification Number (CCN), reporting would be mandatory. These exclusions only affect quality reporting requirements and do not affect the HHA's reporting responsibilities under the CoP.

HHAs that meet the reporting requirements would be eligible for the

full home health market basket percentage increase. HHAs that do not meet the reporting requirements would be subject to a 2 percent reduction to the home health market basket increase. We provide the proposed payment rates in Tables 1, 2, and 3.

Section 1895(b)(3)(B)(v)(III) of the Act further requires that “[t]he Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.” To meet the requirement for making such data public, we propose to continue using the *Home Health Compare* Web site, which lists HHAs geographically. Currently, the Home Health Compare Web site lists 12 quality measures from the OASIS set as described above. The Home Health Compare Web site is located at the following Web address: <http://www.medicare.gov/HHCompare/Home.asp>. Each HHA currently has pre-publication access (through the CMS contractor) to its own quality data (which the contractor updates periodically). We plan to continue this process, to enable each agency to view its quality measures before public posting of data on *Home Health Compare*.

CMS is requesting OMB approval to modify the OASIS data set. This process is in the final stages of OMB clearance. Pending OMB approval, CMS intends to implement the use of the OASIS–C (Form Number CMS–R–245 (OMB# 0938–0760)) on January 1, 2010. This revision to the current OASIS version B–1 has undergone additional testing as part of the information collection request approved under OMB control number 0938–1040. As part of the OMB approval process, the revision to the current OASIS version was also distributed for public comment and other technical expert recommendations over the past few years. We propose that this new version of OASIS be collected on episodes of care with a corresponding OASIS item (M0090) date of January 1, 2010 or later. The OASIS–C can be found using the following link: <http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1217682&intNumPerPage=10>.

We are also planning to update *Home Health Compare* to reflect the addition of the following 13 new process of care measures:

- Timely initiation of care,

- Influenza immunization received for current flu season,
- Pneumococcal polysaccharide vaccine ever received,
- Heart failure symptoms addressed during short-term episodes,
- Diabetic foot care and patient education implemented during short-term episodes of care,
- Pain assessment conducted,
- Pain interventions implemented during short-term episodes,
- Depression assessment conducted,
- Drug education on all medications provided to patient/caregiver during short-term episodes.
- Falls risk assessment for patients 65 and older,
- Pressure ulcer prevention plans implemented,
- Pressure ulcer risk assessment conducted, and
- Pressure ulcer prevention included in the plan of care.

Also under consideration are three additional process of care measures that may be added to Home Health Compare based on results of consumer testing. Those additional process measures are:

- Drug education on high risk medications provided to patient/caregiver at start of episode;
- Potential medication issues identified and timely physician contact at start of episode;
- Potential medication issues identified and timely physician contact during episode.

The implementation of OASIS-C will impact the quality data reporting requirement for the CY 2011 HH PPS. However, we expect the conversion from OASIS-B1 to OASIS-C to have little to no impact on HHAs' ability to meet the quality data reporting requirements under Section 1895(b)(3)(B)(v).

For CY 2011, CMS proposes to expand the home health quality measures reporting requirements to include the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey (pending OMB approval). The CAHPS® Home Health Care Survey (hereafter "HHCAHPS") is a quality tool that we believe that we can use to collect quality of care data, as required by section 1895(b)(3)(B)(v)(II) of the Act, and as permitted under section 1861(o)(8) of the Act, which requires any Medicare participating HHA to "meet [] such additional requirements * * * as the Secretary finds necessary for the effective and efficient operation of the program". The HHCAHPS data collection will support the effective and efficient operation of the program because patients' feedback on their

perspectives of the home health quality of care from the agency cannot be obtained from any other quality measure in the program. The Home Health Care Survey is part of a family of CAHPS® surveys that ask patients to report on and rate their experiences with health care. The HHCAHPS survey developed by the Agency for Healthcare Research and Quality (AHRQ), which is part of the Department of Health and Human Services, presents home health patients with a set of standardized questions about their home health care providers and the quality of their home health care. Prior to this survey, there was no national standard for collecting information about patient experiences that would enable valid comparisons across all HHAs.

AHRQ developed the HHCAHPS survey with the assistance of many entities (for example, government agencies, professional stakeholders, consumer groups and other key individuals and organizations involved in home health care). The HHCAHPS survey was designed to measure and assess the experiences of those persons receiving home health care with the following three goals in mind:

- To produce comparable data on patients' perspectives of care that allow objective and meaningful comparisons between home health agencies on domains that are important to consumers;
- To create incentives for agencies to improve their quality of care through public reporting of survey results; and
- To hold health care providers accountable by informing the public about the providers' quality of care (<http://www.homehealthcahps.org>).

These three goals support Section 1861(o)(8) of the Act, which requires any Medicare participating HHA to "meet [] such additional requirements * * * as the Secretary finds necessary for the effective and efficient operation of the program."

The development process for the survey began in 2006 and included a public call for measures, review of the existing literature, consumer input, stakeholder input, public response to **Federal Register** notices, and a field test conducted by AHRQ. AHRQ conducted this field test to validate the length and content of the HHCAHPS survey. CMS submitted the survey to the National Quality Forum (NQF) for consideration and endorsement via their consensus process. NQF endorsement represents the consensus opinion of many healthcare providers, consumer groups, professional organizations, health care purchasers, Federal agencies and research and quality organizations. The

survey received NQF endorsement on March 31, 2009.

The HHCAHPS survey includes 34 questions that cover topics such as specific types of care provided by home health providers, communication with providers, interactions with the HHA, and global ratings of the agency. For public reporting purposes, CMS will utilize composite measures and global ratings of care. Each composite measure consists of four or more questions that ask about one of the following related topics:

- Patient care;
- Communications between providers and patients;
- Specific care issues (medications, home safety and pain).

There are also two global ratings; the first rating asks the patient to assess the care given by the HHA's care providers, and the second asks the patient about his/her willingness to recommend the HHA to family and friends.

We are proposing two options for administering the HHCAHPS survey. The agency can choose to administer the existing HHCAHPS survey, or the HHA can integrate additional questions within the HHCAHPS survey. If an agency chooses to implement an integrated survey, the core questions from the HHCAHPS survey (questions 1 through 25) must be placed before any specific/supplemental questions that the HHA wishes to add to the survey. Questions 26 through 34 (the "About You" survey questions) must be administered as a unit—although they may be placed either before or after any supplemental questions that the HHA wishes to add to the HHCAHPS survey. If no HHA-specific questions are to be added to the HHCAHPS survey, the "About You" questions should follow the core questions (numbered 1 through 25) on the HHCAHPS survey.

The survey is currently available in both English and Spanish. HHAs and their survey vendors will *not* be permitted to translate the HHCAHPS survey into any other languages on their own. However, CMS will provide additional translations of the survey over time. The Web site <https://www.homehealthcahps.org> will provide information about the subsequent availability of additional translations. CMS also solicits user suggestions for any additional language translations. Such suggestions should be submitted online to the HHCAHPS Survey Coordination Team, at HHCAHPS@rti.org. HHAs interested in learning about the survey are encouraged to view the HHCAHPS survey Web site, at [https://](https://www.homehealthcahps.org)

www.homehealthcahps.org. Agencies can also call toll-free 1-866-354-0985, or send an e-mail to the HHCAHPS Survey Coordination Team at HHCAHPS@rti.org for more information.

The following types of home health care patients will be considered eligible to participate in the HHCAHPS survey:

- Current or discharged patients who had at least one home health visit at any time during the sample month;
- Patients who were at least 18 years of age at any time during the sample period, and are believed to be alive;
- Patients who received *at least two visits* from HHA personnel during a 60-day look-back period (Note that the 60-day look-back period is defined as the 60-day period prior to and including the last day in the sample month.);
- Patients who have not been selected for the monthly sample during any month in the current quarter or during the 5 months immediately prior to the sample month;
- Patients who are not currently receiving hospice care;
- Patients who do not have routine "maternity" care as the primary reason for receiving home health care; and
- Patients who have *not* requested "no publicity status."

CMS has modeled HHCAHPS after the Hospital CAHPS survey where both the CAHPS and clinical data are collected for both Medicare and non-Medicare patients to get a complete picture of hospital quality. Since HHCAHPS data used to develop case-mix collection of data for HHCAHPS are not carried out under the auspices of section 4602(e) of the BBA, such collections are not subject to the OASIS limitation to Medicare and Medicaid patients only, set out under section 704(a) of the MMA. To collect and submit HHCAHPS data to CMS, Medicare-certified agencies will need to contract with an approved HHCAHPS survey vendor. Interested vendors can now apply to become approved HHCAHPS vendors. The application process is delineated online at <https://www.homehealthcahps.org>. Vendors will also be required to attend training conducted by CMS and the HHCAHPS Survey Coordination Team. HHAs that are interested in participating in the HHCAHPS survey may do so on a voluntary basis for the remaining months of 2009. Such agencies must select a vendor from the list of HHCAHPS approved survey vendors. This listing will be available on the Web site <https://www.homehealthcahps.org> during the summer of 2009.

CMS proposes that beginning in the first quarter of CY 2010, all Medicare-certified HHAs shall begin to collect the

CAHPS® Home Health Care (HHCAHPS) survey data in accordance with the Protocols and Guidelines Manual located on the HHCAHPS Web site <https://www.homehealthcahps.org>. HHAs shall contract with approved HHCAHPS survey vendors that are posted on <https://www.homehealthcahps.org> to conduct the survey on behalf of HHAs. CMS proposes that participating home health agencies conduct a dry run of the survey for at least one month in the first quarter of 2010 (January, and/or February, and/or March 2010), and submit the dry run data to the Home Health CAHPS® Data Center by 11:59 p.m. EST on June 23, 2010. The dry run data would not be publicly reported on the *Home Health Compare*. This dry run would provide an opportunity for vendors and HHAs to acquire first-hand experience with data collection, including sampling and data submission to the Home Health CAHPS® Data Center, with no public reporting of the results. CMS proposes that all Medicare-certified HHAs continuously collect HHCAHPS survey data every quarter beginning in the second quarter (April, May and June) of 2010, and submit these data for the second quarter of 2010 to the Home Health CAHPS® Data Center by 11:59 p.m. EST on September 22, 2010. CMS proposes that these data submission deadlines are firm; that is, there will be no late submissions allowed.

The Medicare-certified HHAs will need to provide their respective survey vendors with information about their survey-eligible patients (either current or discharged) every month in accordance with the Protocols and Guidelines Manual posted on <https://www.homehealthcahps.org>. The details about selecting the HHA sample are delineated in the Protocols and Guidelines manual on the Web site <https://www.homehealthcahps.org>. It is proposed that the HHCAHPS survey data be submitted and analyzed quarterly, and that the sample selection and data collection occur on a monthly basis. HHAs should target 300 HHCAHPS survey completes annually. Smaller agencies that are unable to reach 300 survey completes by sampling should survey all HHCAHPS eligible patients. For reasons of statistical precision, a target minimum of 300 or more completed Home Health CAHPS surveys has been set for each home health agency. 300 completes is based on a reliability target of 0.8 or higher. We propose that survey vendors initiate the survey for each monthly sample within three weeks after the end of the sample month. All data collection for

each monthly sample would have to be completed within six weeks (42 days) after data collection began. CMS has approved three modes of the survey to be used: Mail only, telephone only, and mail with telephone follow-up (the "mixed mode"). We are proposing that for mail-only and mixed-mode surveys, data collection for a monthly sample would have to end six weeks after the first questionnaire was mailed. For telephone-only surveys, data collection would have to end six weeks following the first telephone attempt.

CMS is aware that there is a wide variation in the size of Medicare-certified HHAs. CMS proposes that the requirement to collect HHCAHPS survey data be waived for agencies that serve fewer than 60 HHCAHPS eligible patients annually. We are proposing this threshold amount in order to exempt agencies that serve a very small home health eligible population. These agencies serve, on average, 5 or fewer patients per month. The HHCAHPS eligible, unduplicated patient counts for the period of October 1 through September 30 for a given year would be used to determine if the HHA would have to participate in the HHCAHPS survey in the next calendar year. If a Medicare-certified HHA had fewer than 60 eligible, unduplicated HHCAHPS eligible patients for the period October 1 through September 30, then they would be excluded from the HHCAHPS requirement for the next calendar year. For example, if a small HHA had 85 patients in the period October 1, 2008 through September 30, 2009, and 45 of the patients were routine maternity patients, then there would only be 40 HHCAHPS eligible patients. This agency would therefore not be required to participate in the HHCAHPS survey. Alternatively, if a small HHA had 85 patients for the period October 1, 2008 through September 30, 2009, and 70 of these patients were eligible to participate in the HHCAHPS survey (*i.e.*, because they: (1) Were 65 years or older; (2) were recently discharged from the hospital to their homes; (3) were not receiving hospice care; (4) were not designated as "no publicity" patients; and (5) had received at least two home health visits) this agency would be required to participate in the HHCAHPS survey. Only Medicare-certified HHAs with fewer than 60 eligible, unduplicated patients for the period October 1, 2008 through September 30, 2009 would submit their patient counts to the HHCAHPS Data Center by Wednesday, January 13, 2010.

We also propose that newly Medicare-certified HHAs (that is, those certified on or after January 1, 2010 for payments

to be made in CY 2011) be excluded from the HHCAHPS survey reporting requirement, as data submission and analysis would not be possible for an agency so late in the reporting period. In future years, agencies that first certify on or after January 1 of the preceding year would be excluded from any payment penalty for reporting purposes in the following CY. We note that this exclusion for new HHAs pertains only to the HHCAHPS survey reporting requirement.

CMS strongly recommends that HHAs participating in the HHCAHPS survey promptly review the required Data Submission Summary Reports that are delineated in the Protocols and Guidelines Manual posted on <https://www.homehealthcahps.org>. These reports will enable the HHA to ensure that its survey vendor has submitted their data on time, and that the data have been accepted/received by the Home Health CAHPS® Data Center.

CMS anticipates first reporting HHCAHPS survey data in early 2011 on *Home Health Compare*. The HHCAHPS survey data would be updated quarterly. HHAs would be provided a preview of the data each quarter before it was reported on *Home Health Compare*.

CMS proposes that vendors and HHAs be required to participate in HHCAHPS survey oversight activities to ensure compliance with HHCAHPS survey protocols, guidelines and survey requirements. The purpose of the oversight activities is to ensure that HHAs and approved survey vendors follow the Protocols and Guidelines Manual. It is proposed that all approved survey vendors develop a Quality Assurance Plan (QAP) for survey administration in accordance with the Protocols and Guidelines Manual. The QAP should include the following:

- Organizational chart;
- Work plan for survey implementation;
- Description of survey procedures and quality controls;
- Quality assurance oversight of on-site work and of all subcontractors work; and
- Confidentiality/Privacy and Security procedures in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

As part of the oversight activities the HHCAHPS Survey Coordination Team would conduct on-site visits or conference calls. The HHCAHPS Survey Coordination Team would review the survey vendor's survey systems, and will assess administration protocols based on the Protocols and Guidelines Manual posted on <https://www.homehealthcahps.org>. All

materials relevant to survey administration would be subject to review. The proposed systems and program review would include, but not be limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) data receipt, entry and storage facilities; and (d) written documentation of survey processes. Organizations would be given a defined time period in which to correct any problems and provide follow-up documentation of corrections for review. Survey vendors will be subject to follow-up site visits as needed.

CMS strongly recommends that all HHAs participating in the HHCAHPS survey regularly check the Web site, <https://www.homehealthcahps.org> for program updates and information.

As mandated in current law, all HHAs, unless covered by specific exclusions, will continue to be required to meet the quality reporting requirements or be subject to a 2 percent reduction in the home health market basket percentage increase in accordance with section 1895(b)(3)(B)(v)(I) of the Act. A reconsideration and appeals process is being developed for HHAs who fail to meet the HHCAHPS reporting requirements. These procedures would be outlined in the HH PPS proposed rule for CY 2011 in which we are proposing that the HHCAHPS survey would be linked to home health payment, as a requirement under the regulation requiring the reporting of quality data.

3. Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to establish area wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services and to provide appropriate adjustments to the episode payment amounts under the HH PPS to account for area wage differences. As discussed previously, we apply the appropriate wage index value to the labor portion (77.082 percent) of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence). Generally, we determine each HHA's labor market area based on definitions of Metropolitan Statistical Areas (MSAs) issued by the Office of Management and Budget (OMB). We have consistently used the pre-floor, pre-reclassified hospital wage index data to adjust the labor portion of the HH PPS rates. We believe the use of the pre-floor, pre-reclassified hospital wage index data

results in the appropriate adjustment to the labor portion of the costs as required by statute.

In the November 9, 2005 final rule for CY 2006 (70 FR 68132), we adopted revised labor market area definitions based on Core-Based Statistical Areas (CBSAs). At the time, we noted that these were the same labor market area definitions (based on OMB's new CBSA designations) implemented under the Hospital Inpatient Prospective Payment System (IPPS). In adopting the CBSA designations, we identified some geographic areas where there are no hospitals and, thus, no hospital wage data on which to base the calculation of the home health wage index. We continue to use the methodology discussed in the November 9, 2006 final rule for CY 2007 (71 FR 65884) to address the geographic areas that lack hospital wage data on which to base the calculation of their home health wage index. For rural areas that do not have IPPS hospitals, we use the average wage index from all contiguous CBSAs as a reasonable proxy. This methodology is used to calculate the wage index for rural Massachusetts. However, we could not apply this methodology to rural Puerto Rico due to the distinct economic circumstances that exist there, but instead continue using the most recent wage index previously available for that area (from CY 2005). For urban areas without IPPS hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. The only urban area without IPPS hospital wage data is Hinesville-Fort Stewart, Georgia (CBSA 25980).

On November 20, 2008, OMB issued Bulletin No. 09-01 located at Web address <http://www.whitehouse.gov/omb/bulletins/fy2009/09-01.pdf>. This bulletin highlights three geographic areas that were previously classified as Micropolitan Statistical Areas but now qualify as Metropolitan Statistical Areas. The three areas are (1) CBSA 16020, Cape Girardeau-Jackson, MO-IL (this includes Alexander County in Illinois and Bollinger and Cape Girardeau Counties in Missouri); (2) CBSA 31740, Manhattan, KS (this includes Geary, Pottawatomie, and Riley Counties in Kansas); and (3) CBSA 31860, Mankato-North Mankato, MN (this includes Blue Earth and Nicollet Counties in Minnesota). These three new CBSAs and their associated wage index values are shown in Addendum B.

4. Proposed CY 2010 Payment Update

a. National Standardized 60-Day Episode Rate

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the final rule published July 3, 2000 in the **Federal Register** (65 FR 41128), the unit of payment under the Medicare HH PPS is a national standardized 60-day episode rate. As set forth in § 484.220, we adjust the national standardized 60-day episode rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

In the CY 2008 HH PPS final rule with comment period, we refined the case-mix methodology and also rebased and revised the home health market basket. The labor-related share of the case-mix adjusted 60-day episode rate is 77.082 percent and the non-labor-related share is 22.918 percent. The proposed CY 2010 HH PPS rates use the same case-mix methodology and application of the wage index adjustment to the labor portion of the HH PPS rates as set forth in the CY 2008 HH PPS final rule with comment period. We multiply the national 60-day episode rate by the patient's applicable case-mix weight. We divide the case-mix adjusted amount into a labor and non-labor portion. We multiply the labor portion by the applicable wage index based on the site of service of the beneficiary. We add the wage-adjusted portion to the non-labor portion yielding the case-mix and wage adjusted 60-day episode rate subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, we update the HH PPS rates annually in a separate **Federal Register** document. The HH PPS regulations at 42 CFR 484.225 set forth the specific annual percentage update. In accordance with § 484.225(i), in the case of a HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be taken into account in computing the prospective payment amount for a subsequent calendar year.

For CY 2010, we will base the wage index adjustment to the labor portion of the HH PPS rates on the most recent pre-floor and pre-reclassified hospital wage index. As discussed in the July 3, 2000 HH PPS final rule, for episodes with four or fewer visits, Medicare pays the national per-visit amount by discipline, referred to as a LUPA. We update the national per-visit rates by discipline annually by the applicable home health market basket percentage. We adjust the national per-visit rate by the appropriate wage index based on the site of service for the beneficiary, as set forth in § 484.230. We will adjust the labor portion of the updated national per-visit rates used to calculate LUPAs by the most recent pre-floor and pre-reclassified hospital wage index, as discussed in the CY 2008 HH PPS final rule with comment period. We are also updating the LUPA add-on payment amount and the NRS conversion factor by the applicable home health market basket update of 2.2 percent for CY 2010.

Medicare pays the 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and § 484.205(b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare would use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low utilization payment provided on a per-visit basis as set forth in § 484.205(c) and § 484.230.
- A partial episode payment adjustment as set forth in § 484.205(d) and § 484.235.

- An outlier payment as set forth in § 484.205(e) and § 484.240.

b. Proposed Updated CY 2010 National Standardized 60-Day Episode Payment Rate

In calculating the annual update for the CY 2010 national standardized 60-day episode payment rates, we first look at the CY 2009 rates as a starting point. The CY 2009 national standardized 60-day episode payment rate is \$2,271.92.

As previously discussed in section II.B., "Outlier Policy", of this proposed rule, in our proposed policy of targeting outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010, we are proposing to return 2.5 percent back into the HH PPS rates, to include the national standardized 60-day episode payment rate. As such, to calculate the proposed CY 2010 national standardized 60-day episode payment rate, we first increase the CY 2009 national standardized 60-day episode payment rate (\$2,271.92) to adjust for the 5 percent originally set aside for outlier payments. We then reduce that adjusted payment amount by 2.5 percent, the proposed target percentage of outlier payments as a percentage of total HH PPS payment. Next, we update by the current proposed CY 2010 home health market basket update percentage of 2.2 percent.

As previously discussed in Section II.C., "Case-Mix Measurement Analysis", of this proposed rule, our updated analysis of the change in case-mix not due to an underlying change in patient health status reveals additional increase in nominal change in case-mix. However, we are maintaining our existing policy to reduce rates by 2.75 percent in CY 2010. Consequently, to calculate the proposed CY 2010 national standardized 60-day episode payment rate, we then reduce the rate by 2.75 percent, for a proposed updated CY 2010 national standardized 60-day episode payment rate of \$2,325.79. The proposed updated CY 2010 national standardized 60-day episode payment rate for an HHA that submits the required quality data is shown in Table 2. The proposed updated CY 2010 national standardized 60-day episode payment rate for an HHA that does not submit the required quality data (home health market basket update of 2.2 percent is reduced by 2 percent) is shown in Table 3.

TABLE 2—PROPOSED NATIONAL STANDARDIZED 60-DAY EPISODE PAYMENT RATE UPDATED BY THE PROPOSED HOME HEALTH MARKET BASKET UPDATE FOR CY 2010, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

CY 2009 National Standardized 60-Day Episode Payment Rate	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the proposed home health market basket update (2.2 percent) ¹	Reduce by 2.75 percent for nominal change in case-mix	Proposed CY 2010 National Standardized 60-Day Episode Payment Rate
\$2,271.92	/ 0.95	× 0.975	× 1.022	× 0.9725	\$2,317.47

¹ The proposed estimated home health market basket update of 2.2 percent for CY 2010 is based on Global Insight Inc., 1st Qtr 2009 forecast with historical data through 4th Qtr 2008.

TABLE 3—FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA; PROPOSED NATIONAL STANDARDIZED 60-DAY EPISODE PAYMENT RATE UPDATED BY THE PROPOSED HOME HEALTH MARKET BASKET UPDATE FOR CY 2010, BEFORE CASE-MIX ADJUSTMENT AND WAGE ADJUSTMENT BASED ON THE SITE OF SERVICE FOR THE BENEFICIARY

Total CY 2009 National Standardized 60-Day Episode Payment Rate	Adjusted to return the outlier funds, that paid for the original 5% target for outliers	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the proposed home health market basket update (2.2 percent) ¹ minus 2 percent for a 0.2 percent update	Reduce by 2.75 percent for nominal change in case-mix	Proposed CY 2010 National Standardized 60-Day Episode Payment Rate for HHAs That Do Not Submit Required Quality Data
\$2,271.92	/ 0.95	× 0.975	× 1.002	× 0.9725	\$2,272.12

¹ The proposed estimated home health market basket update of 2.2 percent for CY 2010 is based on Global Insight Inc., 1st Qtr 2009 forecast with historical data through 4th Qtr 2008.

c. Proposed National Per-Visit Rates Used To Pay LUPAs and Compute Imputed Costs Used in Outlier Calculations

In calculating the proposed CY 2010 national per-visit rates used to calculate payments for LUPA episodes and to compute the imputed costs in outlier calculations, we start with the CY 2009 national per-visit rates. We first adjust the CY 2009 national per-visit rates to

adjust for the 5 percent originally set aside for outlier payments. We then reduce those national per-visit rates by 2.5 percent, the proposed target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the by the current proposed CY 2010 home health market basket update percentage of 2.2 percent. National per-visit rates are not subject to the 2.75 percent reduction related to the

nominal increase in case-mix because they are per-visit rates and hence not case-mix adjusted. The proposed CY 2010 national per-visit rates per discipline are shown in Table 4. The six home health disciplines are Home Health Aide (HH aide), Medical Social Services (MSS), Occupational Therapy (OT), Physical Therapy (PT), Skilled Nursing (SN), and Speech Language Therapy (SLP).

TABLE 4—PROPOSED NATIONAL PER-VISIT RATES FOR LUPAS (NOT INCLUDING THE LUPA ADD-ON PAYMENT AMOUNT FOR A BENEFICIARY'S ONLY EPISODE OR THE INITIAL EPISODE IN A SEQUENCE OF ADJACENT EPISODES) AND OUTLIER CALCULATIONS UPDATED BY THE PROPOSED CY 2010 HOME HEALTH MARKET BASKET UPDATE, BEFORE WAGE INDEX ADJUSTMENT

Home Health Discipline Type	CY 2009 Per-Visit Amounts Per 60-Day Episode for LUPAs	Adjusted to return the outlier funds that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
				Multiply by the proposed home health market basket update (2.2 percent) ¹	CY 2010 per-visit payment amount for HHAs that DO submit the required quality data	Multiply by the proposed home health market basket update (2.2 percent) ¹ minus 2 percent, for a 0.2 percent update	CY 2010 per-visit payment amount for HHAs that DO NOT submit the required quality data
Home Health Aide	\$48.89	/ 0.95	× 0.975	× 1.022	\$51.28	× 1.002	\$50.28
Medical Social Services	173.05	/ 0.95	× 0.975	× 1.022	181.51	× 1.002	177.96
Occupational Therapy	118.83	/ 0.95	× 0.975	× 1.022	124.64	× 1.002	122.20
Physical Therapy	118.04	/ 0.95	× 0.975	× 1.022	123.81	× 1.002	121.39
Skilled Nursing	107.95	/ 0.95	× 0.975	× 1.022	113.23	× 1.002	111.01
Speech-Language Pathology	128.26	/ 0.95	× 0.975	× 1.022	134.53	× 1.002	131.90

¹ The proposed estimated home health market basket update of 2.2 percent for CY 2010 is based on Global Insight Inc., 1st Qtr 2009 forecast with historical data through 4th Qtr 2008.

d. Proposed LUPA Add-on Payment Amount Update

Beginning in CY 2008, LUPA episodes that occur as the only episode or initial episode in a sequence of adjacent episodes are adjusted by adding an additional amount to the LUPA payment before adjusting for area wage differences. As previously discussed, we are proposing to return 2.5 percent back into the HH PPS rates, to include the LUPA add-on payment amount, as a result of our proposed policy to target outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010. As such, we first adjust the CY 2009 LUPA add-on payment amount to

adjust for the 5 percent originally set aside for outlier payments. We then reduce that amount by 2.5 percent, the proposed target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the current proposed CY 2010 home health market basket update percentage of 2.2 percent. The LUPA add-on payment amount is not subject to the 2.75 percent reduction related to the nominal increase in case-mix because it is an add-on to the per-visit rates which are not case-mix adjusted. The proposed CY 2010 LUPA add-on payment amount is shown in Table 5 below. Just as the standardized 60-day episode rate and

the per-visit rates paid to HHAs that do not submit the required quality are reduced by 2 percent, the additional LUPA payment should be reduced by 2 percent also. In neither the CY 2008 nor the CY 2009 HH PPS rulemaking did we include such an adjustment to the LUPA add-on payment amount. For CY 2010, we propose that the add-on to the LUPA payment to HHAs that submit the required quality data would be updated by the home health market basket update. We propose that the add-on to the LUPA payment to HHAs that do not submit the required quality data would be updated by the home health market basket update minus two percent.

TABLE 5—PROPOSED CY 2010 LUPA ADD-ON PAYMENT AMOUNTS

CY 2009 LUPA add-on payment amount adjusted to return the outlier funds, that paid for the original 5% target for outliers	Adjusted to return the outlier funds, that paid for the original 5% target for outliers	Adjusted to account for the proposed 2.5% outlier policy	For HHAs that DO submit the required quality data		For HHAs that DO NOT submit the required quality data	
			Multiply by the proposed home health market basket update (2.2 percent) ¹	Proposed CY 2010 LUPA add-on payment amount for HHAs that DO submit required quality data	Multiply by the proposed home health market basket update (2.2 percent) ¹ minus 2 percent, for a 0.2 percent update	Proposed CY 2010 LUPA add-on payment amount for HHAs that DO NOT submit required quality data
\$90.48	/ 0.95	× 0.975	× 1.022	\$94.90	× 1.002	\$93.05

¹ The proposed estimated home health market basket update of 2.2 percent for CY 2010 is based on Global Insight Inc., 1st Qtr 2009 forecast with historical data through 4th Qtr 2008.

e. Proposed Non-Routine Medical Supply Conversion Factor Update

Payments for non-routine medical supplies (NRS) are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. We first adjust the CY 2009 NRS conversion factor (\$52.39) to

adjust for the 5 percent originally set aside for outlier payments. We then reduce that amount by 2.5 percent, the proposed target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the current proposed CY 2010 home health market basket update percentage of 2.2 percent. Finally, we then reduce that

adjusted payment amount by 2.75, to account for the increase in nominal case-mix. The proposed CY 2010 NRS conversion factor is shown in Table 6a below. The NRS conversion factor for CY 2009 was \$52.39. Consequently, for CY 2010, the proposed NRS conversion factor would be \$53.44.

TABLE 6a—PROPOSED CY 2010 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2009 NRS conversion factor	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the proposed home health market basket update (2.2 percent)	Reduce by 2.75 percent for nominal change in case-mix	Proposed CY 2010 NRS conversion factor for HHAs that do submit the required quality data
\$52.39	/ 0.95	× 0.975	× 1.022	× 0.9725	\$53.44

The proposed payment amounts, using the above computed proposed CY

2010 NRS conversion factor (\$53.44), for the various severity levels based on the

proposed updated conversion factor are calculated in Table 6b.

TABLE 6b—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM

Severity level	Points (scoring)	Relative weight	Proposed NRS payment amount
1	0	0.2698	\$14.42
2	1 to 14	0.9742	52.06
3	15 to 27	2.6712	142.75
4	28 to 48	3.9686	212.08
5	49 to 98	6.1198	327.04

TABLE 6b—RELATIVE WEIGHTS FOR THE 6-SEVERITY NRS SYSTEM—Continued

Severity level	Points (scoring)	Relative weight	Proposed NRS payment amount
6	99+	10.5254	562.48

For HHAs that do not submit the required quality data, we again begin with the CY 2009 NRS conversion factor. We first adjust the CY 2009 NRS conversion factor (\$52.39) to adjust for the 5 percent originally set aside for outlier payments. We then reduce that

amount by 2.5 percent, the proposed target percentage of outlier payments as a percentage of total HH PPS payment. Next we update by the current proposed CY 2010 home health market basket update percentage of 2.2 percent minus 2 percent) for a 0.002 percent update.

Finally, we then reduce that adjusted payment amount by 2.75, to account for the increase in nominal case-mix. The proposed CY 2010 NRS conversion factor is shown in Table 7a below.

TABLE 7a—PROPOSED CY 2010 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2009 NRS conversion factor	Adjusted to return the outlier funds, that paid for the original 5% target for outlier payments	Adjusted to account for the proposed 2.5% outlier policy	Multiply by the proposed home health market basket update (2.2 percent) minus 2 percent for a 0.25 update	Reduce by 2.75 percent for nominal change in case-mix	Proposed CY 2010 NRS conversion factor for HHAs that do submit the required quality data
\$52.39	/ 0.95	× 0.975	× 1.002	× 0.9725	\$52.39

The proposed payment amounts for the various severity levels based on the proposed updated conversions factor,

for HHAs that do not submit quality data, are calculated in Table 7b, below.

TABLE 7b—RELATIVE WEIGHTS FOR THE 6-SEVERITY FOR HHAS THAT DO NOT SUBMIT QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed NRS payment amount
1	0	0.2698	\$14.13
2	1 to 14	0.9742	51.04
3	15 to 27	2.6712	139.94
4	28 to 48	3.9686	207.91
5	49 to 98	6.1198	320.62
6	99+	10.5254	551.43

D. OASIS Issues

1. HIPPS Code Reporting

We would first like to clarify our policy regarding the submission of the Health Insurance Prospective Payment System (HIPPS) code to CMS via the OASIS. § 484.250 requires HHAs to submit to CMS the OASIS data described in § 484.55(b)(1) and § 484.55(d)(1) in order for CMS to administer the payment rate methodologies. Also, as described in § 484.20, HHAs must electronically report all OASIS data collected in accordance with § 484.55 as a condition of participation, and HHAs must encode and electronically transmit the completed OASIS assessment to CMS in the standard data format as described in § 484.20(d). For those OASIS assessments required for payment, the standard format which is electronically

transmitted by the HHA to CMS includes a HIPPS code, generated by grouper software at the HHA. When an HHA electronically transmits OASIS assessments to CMS (via the State agency), the CMS OASIS submission system performs a validation check of the transmitted OASIS items, including the submitted HIPPS code. If the CMS OASIS submission system validation determines that the submitted HIPPS code is in error, it informs HHAs of that error via the Final Validation Report which is returned to HHA. The Final Validation Report will include the valid, CMS OASIS submission system calculated HIPPS code. We have become aware of a proliferation of incidents where the HIPPS code submitted to CMS on the OASIS does not match the HIPPS code which is calculated by the CMS OASIS submission system. The HH PPS Grouper Software, which is

used by the CMS OASIS submission system in its validation, is the official grouping software of the HH PPS, and thus the HIPPS code produced by the CMS OASIS submission system is the HIPPS code that should ultimately be billed on the claim. Consequently, in the interest of accurate coding and billing, we propose that the HHA be required to ensure that the HIPPS code billed on the claim is consistent with that which CMS' OASIS submission system calculated. In the case where the Final Validation Report returns to the HHA a HIPPS code which is different than the HIPPS code submitted to CMS by the HHA on the OASIS, the HHA must ensure that the HIPPS code from the Final Validation report is the HIPPS code reported on the bill.

2. OASIS Submission as a "Condition of Payment"

Section 484.20 requires that HHAs must electronically report to CMS (via the State agency or OASIS contractor) all OASIS data collected in accordance with § 484.55 as a condition of participation. Additionally, § 484.250 requires that HHAs must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies. Building on the above clarification for HHAs to ensure the HIPPS code reported on the bill is consistent with that which CMS' OASIS submission system calculated, and in order to be consistent with § 484.250, we are proposing to require the electronic reporting of OASIS to CMS as a condition of payment in § 484.210. Currently, as a requirement for pay for reporting, HHAs are required to submit quality data (that being OASIS data) in order to receive the full home health market basket update to the rates. The burden associated with the requirement for the HHA to submit the OASIS is currently accounted for under OMB# 0938-0761. Making OASIS submission a condition for payment is consistent with both OASIS submissions being a condition of participation and a requirement to receive full market basket updates under pay for reporting. As such, we are proposing to revise § 484.210 "Data used for the calculation of the national prospective 60-day episode payment" to reflect this requirement.

E. Qualifications for Coverage as They Relate to Skilled Services Requirements

To qualify for Medicare coverage of home health services a Medicare beneficiary must meet each of the following requirements as stipulated in § 409.42: Be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of Act; be under the care of a physician as described in § 409.42(b); be under a plan of care that meets the requirements specified in § 409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in § 409.42(c). Subsection 409.42(c) of our regulations requires that the beneficiary need at least one of the following services as certified by a physician in accordance with § 424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in § 409.32; Physical therapy which meets the requirements of § 409.44(c), Speech-

language pathology which meets the requirements of § 409.44(c); or have a continuing need for occupational therapy that meets the requirements of § 409.44(c), subject to the limitations described in § 409.42(c)(4).

Basis for Revisions to § 409.42(c)(1), 409.44(b), and § 424.22

In recent years, MedPAC, the HHS Office of the Inspector General (OIG), and Medicaid State agencies suggested the need for CMS to clarify the Medicare home health coverage criteria regarding the skilled services specified at § 409.42. In their March 2004 report (http://www.medpac.gov/documents/Mar04_Entire_reportv3.pdf), MedPAC reported that the Medicare eligibility criteria for the home health benefits leaves a great deal open to interpretation, describing a particular concern with the lack of clarity regarding the Medicare home health skilled nursing services requirement. In their Memorandum Report dated February 5, 2009 titled "Medicaid and Medicare Home Health Payments for Skilled Nursing and Home Health Aide Services" (<http://oig.hhs.gov/oei/reports/oei-07-06-00641.pdf>), the OIG also stated that Medicare coverage policy regarding skilled nursing services lacked clarity. The OIG indicated that our payment methodology might be prone to error. HHAs were unclear about which skilled nursing services were covered by Medicare's home health benefit. Further, Medicaid State agencies have also communicated to CMS their concerns that HHAs find it difficult to accurately determine when services provided to dually Medicare and Medicaid eligible individuals ("dual eligibles") meet the Medicare coverage criteria, especially the requirements for needing skilled nursing care on an intermittent basis. State Medicaid agencies have communicated to CMS that this ambiguity is resulting in some HHAs routinely submitting all claims for dual-eligible persons with chronic care needs to their State Medicaid agencies for payment. State Medicaid agencies and CMS are concerned about this practice, referencing the requirement under the Social Security Act that Medicaid must be the payer of last resort. State agencies have told CMS that some of these claims would have been covered and paid by Medicare if they were submitted for payment. Other State agencies have used Medicaid post payment reviews to identify claims they believe should have been paid by another payer (e.g., Medicare).

In 2006, CMS and certain Medicaid State Agencies embarked on an

educational initiative to improve the ability of HHAs, State Agencies, and CMS contractors to make appropriate coverage decisions, resulting in an improved ability by HHAs to identify the appropriate payer for services provided, ultimately improving HHA billing accuracy.

As part of its provider education program, CMS focused on clarifying § 409.42 "Beneficiary qualifications for coverage of services". During the course of the training, it became apparent that confusion existed among certain Medicaid State Agencies and HHAs regarding under what circumstances the overall management and evaluation of a care plan would constitute a skilled service. HHAs asked what underlying conditions, complications, or circumstances would require a patient otherwise receiving unskilled services to need care plan management and evaluation by a registered nurse, thus rendering such care skilled. CMS therefore ensured that the training provided a particular focus on the requirement that a beneficiary be in need of skilled services. CMS provided comprehensive guidance to clarify that in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service only when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. Another area of confusion that surfaced during the training was when the need for patient education services constitutes skilled services in the home health setting. HHAs questioned which specific sorts of educational services would render the education a skilled service in the home health setting.

To address the concerns identified by OIG, MedPAC, State Medicaid agencies and the clarity concerns home health agencies communicated to CMS during the 2006 training, we propose to revise § 409.42(c)(1) to further clarify that in order for services to be considered skilled in the home health setting, certain limitations (discussed below) would apply. We believe these revisions would assist HHAs in their determination of home health eligibility and will enable HHAs to more accurately bill for their dual eligible population.

Proposed Revisions to § 409.42(c)(1)

To clarify what constitutes skilled services in the home health setting, we are proposing the following revision to § 409.42. We propose to add a qualifying instruction to § 409.42(c)(1) to explain that intermittent skilled nursing services

meeting the criteria for skilled services and the need for skilled services found in § 409.32 (with examples in § 409.33 (a) and (b)) are subject to certain limitations in the home health setting. We propose to describe the limitations in two new paragraphs, § 409.42(c)(1)(i) and § 409.42(c)(1)(ii).

**Proposed New Paragraph
§ 409.42(c)(1)(i)**

Our policy at § 409.33(a)(1) describes that the development, management, and evaluation of a patient's care plan based on physician's orders constitute skilled services when, because of the patient's physical or medical condition, oversight by technical or professional personnel is needed to promote recovery and ensure medical safety. The examples described in § 409.33(a)(1)(ii) further describe that when the patient's overall condition supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

We propose in § 409.42(c)(1)(i) that in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service only when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose.

Further, in § 409.42(c)(1)(i) we also propose to clarify that to be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service.

Additionally, we propose to further clarify in § 409.42(c)(1)(i) that in some cases, the condition of the patient may require that a service that would normally be considered unskilled be classified as a skilled nursing service given a patient's unique circumstances. This would occur when the patient's underlying condition or complication required that only a registered nurse could ensure that essential non-skilled care was achieving its purpose. The registered nurse would ensure that services were safely and effectively performed. However, any individual

service would not be deemed a skilled nursing service merely because it was performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by the average non-medical person without the direct supervision of a nurse, the service cannot be regarded as a skilled service although a nurse actually provided the service.

**Proposed New Paragraph
§ 409.42(c)(1)(ii)**

Additionally, we also propose a new § 409.42(c)(1)(ii), which would clarify when patient education services as described in § 409.33(a)(3) constituted skilled services in the home health setting. Current § 409.32(a)(3) states that patient education services are skilled services if the use of technical or professional personnel is necessary to teach patient self-maintenance. However, to address the concerns and lack of clarity surrounding when education services are skilled services as described above, we are proposing to add a new paragraph, § 409.42(c)(1)(ii). In the home health setting, skilled education services would be deemed to no longer be needed when it became apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

Proposed Change to § 409.44(b)

We are proposing to revise the introductory material at § 409.44(b)(1), to refer to the newly proposed limitations of skilled services in the home health benefit at § 409.42(c)(1)(i) and 409.42(c)(1)(ii). The clauses under the revised paragraphs (i) through (iv) would remain unchanged.

**Proposed Revision to § 424.22(a)(1)(i)
and § 424.22(b)(2)**

We also propose to revise § 424.22(a)(1)(i) and § 424.22(b)(2) to require a written narrative of clinical justification on the physician certification and recertification for the targeted condition where the patient's overall condition supports a finding that

recovery and safety could be ensured only if the care was planned, managed, and evaluated by a registered nurse. We believe that this revision would address HHAs' questions regarding the specific circumstances which would necessitate the need for skilled management and evaluation of the care plan. Additionally, we believe this requirement would be an important step in enhancing the physician accountability and involvement in the patient's plan of care.

As we described above, many Medicaid State Agencies and HHAs contend that there is confusion as to when overall management and evaluation of a care plan constitute a skilled service. They questioned what specific beneficiary underlying conditions, or complications or circumstances would warrant a patient who was receiving unskilled services to need care plan management and evaluation by a registered nurse, thus rendering the care skilled. To clarify for home health agencies what specific circumstances would necessitate the involvement of a registered nurse in the development, management, and evaluation of a patient's care plan when only unskilled services are being provided, we propose additions to the home health certification content requirements as described at § 424.22(a)(i) and recertification content requirements at § 424.22(b)(2). Specifically, when a patient's underlying condition or complication requires exclusively that a registered nurse ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, we propose to require the physician include a written narrative on the certification and recertification describing the physician's clinical justification of this need.

In the Physician Fee Schedule proposed rule published in the July 7, 2008 **Federal Register** (73 FR 38578), we solicited comments asking the industry to suggest options to enhance contact between the physician and the patient. In that solicitation of comments, we described policy options that we had been considering such as a review of the RVUs associated with the certification and recertification of the HH plan of care (POC), and that we were considering proposing new requirements, for example, a requirement for "direct" patient contact with the physician, to ensure more active physician involvement in the

certification and recertification of the HH POC.

As a result of this solicitation, some commenters suggested that CMS establish documentation expectations associated with the certification and recertification of the need for Medicare home health services. We are continuing to consider policy options to enhance the physician-patient interaction in the home health setting. We believe that the commenters' suggestion that CMS establish documentation expectations associated with the certification and recertification, such as our proposed clinical justification narrative requirement, may be a first step in achieving this goal.

Finally, we believe that this new requirement would increase physician accountability and oversight of the certification and recertification of home health services and plan of care by focusing attention on the physician's responsibility to set out the clinical basis for this skilled need as indicated in the patient's medical record.

This brief narrative could be written or typed on the certification form itself. We do not believe that this brief narrative should be allowed as an attachment to the certification form because an attachment could easily be prepared by someone other than the physician, and what we are seeking is more direct involvement on part of the physician. We seek comments on whether this proposed requirement would increase physician engagement in the certification and recertification process, and clarify industry confusion associated with when a patient's condition would require the need for a registered nurse to oversee the patient's care plan, thus rendering such "skilled care" under our payment system.

F. OASIS for Significant Change in Condition: No Longer Associated With Payment

We propose to remove an obsolete reference to "new case-mix assignments" as a result of significant changes in a patient's condition that appears in 42 CFR 484 subpart E at § 484.55(d)(1)(ii). The significant change in condition (SCIC), as it relates to new case-mix assignments affecting payment, was an element of the HH PPS at the time of its first implementation in fiscal year 2000. However, as part of the HH PPS payment refinements implemented in CY 2008, we eliminated the SCIC policy, and the assignment of subsequent case-mix assignments under the HH PPS. However, it should be noted that it was not the SCIC payment policy that required the HHA to perform the assessment, but rather the

significant change in the patient's condition. We are not proposing to change that requirement. An HHA would still be required to perform an assessment in the event that a patient experienced a significant change in condition. The proposed modification is only that a new case-mix assignment is no longer associated with this assessment.

In addition, we propose to revise § 484.250 to delete an obsolete reference to § 484.237. § 484.237 referred to the SCIC payment policy and was removed in the CY 2008 HH PPS final rule (72 FR 49879).

G. Proposed Payment Safeguards for Home Health Agencies

The provisions contained in this section are designed to: (1) Improve our ability to verify that home health agencies (HHAs) meet minimum enrollment criteria; (2) ensure that HHAs that are changing ownership meet and continue to meet the Conditions of Participation for HHAs found in 42 CFR Part 484; and (3) improve the quality of care that Medicare beneficiaries receive from HHAs.

1. Program Integrity Concerns Involving Home Health Agencies (HHAs)

The fraudulent business practices of certain HHAs continue to cost the Medicare program millions of dollars nationwide. This issue was discussed in a recent report issued by the Government Accountability Office (GAO) entitled "Improvements Needed to Address Improper Payments in Home Health" (GAO-09-185). This report, discussed in more detail below, concluded, in part, that "In the absence of greater prevention, detection, and enforcement efforts, the Medicare home health benefit will continue to be a ready target for fraud and abuse."

The problem has been especially acute in, though by no means limited to, the States of Texas and California. In Los Angeles County in California, for instance, the amount of money for which HHAs in that county billed Medicare between Fiscal Years 2003 and 2006 rose from \$569 million to \$921 million—an increase of 62 percent, and one that was not accompanied by a similar increase in the county's Medicare beneficiary population. There has also been an abnormal proliferation of HHAs in California as a whole. Between October 2002 and May 2007, the number of HHAs in the State rose by 25 percent—again, without a concomitant upswing in the number of Medicare beneficiaries in California. This suggests that there may also be an increase in improper billing. HHA

proliferation has been an even bigger problem in Texas. Between October 2002 and October 2006, the number of HHAs in the State doubled, while—during this same period—the number of HHAs in Harris County, Texas (which includes the city of Houston) increased by almost 150 percent. As with California, these figures are out of all proportion with any increase in the beneficiary population or demand for HHA services in Texas or Harris County.

The aforementioned GAO report expressed similar concerns. It noted that, nationwide, "spending on the Medicare home health benefit grew about 44 percent from 2002 through 2006, despite an increase of just less than 17 percent in the number of beneficiaries using the benefit during that 5-year period." The report also noted discrepancies in States other than Texas and California. To illustrate, between 2002 and 2006, the number of HHAs that billed Medicare rose in Florida by 100 percent, in Michigan by 62 percent, in Illinois by 59 percent, in Ohio by 42 percent, in Arizona by 32 percent, and in the District of Columbia by 67 percent. However, the increases in the number of Part A beneficiaries who used HHA services in these six jurisdictions were as follows: Florida—28 percent; Michigan—19 percent; Illinois—23 percent; Ohio—14 percent; Arizona—4 percent; and the District of Columbia—2 percent.

The disparity in many jurisdictions between the increase in the number of HHAs and the rise in the number of beneficiaries is so overwhelming that it cannot be attributed solely to an aging populace. The fact that, as shown above, between 2002 and 2006, the number of HHAs in Arizona rose at a rate 8 times greater than the number of Part A beneficiaries that use HHA services—and that the rate was an astounding 33 times greater in Washington, DC—must raise serious questions as to the legitimacy of some of these entities.

The GAO report also outlined a number of instances of allegedly fraudulent activities on the part of HHAs. In a particularly glaring example in Houston, Texas, the GAO noted the following: "One PSC (Program Safeguard Contractor) interviewed 670 Houston beneficiaries who had the most severe clinical rating and who were patients of HHAs identified by the PSC as having aberrant billing patterns. The PSC found 91 percent of claims for these beneficiaries to be in error. Nearly 50 percent of the beneficiaries were not homebound and therefore were not eligible to receive any Medicare home health services. The investigators also found that while 39 percent of the

beneficiaries they interviewed were eligible for the benefit, their clinical severity had been exaggerated. The PSC concluded that only 9 percent of claims for the 670 beneficiaries were properly coded. In addition, the PSC found that other home health beneficiaries it interviewed were not homebound; for instance, some were mowing their lawns when investigators came to interview them."

Of particular concern to CMS is that the problems discussed above have been seen with HHAs on a far greater scale than with any other type of certified provider. The dramatic rise in the number of HHAs in relation to the increase in Medicare beneficiaries has not been even remotely duplicated with other Part A entities. In sum, the relative level of potentially fraudulent behavior among HHAs exceeds that of other certified provider types, and it is for this reason that CMS needs to take additional steps to ensure that only legitimate, bona fide HHAs remain enrolled in the Medicare program.

2. Prohibition on Sharing of Practice Location

In 2008, we determined that a number of HHAs had enrolled or attempted to enroll into the Medicare program using the same practice location or base of operations listed in Section 4 of their respective Medicare provider enrollment applications. In one case, a business attempted to enroll more than twenty different HHAs with the same Section 4 practice location as the base of operations.

We believe that allowing HHAs to share practice locations, operations, and other aspects of the provider's operations (for example, patient and financial records) in this manner constitutes a significant risk to the Medicare program. To allow an HHA to share its Section 4 practice location or base of operations with another Medicare-enrolled HHA or supplier limits the ability of CMS, a State survey agency, or an accreditation organization to ensure that each HHA meets the Conditions of Participation specified at 42 CFR part 484. Indeed, pursuant to Section 1866(j)(1)(A) of the Act, the Secretary is required to establish by regulation a process for the enrollment of providers and suppliers into the Medicare program. However, the sharing of HHA practice locations or bases of operations listed in Section 4 of the Medicare provider enrollment application hinders CMS's ability to properly enroll HHAs into Medicare because of the extreme difficulty in determining which site is in operation at a particular time, and which provider

has control over the space, staff, equipment, *etc.* We do not believe that legitimate HHA providers share Section 4 practice locations or bases of operations with another Medicare-enrolled HHA or supplier.

At § 489.19, we are proposing a provision that would prohibit an HHA from sharing, leasing, or subleasing its practice location or base of operations listed in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier. We believe that this provision is consistent with existing provisions found in § 410.33(g)(15), which established limitations on the sharing of space (that is, a practice location) by independent diagnostic testing facilities (IDTF).

At § 489.12(a)(5), we are proposing to allow CMS to refuse to enter into a provider agreement with a prospective HHA if we determined, under proposed 42 CFR 489.19, that the HHA was sharing, leasing, or subleasing its practice location or base of operations listed in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.

At § 424.530(a)(8), we are proposing to allow a Medicare contractor, including a Regional Home Health Intermediary or A/B MAC, to deny Medicare billing privileges to an HHA if it determined, under proposed 42 CFR 489.19, that the HHA was sharing, leasing, or subleasing its practice location or base of operations listed in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.

At § 424.535(a)(11), we are proposing to allow a Medicare contractor, including a Regional Home Health Intermediary or A/B MAC, to revoke the Medicare billing privileges of an HHA that it determined, under proposed 42 CFR 489.19, was sharing, leasing, or subleasing its practice location or base of operations listed in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.

We are, nevertheless, soliciting comments on whether there are legitimate business reasons for a Medicare-enrolled HHA to share space with another Medicare-enrolled HHA or supplier when there is common ownership. We are also soliciting comments on whether there are legitimate business reasons for a Medicare-enrolled HHA to be co-located with another Medicare-enrolled HHA or supplier when there is no common ownership. In addition, we are soliciting

comments on whether there are legitimate business reasons for a Medicare-enrolled HHA to engage in leasing or subleasing arrangements with a Medicare-enrolled supplier when there is common ownership.

3. Sale or Transfer of Ownership Within 3 Years of Enrollment

We have recently found instances where owners of a HHA, some of which were working in concert with brokers or organizations operating "turn-key" businesses, have enrolled or have attempted to enroll in the Medicare program for the specific purpose of selling the Medicare billing privileges and the Medicare provider agreement of their HHA to a third-party. In this scenario, the buyer or seller of the HHA typically would notify Medicare of the sale or change of ownership via the Medicare enrollment application (CMS-855A) after the billing privileges have been transferred when the HHA is sold.

Current CMS policy recommends surveys when there is a change of ownership. However, surveys in cases of a change of ownership do not occur with the frequency that they do when providers initially enroll in Medicare. Consequently, there are instances in which a change of ownership takes place yet the new owner does not undergo a survey, in which case Medicare cannot conclusively ascertain whether the business, under new ownership, meets the Conditions of Participation under 42 CFR part 484. This serves as an incentive for certain prospective providers to enroll in the Medicare program with the sole purpose of transferring Medicare billing privileges and the associated provider agreement when the business is sold.

This is problematic for two reasons. First, the prospective provider has minimal incentive for ensuring quality care for its patients after it is enrolled because its exclusive objective for participating in Medicare in the first place is to sell the business shortly after receiving Medicare billing privileges. In other words, the provider, aware that it may be able to sell the business without the HHA having to undergo a survey, may have little motivation to ensure that it is in compliance with the Conditions of Participation under 42 CFR part 484, since it intends on selling the business in any event. Medicare beneficiaries, therefore, may receive inadequate services as a result of this activity. Second, without the protection that a survey provides, the HHA may attempt to bill Medicare for these insufficient services. These circumstances increase the risk for an HHA to submit inappropriate and potentially fraudulent

claims to Medicare, which places the Medicare Trust Funds at risk.

We further note that 42 CFR 424.550(a) states that a provider or supplier "is prohibited from selling its Medicare billing number or privileges to any individual or entity, or allowing another individual or entity to use its Medicare billing number." We believe that the "turn-key" scenarios described in this subsection 2 fall within the general intent and purview of this provision, in that the broker may focus more on the selling of the HHA's billing privileges, rather than of the HHA itself. Nevertheless, while the provisions of 42 CFR § 424.550(a) and (b) were designed to prohibit this type of practice, we cannot realistically enforce the prohibitions on the sale, including an asset sale or stock transfer, or transfer of billing privileges, unless we can confirm the nature of the financial arrangements involved therein.

We recognize that the issue of a potential lack of a survey in HHA ownership changes exists with respect to other types of providers and certified suppliers. Yet there are several reasons as to why this concern is more acute with HHAs than with other provider types. First, and as already outlined in subsection 1, the level of fraud in the HHA sector appears to be more prevalent than with other provider categories. Second, CMS has not seen the types of turn-key arrangements described above with any type of provider or certified supplier other than HHAs. It is the combination of these two factors that, in our view, make it necessary for us to focus the proposed provisions below on HHAs, rather than on provider types with whom our concerns are not nearly as acute. We stress that CMS in the past has undertaken a number of enrollment initiatives to ensure that only eligible and qualified providers and suppliers obtain and maintain Medicare billing privileges; specifically, CMS promulgated rules to address fraud and abuse and quality of care concerns for IDTFs (in 42 CFR 410.33(g)) as well as suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) (42 CFR 424.57(c)). We therefore believe, for the reasons just stated, that a similar approach is warranted here with respect to HHAs. With that said, and in view of the aforementioned schemes that appear to be designed to subvert Medicare's existing statutory and regulatory authorities related to enrollment and State survey procedures, we maintain that additional tools are needed to address this program vulnerability.

At 42 CFR 424.550(b)(1), we are proposing that an HHA undergoing an ownership change (including asset sales and stock transfers) must obtain an initial State survey or accreditation by an approved accreditation organization if the change takes place within 36 months after the effective date of the HHA's enrollment in Medicare. This means that any change of ownership that occurs during the 36 months following an initial enrollment would not result in the transfer of the HHA's provider agreement and Medicare billing privileges to the new owner. The new owner of the existing HHA would instead be required to enroll in the Medicare program as a new provider under the provisions of § 424.510 and obtain an initial State survey or accreditation by an approved accreditation organization. This is to ensure that the HHA under new ownership remains in compliance with the Conditions of Participation in 42 CFR part 484. We believe that this will help deter turn-key entities from purchasing HHAs for the sole purpose of selling them, in that the facility will be unable to undergo a change of ownership within the above-referenced 36-month period without the HHA being subject to a State survey.

We further believe that 36 months is an appropriate period of time for which to apply this requirement. It is long enough to ensure that a newly-enrolled HHA is serious about furnishing quality services to Medicare beneficiaries and is not merely looking to sell the HHA's Medicare billing privileges at the earliest possible moment. Conversely, a 36-month timeframe is, in our view, not so extensive as to greatly hinder the ability of a bonafide HHA to sell its business after the HHA has been operational and providing legitimate Medicare services for a reasonable period of time. While we do recognize that some legitimate, newly-enrolling HHAs may be inconvenienced by their inability to utilize, for a certain amount of time, the change of ownership provisions in 42 CFR 489.18, we also stress that the aforementioned survey requirement will, to a substantial extent, benefit legitimate members of the HHA provider community, in that it will help ensure that unqualified HHAs are no longer in the Medicare program. This will, for bonafide HHAs, reduce competition from less than legitimate HHAs and, on a larger level, help protect the Medicare Trust Funds.

Finally, if adopted, we believe that any change of ownership (including asset sales or stock transfers) that is pending a Medicare contractor's review and approval at the time this rule

becomes effective, would be subject to this provision.

4. Home Health Agency Reactivations of Medicare Billing Privileges

In order to help address CMS' concerns about potentially inappropriate activity by HHAs, an additional tool that we therefore believe is necessary to help stem this behavior involves enhanced safeguards for use as part of the reactivation process identified in § 424.540(a).

To ensure that HHAs whose Medicare billing privileges have been deactivated for 12 months of non-billing and who seek to reactivate these privileges are still in compliance with the Conditions of Participation in 42 CFR part 484, we propose to revise § 424.540(b)(3) from its current form, "Reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement" to "With the exception of home health agencies, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement." We are also proposing to add § 424.540(b)(3)(i), which states that any HHA whose Medicare billing privileges are deactivated under the provisions found in § 424.540(a) are also required to obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

As already explained, CMS remains concerned about the excessive level of potentially inappropriate activity in the HHA arena. To this end, CMS believes that the proposed provisions outlined in this subsection will, for reasons already identified, help address the concerns outlined in the aforementioned GAO report by ensuring that HHAs are in constant and verifiable compliance with the HHA Conditions of Participation found in 42 CFR part 484, and that only qualified and legitimate home health providers are enrolled in Medicare.

H. Physician Certification and Recertification of the Home Health Plan of Care

a. Background

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require that a plan for furnishing home health services be established and periodically reviewed by a physician in order for Medicare payments for those services to be made. Our regulations at § 409.43(e)

specifically states that a home health plan of care (HH POC) must be reviewed, signed, and dated by the physician who reviews the POC (as specified in § 409.42(b)) in consultation with agency clinical staff at least every 60 days (or more frequently as specified in § 409.43(e)(1)). Additionally, § 424.22(b) states that a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the home health POC. These schedules, for the review of the POC and the recertification, coordinate well with the 60-day episode payment unit under the HH PPS. In implementing the statutory requirement as well as these regulations, we believed that these requirements would encourage enhanced physician involvement in the HH POC and patient management, and would include more direct “in-person” patient encounters (as logistically feasible).

Currently, physicians are paid for both the certification and recertification of the HH POC under HCPCS codes G0180 and G0179, respectively. The basis for the payment amounts of these physician services is the relative resources in RVUs required to furnish these services. We believe physician involvement is very important in maintaining quality of care under the HH PPS.

In the HH PPS proposed rule published in the October 28, 1999 **Federal Register** (64 FR 58196), we had proposed to require the physician to certify the case-mix weight/home health resource group (HHRG) as part of the required physician certification of the POC. This reflected our belief that the physician should be more involved in the decentralized delivery of home health services. However, in the final rule published in the July 3, 2000 **Federal Register** (65 FR 41163), we did not finalize that proposal and decided to focus our attention on physician certification and education in order to better involve the physician in the delivery of home health services.

b. Solicitation of Comments

It has come to our attention that physician involvement in the certification and recertification of HH POC varies greatly. While some physicians have direct contact with their patients in the delivery of home health services, we believe that a significant number of physicians provide only a brief, albeit thorough, review of the HH POC, without any direct contact with the patient. We continue to believe that active involvement of the physician, including

“in-person” contact with the patient, during the certification and recertification of the HH POC is essential for the delivery of high quality HH services.

In the Physician Fee Schedule proposed rule published in the July 7, 2008 **Federal Register** (73 FR 38578), we mentioned several options to enhance direct contact between the physician and the patient. First, we considered a review of the RVUs associated with the certification and recertification of the HH POC. As a result of that review, the payment amounts to physicians could be reduced based on a more accurate determination of the actual RVUs required to provide these services. We also considered proposing new requirements; for example, a requirement for “direct” patient contact with the physician, to ensure more active physician involvement in the certification and recertification of the HH POC. We specifically solicited comments on these policy options. The following is a summary of the comments and our responses as published in the Physician Fee Schedule final rule published in the November 19, 2008 **Federal Register** (73 FR 69855).

Most commenters suggested that we leave our current policies and payment to physicians unchanged, at least until further analysis is completed. To that end, it was suggested that we continue to study the role of the physician in home care and determine which factors enhance a physician’s ability to conduct oversight activities, ensure appropriateness of care, and work collaboratively with HHAs without further burdening Medicare beneficiaries. Commenters urged CMS to engage with industry organizations that represent the physicians that furnish these services, to determine goals and assess options. Commenters further suggested that goals and options could include revising the procedure codes used for billing, assessing the current RVUs, and establishing documentation expectations.

Some commenters suggested that payments to physicians for certifying and recertifying HH POCs should be restructured to provide incentives for greater physician involvement, to include personally seeing the patients. Specifically, some commenters suggested adding different payments for the varying levels of physician involvement in the certification and recertification of HH POCs. Other commenters urged CMS to consider how home telehealth can be employed to a greater degree to increase input of clinical information directly to

physicians in lieu of face-to-face contact.

Other commenters suggested that we actively support amending the Medicare statute to allow nurse practitioners (NPs) to certify and recertify HH POCs. Some commenters suggested that we actively support demonstrations and legislative proposals to build on the concept of merging home care with primary care under a single care management entity for persons in the advanced stages of chronic illnesses. Other commenters suggested that payment to medical directors should be restored to HHAs, along with requirements for their education and a definition of their role, and that we consider reimbursement for a planning teleconference between the physician and home health personnel.

In the November 19, 2008 final rule, we expressed our appreciation for the comments and responded that we would continue to analyze and consider the comments and suggestions in future rulemaking. Additionally, as a result of comments received on the above physician rule, as it relates to physician-patient contact, we are considering the possibility of requiring physicians to make phone calls to patients at various times over the course of home health treatment (prior to recertifications), as a means to promote that physician-patient contact and to help ensure the delivery of high quality HH services to our beneficiaries.

In this HH PPS proposed rule for CY 2010, we are specifically soliciting additional comments on this topic.

I. Routine Medical Supplies

HHAs have expressed to the HHS Office of the Inspector General (OIG) some confusion regarding routine medical supplies and how we account for the cost of those supplies. Therefore, we would like to reiterate our policy regarding routine medical supplies and how they are reimbursed under the HH PPS.

Section 1895(b)(1) states that “all services covered and paid on a reasonable cost basis under the Medicare home health benefit as of the date of the enactment of this section, including medical supplies, shall be paid for on the basis of a prospective payment amount * * *”. The cost of routine medical supplies was included in the average cost per visit amounts derived from the audit sample. These average cost per visit amounts were used to calculate the initial HH PPS rates published in the July 3, 2000 HH PPS final rule (FR 65 41184). Because reimbursement for routine medical supplies is bundled into the HH PPS 60-

day episode rate and the per-visit rates, HHAs may not bill separately for routine supplies.

As noted in Chapter 7—Home Health Services of the Medicare Benefit Policy Manual (Pub. L. 100–02), sections 50.4.1.2 and 50.4.1.3, routine supplies are supplies that are customarily used in small quantities during the course of most home care visits. They are usually included in the staff's supplies and not designated for a specific patient. Routine supplies would not include those supplies that are specifically ordered by the physician or are essential to HHA personnel in order to effectuate the plan of care. Examples of supplies which are usually considered routine include, but are not limited to:

A. Dressings and Skin Care

- Swabs, alcohol preps, and skin prep pads;
- Tape removal pads;
- Cotton balls;
- Adhesive and paper tape;
- Nonsterile applicators; and
- 4x4's.

B. Infection Control Protection

- Nonsterile gloves;
- Aprons;
- Masks; and
- Gowns.

C. Blood Drawing Supplies

- Specimen containers.

D. Incontinence Supplies

- Incontinence briefs and Chux covered in the normal course of a visit. For example, if a home health aide in the course of a bathing visit to a patient determines the patient requires an incontinence brief change, the incontinence brief in this example would be covered as a routine medical supply.

E. Other

- Thermometers; and
- Tongue depressors.

There are occasions when the supplies listed in the above examples would be considered non-routine and thus would be considered a billable supply, *i.e.*, if they are required in quantity, for recurring need, and are included in the plan of care. Examples include, but are not limited to, tape, and 4x4s for major dressings.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information (COI) requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB,

section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. *ICRs Regarding the Requirements for Home Health Services*

Section 424.22 proposes that if a patient's underlying condition or complication required a registered nurse to ensure that essential non-skilled care was achieving its purpose, and necessitated a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician would include a written narrative describing the clinical justification of this need.

The burden associated with this requirement would be the time and effort put forth by the physician to include the written narrative. We estimate it would take one physician approximately 5 minutes to meet this requirement. We estimate the frequency of such a situation to occur in about 5 percent of episodes (or about 345,600 episodes a year); therefore, the total annual burden associated with this requirement would be 28,800 hours for CY 2010.

B. *ICRs Regarding Deactivation of Medicare Billing Privileges*

In the proposed § 424.540(b)(3)(i), an HHA whose Medicare billing privileges are deactivated under the provisions found in 424.540(a) must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privilege can be reactivated.

The burden associated with this requirement would be the time and effort put forth by the HHA to obtain a State survey or accreditation. We estimate it would take the prospective provider/owner 60 hours to obtain a State survey or accreditation. We estimate that there would be 2,000 such occurrences annually; therefore, the total annual burden associated with this requirement would be 120,000 hours.

C. *ICRs Regarding Prohibition Against Sale or Transfer of Billing Privileges*

At § 424.550(b)(1) we propose that an HHA undergoing an ownership change would have to obtain an initial State survey or accreditation by an approved accreditation organization if the change takes place within 36 months after the effective date of the HHA's participation in Medicare. Between April 2008 and April 2009, approximately 2,000 Medicare-enrolled HHAs—or 22.5 percent of the 9,000 total number of HHAs enrolled in Medicare—underwent a change of ownership. Naturally, the magnitude of the ownership changes varied by HHA, but the fact that almost one-quarter of all Medicare-enrolled HHAs changed ownership in some form within the past year is, for the reasons outlined in the preamble to this proposed rule, significant.

It is also important to note that of the 2,000 ownership changes, approximately 20 percent occurred in Texas, another 20 percent in Florida, and 14 percent in California, meaning that over one-half of all changes in ownership occurred in three States. Though it is possible that, if this provision was implemented, the number of total annual ownership changes would decrease, we will assume that the figure of 2,000 would remain constant. The burden associated with the proposed requirement in § 424.550(b)(1) would be twofold. First, the HHA would need to complete and submit a Medicare enrollment application (paper or electronic) as an initial applicant. This can be done electronically via the Internet-Based Provider Enrollment, Chain and Ownership System (PECOS) or by using the paper CMS–855 enrollment application. The estimated burden of completing the entire application as a new enrollee is 3 hours. Thus, the estimated annual burden for the approximately 2,000 HHAs that will change ownership would be 6,000 hours. Second, the provider would need to undergo a survey (or obtain accreditation in lieu of a survey) and perform administrative activities associated therewith. We estimate that the total hourly burden to the HHA for said activities would be 60 hours, for an annual burden of 120,000 hours (2,000 HHAs × 60 hours). Therefore, we estimate that the total annual burden of compliance with § 424.550(b)(1) would be 126,000 hours (120,000 hours + 6,000 hours).

D. *ICRs Regarding Patient Assessment Data*

Section 484.210 would require an HHA to submit to CMS the OASIS data

described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the

payment rate methodologies described in §§ 484.215, 484.230 and 484.235.

The burden associated with this is the time and effort put forth by the HHA to

submit the OASIS data. This burden is currently accounted for under OMB# 0938–0761.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden hours
None	424.22	345,600	1/12	28,800
None	424.540(a)(3)(i)	2,000	60	120,000
None	424.550(b)(1)	2,000	63	126,000
0938–0761	484.210	N/A	N/A	N/A

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, CMS–1560–P. *Fax:* (202) 395–6974; or *E-mail:* OIRA_submission@omb.eop.gov.

E. ICRs Regarding Annual Update of the Unadjusted National Prospective 60-Day Episode Payment Rate

Section 484.225(i) requires the submission of quality measures as specified by the Secretary. As part of this requirement, each HHA sponsoring a Home Health Care CAHPS (HHCAHPS) Survey must prepare and submit to its survey vendor a file containing patient data on patients served the preceding month that will be used by the survey vendor to select the sample and field the survey. This file (essentially the sampling frame) for most home health agencies can be generated from existing databases with minimal effort. For some small HHAs, preparation of a monthly sample frame may require more time. However, data elements needed on the sample frame will be kept at a minimum to reduce the burden on all HHAs.

The burden associated with this requirement is the time and effort put forth by the HHA to prepare and submit the file containing patient data on patients. The survey instrument and procedures for completing the instrument are designed to minimize burden on all respondents. No significant burden is expected for small agencies beyond providing their contracted vendor with a monthly file of patients served.

Initially, we estimate it would take one HHA 5 hours for the first month to meet this requirement. The subsequent monthly burden is estimated to be 30 minutes per HHA. We estimate

approximately 7,000 HHAs would be submitting this data annually. Based on that number, the burden associated with the first month is estimated at 35,000 hours. The burden would decrease to 2,100 for subsequent months. Therefore, the total annual burden for the first year would total 58,100.

The burden associated with the home health patient's submission of the HHCAHPS survey is currently pending OMB approval (CMS–10275/OMB# 0938–NEW). Once OMB approval has been obtained, CMS will revise the package to include the burden on the HHAs as discussed above.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993 as further amended) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866(as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact

analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis, that to the best of our ability, presents the costs and benefits of the rulemaking.

1. HHA Provisions Regarding Co-Mingling, Ownership Changes, and Reactivation of Billing Privileges

We believe that our proposals regarding: (1) The prohibition against co-mingling, (2) HHA changes of ownership, and (3) the reactivation of HHA billing privileges would have minimal budgetary impact, as the total number of entities that will be effected each year would be small. Moreover, we believe that these changes are necessary to ensure that currently enrolled and prospective HHAs are billing for the services provided and are in compliance with the conditions of participation in 42 CFR part 484, and all other Medicare requirements.

As for the issue of beneficiary access, the number of affected HHAs is such that we do not believe that beneficiaries would be adversely impacted by the proposed provisions. To the contrary, any reduction in the number of enrolled HHAs that would result from the implementation of these proposed provisions would be more than offset by the assurance that those HHAs that cannot meet Medicare requirements and quality standards are no longer in the program.

We are unable to determine the exact extent to which currently enrolled and prospective HHAs would be able to meet the requirements outlined in the proposed provisions. In addition, as a result of a dearth of quantifiable data, we cannot effectively derive an estimate of the monetary impacts of these provisions. Accordingly, we are seeking public comment so that the public may provide any data available that provides

a calculable impact or any alternative to the proposed provisions.

1. CY 2010 Update

The update set forth in this proposed rule applies to Medicare payments under HH PPS in CY 2010. Accordingly, the following analysis describes the impact in CY 2010 only. We estimate that the net impact of the proposals in this rule, including a 2.75 percent reduction to the national standardized 60-day episode payment rates and the NRS conversion factor to account for the case-mix change adjustment, is approximately \$100 million in CY 2010 savings. The estimated \$100 million impact reflects the distributional effects of an updated wage index (–\$10 million) as well as the 2.2 percent home health market basket increase (an additional \$390 million in CY 2010 expenditures attributable only to the CY 2010 home health market basket), and the 2.75 percent decrease (–\$480 million for the third year of a 4-year phase-in) to the HH PPS national standardized 60-day episode rate to account for the case-mix change adjustment under the HH PPS. The \$100 million is reflected in column 5 of Table 8 as a 0.86 percent decrease in expenditures when comparing the current CY 2009 system to the CY 2010 system. If the Secretary were to impose a 6.89 percent decrease to the national standardized 60-day episode rates and the NRS conversion factor in CY 2010, to account for the increase in nominal case-mix, the impact would be an estimated decrease in payments to HHAs of 4.9 percent (column 3 of Table 8) or \$1,220 million. Similarly, if the Secretary were to impose a 3.51 percent decrease to the national standardized 60-day episode rates and the NRS conversion factor in CY 2010, to account for the increase in nominal case-mix, the impact would be an estimated decrease in payments to HHAs of 1.6 percent (column 4 of table 8) or \$590 million. For comparison purposes, estimated impacts that take these alternative percentage reductions (6.89 percent and 3.51 percent) into account can be found in columns 3 and 4 of Table 8 in Section VI.B. of this rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7 million to \$34.5 million in any 1

year. For the purposes of the RFA, approximately 75 percent of HHAs are considered to small businesses according to the Small Business Administration's size standards with total revenues of \$13.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. Excluding HHAs in areas of the country where high and suspect outlier payments exist, this proposed rule is estimated to have an overall positive effect upon small entities (see section IB.B "Anticipated Effects", of this proposed rule, for supporting analysis).

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This proposed rule applies to home health agencies. Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of about \$100 million or more in 1995 dollars, updated for inflation. That threshold is currently approximately \$133 million in 2009. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or by the private sector, of \$133 million or more.

Executive Order 13132 established certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of States, local, or tribal governments.

B. Anticipated Effects

This proposed rule sets forth updates to the HH PPS rates contained in the CY 2009 notice (73 FR 65351, November 3, 2008). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes

proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based on Medicare claims from 2007. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the BBA, the BBRA, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the MMA, the DRA, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 8 represents how home health agency revenues are likely to be affected by the policy changes described in this rule. For this analysis, we used linked home health claims and OASIS assessments; the claims represented a 20-percent sample of 60-day episodes occurring in CY 2007. Column one of this table classifies HHAs according to a number of characteristics including provider type, geographic region, and urban versus rural location.

For the purposes of analyzing impacts on payments, we performed three simulations and compared them to each other. Based on our assumption that outliers, as a percentage of total HH PPS payments, will be no more than 5 percent in CY 2009, the 2009 baseline, for the purposes of these simulations, we assumed that the full 5 percent outlay for outliers will be paid under our policy in 2009 of a 0.89 FDL ratio. As described in section III.A. of this proposed rule, given our proposed policies of a 0.67 FDL ratio and a 10 percent cap on outlier payments, we would return 2.5 percent back into the national standardized 60-day episode payment rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor, and then estimate outlier payments to be approximately 2.5 percent of total HH PPS payments in CY 2010. All three

simulations use a CBSA-based wage index reported on the 2007 claims to determine the appropriate wage index.

The first simulation estimates CY 2009 payments under the current system (to include the 2009 wage index). The second simulation estimates CY 2009 payments under the current system, but with the 2010 wage index. The second simulation produces an estimate of what total payments using the sample data would have been in CY 2009 without any of the proposed provisions in this rule, except for that of the 2010 wage index. The third simulation estimates CY 2010 payments with the 2010 wage index, incorporating our maintaining of the 2.75 percent reduction to the HH PPS rates, as well as all the proposed provisions of this rule.

These simulations demonstrate the effects of: A new 2010 wage index, a 2.75 percent reduction to account for the increase in nominal case-mix, a 2.2 percent market basket update, a 2.5 percent increase to account for a new outlier target of 2.5 percent, a 0.67 FDL ratio, and a 10 percent cap on outlier payments. Specifically, the second column of Table 8 shows the percent change due to the effects of the 2010 wage index. The third and fourth columns are for comparison purposes, and show the percent change due to the combined effects of the 2010 wage index, an alternative 6.89 percent reduction (column 3) or an alternative 3.51 percent reduction (column 4) to the rates to account for the increase in nominal case-mix, the 2.2 percent home health market basket update, the 2.5 percent increase to the HH PPS rates to account for an approximate 2.5 percent target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, and a 10 percent outlier cap. The fifth

column of Table 8 shows the percent change due to the combined effects of the 2010 wage index, our maintaining of a 2.75 percent reductions to the rates to account for the increase in nominal case-mix, the 2.2 percent home health market basket update, the 2.5 percent increase to the HH PPS rates to account for an approximate 2.5 percent target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, and a 10 percent outlier cap.

The overall percentage change, for all HHAs, in estimated total payments from CY 2009 to CY 2010 is a decrease of approximately 0.86 percent. Rural HHAs, however, are estimated to see an increase in payments from CY 2009 to CY 2010 of about 3.45 percent. On the other hand, urban HHAs are expected to see a decrease of approximately 1.64 percent in payments from CY 2009 to CY 2010.

Voluntary non-profit HHAs (3.52 percent), facility-based HHAs (3.90 percent), and government owned HHAs (3.11 percent) are estimated to see an increase in the percentage change in estimated total payments from CY 2009 to CY 2010. Proprietary and freestanding HHAs, on the other hand, are estimated to see decreases of 3.14 percent and 1.73 percent, respectively, in estimated total payments from CY 2009 to CY 2010. Freestanding HHAs, broken out, show that voluntary non-profit and governmental HHAs are estimated to see increases of 3.22 percent and 2.63 percent, respectively, in estimated total payments from CY 2009 to CY 2010.

HHAs in the North and Midwest regions are expected to experience a percentage change increase in the estimated total payments from CY 2009 to CY 2010 of 3.79 percent and 3.67 percent, respectively. HHAs in the

South and West regions of the country are estimated to experience decreases in the percentage change in estimated total payments from CY 2009 to CY 2010 of 4.01 percent and 1.52 percent. We believe that the major contributors to the estimated decreases in payments in these areas of the country are those with high and suspect outlier payments.

Breaking this down even further, it is estimated that New England, Mid Atlantic, East South Central, East North Central, and West North Central area HHAs are all expected to experience increases in their payments in CY 2010 ranging from just over 2 percent to almost 5 percent. Conversely, South Atlantic and Pacific HHAs are expected to experience decreases, 11.68 percent and 2.90 percent respectively, in the percentage change in estimated total payments from CY 2009 to CY 2010. Again, we believe that the major contributors to the estimated decreases in payments in these areas of the country are those with high and suspect outlier payments.

Larger HHAs (those with 200 or more Medicare home health initial episodes per year) are estimated to experience an increase in payments from CY 2009 to CY 2010 of approximately 2.44 percent. Mid-size to small agencies are expected to see a decrease in their payments in CY 2010, ranging from 1.77 percent to 15.93 percent. However, we believe that the major contributors to the estimated decreases in payments for mid-size to small agencies are those agencies in areas of the country with high and suspect outlier payments. Consequently, we have provided a more detailed discussion, and analysis in Table 9 below, that demonstrates where, in the country, these estimated large decreases for mid-size to small agencies are occurring.

TABLE 8—IMPACT BY AGENCY TYPE

Group	Comparisons			
	Percent change due to the effects of the updated wage index only (percent)	(For comparison purposes) Impact of CY 2010 proposed policies ¹ (w/alternative 6.89 percent reduction in place of the proposed 2.75 percent reduction) (percent)	(For comparison purposes) Impact of CY 2010 proposed policies ¹ (w/alternative 3.51 percent reduction in place of the proposed 2.75 percent reduction) (percent)	Impact of CY 2010 proposed policies ¹ (percent)
Type of Facility:				
Free-Standing/Other Vol/NP	−0.01	−0.89	2.47	3.22
Free-Standing/Other Proprietary	−0.05	−7.25	−4.00	−3.27
Free-Standing/Other Government	−0.32	−1.49	1.88	2.63
Facility-Based Vol/NP	−0.12	−0.22	3.19	3.96
Facility-Based Proprietary	−0.22	−0.57	2.89	3.66
Facility-Based Government	−0.27	−0.56	2.88	3.65
Subtotal: Freestanding	−0.05	−5.74	−2.46	−1.73
Subtotal: Facility-based	−0.15	−0.29	3.13	3.90
Subtotal: Vol/PNP	−0.06	−0.62	2.76	3.52

TABLE 8—IMPACT BY AGENCY TYPE—Continued

Group	Comparisons			
	Percent change due to the effects of the updated wage index only (percent)	(For comparison purposes) Impact of CY 2010 proposed policies ¹ (w/alternative 6.89 percent reduction in place of the proposed 2.75 percent reduction) (percent)	(For comparison purposes) Impact of CY 2010 proposed policies ¹ (w/alternative 3.51 percent reduction in place of the proposed 2.75 percent reduction) (percent)	Impact of CY 2010 proposed policies ¹ (percent)
Subtotal: Proprietary	−0.05	−7.12	−3.87	−3.14
Subtotal: Government	−0.30	−1.05	2.35	3.11
Total	−0.06	−4.90	−1.60	−0.86
Type of Facility: (Rural * Only)				
Free-Standing/Other Vol/NP	−0.50	−0.61	2.83	3.60
Free-Standing/Other Proprietary	−0.14	−0.98	2.51	3.29
Free-Standing/Other Government	−0.58	−0.52	2.88	3.63
Facility-Based Vol/NP	−0.44	−0.52	2.91	3.68
Facility-Based Proprietary	−0.62	−1.30	2.16	2.93
Facility-Based Government	−0.42	−0.47	2.97	3.74
Type of Facility: (Urban * Only)				
Free-Standing/Other Vol/NP	0.06	−0.93	2.41	3.16
Free-Standing/Other Proprietary	−0.03	−8.11	−4.89	−4.17
Free-Standing/Other Government	−0.04	−2.58	0.76	1.51
Facility-Based Vol/NP	−0.04	−0.14	3.27	4.03
Facility-Based Proprietary	0.03	−0.10	3.35	4.13
Facility-Based Government	−0.03	−0.71	2.75	3.52
Type of Facility: (Urban* or Rural*)				
Rural	−0.31	−0.79	2.67	3.45
Urban	−0.02	−5.64	−2.37	−1.64
Total	−0.06	−4.90	−1.60	−0.86
Facility Location: Region*				
North	0.05	−0.30	3.04	3.79
South	−0.05	−7.95	−4.73	−4.01
Midwest	−0.23	−0.57	2.89	3.67
West	−0.08	−5.55	−2.26	−1.52
Outlying	0.37	0.21	3.68	4.46
Total	−0.06	−4.90	−1.60	−0.86
Facility Location: Area of the Country				
New England	0.53	0.75	4.13	4.88
Mid Atlantic	−0.21	−0.87	2.44	3.19
South Atlantic	0.27	−15.29	−12.34	−11.68
East South Central	−0.23	−0.57	2.94	3.72
West South Central	−0.29	−3.71	−0.34	0.41
East North Central	−0.27	−0.62	2.85	3.62
West North Central	−0.07	−0.37	3.08	3.85
Mountain	0.33	−2.05	1.33	2.09
Pacific	−0.23	−6.88	−3.63	−2.90
Outlying	0.37	0.21	3.68	4.46
Total	−0.06	−4.90	−1.60	−0.86
Facility Size: (Number of First Episodes)				
< 19	0.12	−19.43	−16.57	−15.93
20 to 49	0.03	−15.28	−12.29	−11.62
50 to 99	−0.04	−12.79	−9.72	−9.04
100 to 199	−0.13	−5.79	−2.51	−1.77
200 or More	−0.07	−1.70	1.69	2.44
Total	−0.06	−4.90	−1.60	−0.86

Note: Based on a 20% sample of CY 2007 claims linked to OASIS assessments. *Urban/rural status, for the purposes of these simulations, is based on the wage index on which episode payment is based. The wage index is based on the site of service of the beneficiary.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Middle Atlantic = Pennsylvania, New Jersey, New York; South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central = Alabama, Kentucky, Mississippi, Tennessee; West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central = Arkansas, Louisiana, Oklahoma, Texas; Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific = Alaska, California, Hawaii, Oregon, Washington; Outlying = Guam, Puerto Rico, Virgin Islands.

¹ Percent change due to the effects of the update wage index, the 2.2% home health market basket update, the 2.75% reduction to the national standardized episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor for nominal increase in case-mix, the 2.5% increase in the rates due to the new approximate 2.5% target for outliers as a percentage of total HH PPS payments, a 0.67 FDL ratio, and a 10% outlier cap.

Given the overall large negative impact observed by smaller agencies, we performed more detailed analysis targeted at identifying where the large negative impacts were occurring. Table 9 below presents the results of the regional analysis for small agencies. Column 1, of Table 9, shows the regional and agency size classifications similar to those in Table 8. In column 2 we repeat the overall impacts (from Table 8) for those classifications. In columns 3 through 7, we drill down in our analysis, looking at those classifications by the size of the agency (as defined by the number of first episodes). It is clear from this analysis that, for smaller agencies, the vast majority of the negative impact is

occurring in areas of the country (such as the South and South Atlantic) where there exist high and suspect outlier payments. Specifically, in columns 3, 4, and 5 of Table 9, for the South Atlantic area of the country (which includes Miami-Dade, Florida), the negative percentage impacts in payment ranging from around 40 percent to just over 53 percent are evidence that it is the high and suspect outlier payments in areas such as this, that are skewing the results of the overall impact analysis. Estimated impacts for small agencies in the South (negative impacts ranging around 15 percent to 22 percent) and the Pacific (negative impacts ranging from around 11 percent to 17 percent) areas of the country, reflect similar results.

Conversely, small HHAs in most other parts of the country are estimated to see increases in payments in CY 2010, ranging from 0.20 percent to almost 4.5 percent. Consequently, we believe that small HHAs without high and suspect outlier payments, on average, will see a positive impact on their payments in CY 2010. We do not believe there would be any significant impact on beneficiaries, as a result of the provisions of this rule. Areas where negative impacts have been estimated for HHAs, are primarily urban, and thus we believe that beneficiaries have a reasonable pool of HHAs from which to receive home health services.

TABLE 9—SMALL AGENCY IMPACTS

Group	Comparison of 2009–2010 Changes					
	Overall (percent)	< 20 episodes (percent)	20–49 episodes (percent)	50–99 episodes (percent)	100–199 episodes (percent)	200 or more episodes (percent)
Facility Location: Region of the Country						
North	3.79	0.20	3.05	3.06	3.70	3.83
South	–4.01	–21.93	–17.44	–14.71	–3.67	1.29
Midwest	3.67	2.63	3.45	3.52	3.79	3.75
West	–1.52	–5.67	–10.21	–9.16	–3.78	1.98
Outlying	4.46	4.48	4.41	4.86	4.40	4.44
Total	–0.86	–15.93	–11.62	–9.04	–1.77	2.44
Facility Location: Region of the Country (Census Region)						
New England	4.88	–3.21	3.53	4.79	4.05	5.04
Mid Atlantic	3.19	3.94	2.59	1.42	3.30	3.21
South Atlantic	–11.68	–53.28	–45.86	–40.50	–16.47	–0.59
East South Central	3.72	4.11	2.30	3.90	3.24	3.79
West South Central	0.41	–5.64	–2.55	–1.26	1.67	2.27
East North Central	3.62	2.45	3.21	3.61	3.88	3.69
West North Central	3.85	4.05	4.69	3.17	3.46	3.99
Mountain	2.09	1.59	–1.38	1.52	1.80	2.99
Pacific	–2.90	–11.37	–16.68	–13.11	–6.55	1.65
Outlying	4.46	4.48	4.41	4.86	4.40	4.44
Total	–0.86	–15.93	–11.62	–9.04	–1.77	2.44
Facility Size (Number of First Episodes)						
< 19 episodes	–15.93	–15.93				
20 to 49	–11.62		–11.62			
50 to 99	–9.04			–9.04		
100 to 199	–1.77				–1.77	
200 or More	2.44					2.44
Total	–0.86	–15.93	–11.62	–9.04	–1.77	2.44

Region Key: New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Middle Atlantic = Pennsylvania, New Jersey, New York; South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central = Alabama, Kentucky, Mississippi, Tennessee; West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central = Arkansas, Louisiana, Oklahoma, Texas; Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific = Alaska, California, Hawaii, Oregon, Washington; Outlying = Guam, Puerto Rico, Virgin Islands

C. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the

classification of the expenditures associated with the provisions of this proposed rule.

Table 10, below provides our best estimate of the decrease in Medicare payments under the HH PPS as a result

of the changes presented in this proposed rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of \$100 million.

TABLE 10—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2009 HH PPS CALENDAR YEAR TO THE 2010 HH PPS CALENDAR YEAR

Category	Transfers
Annualized Monetized Transfers From Whom To Whom	Negative transfer—Estimated decrease in expenditures: \$100 million. Federal Government to HH Providers.

D. Conclusion

In conclusion, we estimate that the net impact of the proposals in this rule, including a 2.75 percent reduction to the national standardized 60-day episode rates and the NRS conversion factor to account for the case-mix change adjustment, is approximately \$100 million in CY 2010 savings. The \$100 million impact reflects the distributional effects of an updated wage index (–\$10 million) as well as the 2.2 percent home health market basket increase (an additional \$390 million in CY 2010 expenditures attributable only to the CY 2010 home health market basket), and the 2.75 percent decrease (–\$480 million for the third year of a 4-year phase-in) to the national standardized 60-day episode rates and the NRS conversion factor to account for the case-mix change adjustment under the HH PPS. This analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 409.42 is amended as follows:

- A. Revising paragraph (c)(1).
- B. Adding paragraph (c)(1)(i) and (c)(1)(ii)

The revisions and additions read as follows:

§ 409.42 Beneficiary qualifications for coverage of services.

* * * * *

(c) * * *

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32. (Also see § 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.) These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service only when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may

cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

* * * * *

3. Section 409.43 is amended by revising paragraph (e)(1)(ii) to read as follows:

§ 409.43 Plan of care requirements.

* * * * *

(e) * * *

(1) * * *

(ii) Significant change in condition; or

* * * * *

4. Section 409.44 is amended by revising the introductory paragraph of (b)(1) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

(b) * * *

(1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.4 of this chapter, meet the criteria for skilled nursing services specified in § 409.32, and meet the qualifications for coverage of skilled services specified in § 409.42(c). See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

5. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

6. Section 424.22 is amended as follows:

- A. Revising paragraph (a)(1)(i);
- B. Revising paragraph (b)(2).

§ 424.22 Requirements for home health services.

(a) * * *

(1) * * *

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a written narrative describing the clinical justification of this need.

* * * * *

(b) * * *

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will

include a written narrative describing the clinical justification of this need.

* * * * *

7. Section 424.530 is amended by adding paragraph (a)(8) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(8) A prospective HHA is determined, under 42 CFR § 489.19, to be sharing, leasing, or subleasing its practice location or base of operations identified in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.

* * * * *

8. Section 424.535 is amended by adding paragraph (a)(11) to read as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) * * *

(11) An HHA is determined, under 42 CFR § 489.19, to be sharing, leasing, or subleasing its practice location or base of operations identified in Section 4 of its Medicare provider enrollment application with or to another Medicare-enrolled HHA or supplier.

* * * * *

9. Section 424.540 is amended by revising paragraph

(b)(3) to read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

* * * * *

(b) * * *

(3) With the exception of home health agencies, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at 42 CFR 424.540(a) must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

* * * * *

10. Section 424.550 is amended by adding paragraphs (b)(1) and (2) to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(1) If an owner of a home health agency sells (including asset sales or

stock transfers), transfers or relinquishes ownership of the HHA within 36 months after the effective date of the HHA's enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

(i) Enroll in the Medicare program as a new HHA under the provisions of § 424.510, and

(ii) Obtain a State survey or an accreditation from an approved accreditation organization.

(2) [Reserved]

* * * * *

PART 484—HOME HEALTH SERVICES

11. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart C—Furnishing of Services

12. Section 484.55 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(d) * * *

(1) * * *

(ii) Significant change in condition; or

* * * * *

Subpart E—Prospective Payment System for Home Health Agencies

13. Section 484.210 is amended by revising paragraph (e) to read as follows:

§ 484.210 Data used for the calculation of the national prospective 60-day episode payment.

* * * * *

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix. An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230 and 484.235.

14. Revising § 484.250 to read as follows:

§ 484.250 Patient assessment data.

An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235.

**PART 489—PROVIDER AGREEMENTS
AND SUPPLIER APPROVAL**

15. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

16. Section 489.12 is amended by adding paragraph (a)(5) to read as follows:

§ 489.12 Decision to deny an agreement.

(a) * * *

(5) A prospective HHA is determined to be sharing, leasing, or subleasing its practice location or base of operations identified in Section 4 of its Medicare provider enrollment application with or

to another Medicare enrolled HHA or supplier in violation of the HHA space sharing prohibition set forth in § 489.19.

* * * * *

17. Adding a new § 489.19 to read as follows:

§ 489.19 Prohibition on Space Sharing.

An HHA is prohibited from engaging in the following space sharing and/or leasing arrangements:

(a) Sharing its practice location or base of operations identified in Section 4 of its Medicare provider enrollment application with another Medicare-enrolled HHA or supplier; or

(b) Leasing or subleasing its practice location or base of operations identified in Section 4 of its Medicare provider

enrollment application to another Medicare-enrolled HHA or supplier.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 28, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 17, 2009.

Kathleen Sebelius,

Secretary.

Note: The following addenda will not be published in the Code of Federal Regulations.

BILLING CODE 13–01–00–D

Note: The following addenda will not be published in the Code of Federal Regulations.

ADDENDUM A. CY 2010 WAGE INDEX FOR RURAL AREAS BY CBSA;
APPLICABLE PRE-FLOOR AND PRE-RECLASSIFIED HOSPITAL WAGE INDEX

CBSA Code	Nonurban Area	Wage Index
01	Alabama	0.7335
02	Alaska	1.1680
03	Arizona	0.8801
04	Arkansas	0.7344
05	California	1.1864
06	Colorado	0.9938
07	Connecticut	1.1201
08	Delaware	0.9919
10	Florida	0.8574
11	Georgia	0.7635
12	Hawaii	1.1123
13	Idaho	0.7740
14	Illinois	0.8303
15	Indiana	0.8517
16	Iowa	0.8725
17	Kansas	0.8178
18	Kentucky	0.7810
19	Louisiana	0.7617
20	Maine	0.8587
21	Maryland	0.9139

CBSA Code	Nonurban Area	Wage Index
22	Massachusetts ¹	1.1711
23	Michigan	0.8782
24	Minnesota	0.9182
25	Mississippi	0.7645
26	Missouri	0.7698
27	Montana	0.8424
28	Nebraska	0.8606
29	Nevada	0.9683
30	New Hampshire	0.9960
31	New Jersey ¹	-----
32	New Mexico	0.8946
33	New York	0.8261
34	North Carolina	0.8535
35	North Dakota	0.7792
36	Ohio	0.8504
37	Oklahoma	0.7661
38	Oregon	1.0249
39	Pennsylvania	0.8314
40	Puerto Rico ¹	0.4047
41	Rhode Island ¹	-----
42	South Carolina	0.8378
43	South Dakota	0.8413
44	Tennessee	0.7817
45	Texas	0.7773
46	Utah	0.8371

¹ All counties within the State are classified as urban, with the exception of Massachusetts and Puerto Rico. Massachusetts and Puerto Rico have areas designated as rural, however, no short-term, acute care hospitals are located in the area(s) for CY 2010

CBSA Code	Nonurban Area	Wage Index
47	Vermont	0.9772
48	Virgin Islands	0.6971
49	Virginia	0.7876
50	Washington	1.0233
51	West Virginia	0.7403
52	Wisconsin	0.9211
53	Wyoming	0.9544
65	Guam	0.9611

ADDENDUM B.- CY 2010 WAGE INDEX FOR URBAN AREAS BY CBSA;
 APPLICABLE PRE-FLOOR AND PRE-RECLASSIFIED HOSPITAL WAGE INDEX

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10180	Abilene, TX Callahan County, TX Jones County, TX Taylor County, TX	0.7953
10380	Aguadilla-Isabela-San Sebastián, PR Aguada Municipio, PR Aguadilla Municipio, PR Añasco Municipio, PR Isabela Municipio, PR Lares Municipio, PR Moca Municipio, PR Rincón Municipio, PR San Sebastián Municipio, PR	0.3465
10420	Akron, OH Portage County, OH Summit County, OH	0.8858

CBSA Code	Urban Area (Constituent Counties)	Wage Index
10500	Albany, GA Baker County, GA Dougherty County, GA Lee County, GA Terrell County, GA Worth County, GA	0.8907
10580	Albany-Schenectady-Troy, NY Albany County, NY Rensselaer County, NY Saratoga County, NY Schenectady County, NY Schoharie County, NY	0.8790
10740	Albuquerque, NM Bernalillo County, NM Sandoval County, NM Torrance County, NM Valencia County, NM	0.9408
10780	Alexandria, LA Grant Parish, LA Rapides Parish, LA	0.8020
10900	Allentown-Bethlehem-Easton, PA-NJ Warren County, NJ Carbon County, PA Lehigh County, PA Northampton County, PA	0.9641
11020	Altoona, PA Blair County, PA	0.8871
11100	Amarillo, TX Armstrong County, TX Carson County, TX Potter County, TX Randall County, TX	0.8697
11180	Ames, IA Story County, IA	0.9505
11260	Anchorage, AK Anchorage Municipality, AK Matanuska-Susitna Borough, AK	1.2024
11300	Anderson, IN Madison County, IN	0.9060
11340	Anderson, SC Anderson County, SC	0.8819

CBSA Code	Urban Area (Constituent Counties)	Wage Index
11460	Ann Arbor, MI	1.0302
	Washtenaw County, MI	
11500	Anniston-Oxford, AL	0.7650
	Calhoun County, AL	
11540	Appleton, WI	0.9298
	Calumet County, WI	
11700	Outagamie County, WI	
	Asheville, NC	0.9079
	Buncombe County, NC	
	Haywood County, NC	
	Henderson County, NC	
	Madison County, NC	
12020	Athens-Clarke County, GA	0.9501
	Clarke County, GA	
	Madison County, GA	
	Oconee County, GA	
	Oglethorpe County, GA	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12060	Atlanta-Sandy Springs-Marietta, GA	0.9597
	Barrow County, GA	
	Bartow County, GA	
	Butts County, GA	
	Carroll County, GA	
	Cherokee County, GA	
	Clayton County, GA	
	Cobb County, GA	
	Coweta County, GA	
	Dawson County, GA	
	Dekalb County, GA	
	Douglas County, GA	
	Fayette County, GA	
	Forsyth County, GA	
	Fulton County, GA	
	Gwinnett County, GA	
	Haralson County, GA	
	Heard County, GA	
	Henry County, GA	
	Jasper County, GA	
	Lamar County, GA	
	Meriwether County, GA	
	Newton County, GA	
	Paulding County, GA	
	Pickens County, GA	
	Fike County, GA	
	Rockdale County, GA	
	Spalding County, GA	
	Walton County, GA	
12100	Atlantic City, NJ	1.1565
	Atlantic County, NJ	
12220	Auburn-Opelika, AL	0.8146
	Lee County, AL	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
13140	Beaumont-Port Arthur, TX Hardin County, TX Jefferson County, TX Orange County, TX	0.8391
13380	Bellingham, WA Whatcom County, WA	1.1406
13460	Bend, OR Deschutes County, OR	1.1457
13644	Bethesda-Frederick-Rockville, MD Frederick County, MD Montgomery County, MD	1.0307
13740	Billings, MT Carbon County, MT Yellowstone County, MT	0.8790
13780	Binghamton, NY Broome County, NY Tioga County, NY	0.8785
13820	Birmingham-Hoover, AL Bibb County, AL Blount County, AL Chilton County, AL Jefferson County, AL St. Clair County, AL Shelby County, AL Walker County, AL	0.8530
13900	Bismarck, ND Burleigh County, ND Morton County, ND	0.7644
13980	Blacksburg-Christiansburg-Radford, VA Giles County, VA Montgomery County, VA Pulaski County, VA Radford City, VA	0.8381
14020	Bloomington, IN Greene County, IN Monroe County, IN Owen County, IN	0.9031
14060	Bloomington-Normal, IL McLean County, IL	0.9387

CBSA Code	Urban Area (Constituent Counties)	Wage Index
12260	Augusta-Richmond County, GA-SC Burke County, GA Columbia County, GA McDuffie County, GA Richmond County, GA Aiken County, SC Edgefield County, SC	0.9125
12420	Austin-Round Rock, TX Bastrop County, TX Caldwell County, TX Hays County, TX Travis County, TX Williamson County, TX	0.9535
12540	Bakersfield, CA Kern County, CA	1.1215
12580	Baltimore-Towson, MD Anne Arundel County, MD Baltimore County, MD Carroll County, MD Harford County, MD Howard County, MD Queen Anne's County, MD Baltimore City, MD	1.0223
12620	Bangor, ME Penobscot County, ME	1.0163
12700	Barnstable Town, MA Barnstable County, MA	1.2629
12940	Baton Rouge, LA Ascension Parish, LA East Baton Rouge Parish, LA East Feliciana Parish, LA Iberville Parish, LA Livingston Parish, LA Pointe Coupee Parish, LA St. Helena Parish, LA West Baton Rouge Parish, LA West Feliciana Parish, LA	0.8187
12980	Battle Creek, MI Calhoun County, MI	1.0009
13020	Bay City, MI Bay County, MI	0.9276

CBSA Code	Urban Area (Constituent Counties)	Wage Index
15804	Camden, NJ Burlington County, NJ Camden County, NJ Gloucester County, NJ	1.0146
15940	Canton-Massillon, OH Carroll County, OH Stark County, OH	0.8803
15980	Cape Coral-Fort Myers, FL Lee County, FL	0.9084
16020	Cape Girardeau-Jackson, MO-IL Alexander County, IL Bollinger County, MO Cape Girardeau County, MO	0.9055
16180	Carson City, NV Carson City, NV	1.0540
16220	Casper, WY Natrona County, WY	0.9529
16300	Cedar Rapids, IA Benton County, IA Jones County, IA Linn County, IA	0.8992
16580	Champaign-Urbana, IL Champaign County, IL Ford County, IL Piatt County, IL	1.0117
16620	Charleston, WV Boone County, WV Clay County, WV Kanawha County, WV Lincoln County, WV Putnam County, WV	0.8149
16700	Charleston-North Charleston-Summerville, SC Berkeley County, SC Charleston County, SC Dorchester County, SC	0.9258
16740	Charlotte-Gastonia-Concord, NC-SC Anson County, NC Cabarrus County, NC Gaston County, NC Mecklenburg County, NC Union County, NC York County, SC	0.9483

CBSA Code	Urban Area (Constituent Counties)	Wage Index
14260	Boise City-Nampa, ID Ada County, ID Boise County, ID Canyon County, ID Gem County, ID Owyhee County, ID	0.9297
14484	Boston-Quincy, MA Norfolk County, MA Plymouth County, MA Suffolk County, MA	1.2160
14500	Boulder, CO Boulder County, CO	1.0276
14540	Bowling Green, KY Edmonson County, KY Warren County, KY	0.8474
14600	Bradenton-Sarasota-Venice, FL Manatee County, FL Sarasota, FL	0.9741
14740	Bremerton-Silverdale, WA Kitsap County, WA	1.0765
14860	Bridgeport-Stamford-Norwalk, CT Fairfield County, CT	1.2798
15180	Brownsville-Harlingen, TX Cameron County, TX	0.9029
15260	Brunswick, GA Brantley County, GA Glynn County, GA McIntosh County, GA	0.9371
15380	Buffalo-Niagara Falls, NY Erie County, NY Niagara County, NY	0.9739
15500	Burlington, NC Alamance County, NC	0.8757
15540	Burlington-South Burlington, VT Chittenden County, VT Franklin County, VT Grand Isle County, VT	1.0116
15764	Cambridge-Newton-Framingham, MA Middlesex County, MA	1.1288

CBSA Code	Urban Area (Constituent Counties)	Wage Index
16820	Charlottesville, VA Albemarle County, VA Fluvanna County, VA Greene County, VA Nelson County, VA Charlottesville City, VA	0.9380
16860	Chattanooga, TN-GA Catoosa County, GA Dade County, GA Walker County, GA Hamilton County, TN Marion County, TN Sequatchie County, TN	0.8839
16940	Cheyenne, WY Laramie County, WY	0.9353
16974	Chicago-Naperville-Joliet, IL Cook County, IL DeKalb County, IL DuPage County, IL Grundy County, IL Kane County, IL Kendall County, IL McHenry County, IL Will County, IL	1.0478
17020	Chico, CA Butte County, CA	1.1209

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17140	Cincinnati-Middletown, OH-KY-IN Dearborn County, IN Franklin County, IN Ohio County, IN Boone County, KY Bracken County, KY Campbell County, KY Gallatin County, KY Grant County, KY Kenton County, KY Pendleton County, KY Brown County, OH Butler County, OH Clermont County, OH Hamilton County, OH Warren County, OH	0.9488
17300	Clarksville, TN-KY Christian County, KY Trigg County, KY Montgomery County, TN Stewart County, TN	0.7987
17420	Cleveland, TN Bradley County, TN Polk County, TN	0.7571
17460	Cleveland-Elyria-Mentor, OH Cuyahoga County, OH Geauga County, OH Lake County, OH Lorain County, OH Medina County, OH	0.8922
17660	Coeur d'Alene, ID Kootenai County, ID	0.9243
17780	College Station-Bryan, TX Brazos County, TX Burleson County, TX Robertson County, TX	0.9507
17820	Colorado Springs, CO El Paso County, CO Teller County, CO	0.9830
17860	Columbia, MO Boone County, MO Howard County, MO	0.8625

CBSA Code	Urban Area (Constituent Counties)	Wage Index
19140	Dalton, GA Murray County, GA Whitfield County, GA	0.8674
19180	Danville, IL Vermilion County, IL	0.8746
19260	Danville, VA Pittsylvania County, VA Danville City, VA	0.8331
19340	Davenport-Moline-Rock Island, IA-IL Henry County, IL Mercer County, IL Rock Island County, IL Scott County, IA	0.8291
19380	Dayton, OH Greene County, OH Miami County, OH Montgomery County, OH Preble County, OH	0.9220
19460	Decatur, AL Lawrence County, AL Morgan County, AL	0.7806
19500	Decatur, IL Macon County, IL	0.8002
19660	Deltona-Daytona Beach-Ormond Beach, FL Volusia County, FL	0.8874
19740	Denver-Aurora-Broomfield, CO Adams County, CO Arapahoe County, CO Broomfield County, CO Clear Creek County, CO Denver County, CO Douglas County, CO Elbert County, CO Gilpin County, CO Jefferson County, CO Park County, CO	1.0733

CBSA Code	Urban Area (Constituent Counties)	Wage Index
17900	Columbia, SC Calhoun County, SC Fairfield County, SC Kershaw County, SC Lexington County, SC Richland County, SC Saluda County, SC	0.8757
17980	Columbus, GA-AL Russell County, AL Chattahoochee County, GA Harris County, GA Marion County, GA Muscogee County, GA	0.8732
18020	Columbus, IN Bartholomew County, IN	0.9545
18140	Columbus, OH Delaware County, OH Fairfield County, OH Franklin County, OH Licking County, OH Madison County, OH Morrow County, OH Pickaway County, OH Union County, OH	1.0092
18580	Corpus Christi, TX Aransas County, TX Nueces County, TX San Patricio County, TX	0.8701
18700	Corvallis, OR Benton County, OR	1.1013
19060	Cumberland, MD-WV Allegany County, MD Mineral County, WV	0.8053
19124	Dallas-Plano-Irving, TX Collin County, TX Dallas County, TX Delta County, TX Denton County, TX Ellis County, TX Hunt County, TX Kaufman County, TX Rockwall County, TX	0.9908

CBSA Code	Urban Area (Constituent Counties)	Wage Index
21340	El Paso, TX	0.8549
	El Paso County, TX	
21500	Erie, PA	0.8464
	Erie County, PA	
21660	Eugene-Springfield, OR	1.1045
	Lane County, OR	
21780	Evansville, IN-KY	0.8530
	Gibson County, IN	
	Fossey County, IN	
	Vanderburgh County, IN	
	Warrick County, IN	
	Henderson County, KY	
	Webster County, KY	
21820	Fairbanks, AK	1.1124
	Fairbanks North Star Borough, AK	
21940	Fajardo, PR	0.3793
	Ceiba Municipio, PR	
	Fajardo Municipio, PR	
	Luquillo Municipio, PR	
22020	Fargo, ND-MN	0.8180
	Cass County, ND	
	Clay County, MN	
22140	Farmington, NM	0.7896
	San Juan County, NM	
22180	Fayetteville, NC	0.9366
	Cumberland County, NC	
	Hoke County, NC	
22220	Fayetteville-Springdale-Rogers, AR-MO	0.8772
	Benton County, AR	
	Madison County, AR	
	Washington County, AR	
	McDonald County, MO	
22380	Flagstaff, AZ	1.2486
	Coconino County, AZ	
22420	Flint, MI	1.1134
	Genesee County, MI	
22500	Florence, SC	0.8141
	Darlington County, SC	
	Florence County, SC	
22520	Florence-Muscle Shoals, AL	0.7981
	Colbert County, AL	
	Lauderdale County, AL	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
19780	Des Moines-West Des Moines, IA	0.9658
	Dallas County, IA	
	Guthrie County, IA	
	Madison County, IA	
	Polk County, IA	
	Warren County, IA	
19804	Detroit-Livonia-Dearborn, MI	0.9737
	Wayne County, MI	
20020	Dothan, AL	0.7413
	Geneva County, AL	
	Henry County, AL	
	Houston County, AL	
20100	Dover, DE	0.9940
	Kent County, DE	
20220	Dubuque, IA	0.8877
	Dubuque County, IA	
20260	Duluth, MN-WI	1.0458
	Carlton County, MN	
	St. Louis County, MN	
	Douglas County, WI	
20500	Durham-Chapel Hill, NC	0.9548
	Chatham County, NC	
	Durham County, NC	
	Orange County, NC	
	Person County, NC	
20740	Eau Claire, WI	0.9575
	Chippewa County, WI	
	Eau Claire County, WI	
20764	Edison-New Brunswick, NJ	1.1072
	Middlesex County, NJ	
	Monmouth County, NJ	
	Ocean County, NJ	
	Somerset County, NJ	
20940	El Centro, CA	0.8774
	Imperial County, CA	
21060	Elizabethtown, KY	0.8396
	Hardin County, KY	
	Larue County, KY	
21140	Elkhart-Goshen, IN	0.9497
	Elkhart County, IN	
21300	Elmira, NY	0.8348
	Chemung County, NY	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
24220	Grand Forks, ND-MN Polk County, MN	0.7782
24300	Grand Forks County, ND Grand Junction, CO Mesa County, CO	0.9730
24340	Grand Rapids-Wyoming, MI Barry County, MI Tonia County, MI Kent County, MI Newaygo County, MI	0.9187
24500	Great Falls, MT Cascade County, MT	0.8361
24540	Greeley, CO Weld County, CO	0.9587
24580	Green Bay, WI Brown County, WI Kewaunee County, WI Oconto County, WI	0.9630
24660	Greensboro-High Point, NC Guilford County, NC Randolph County, NC Rockingham County, NC Greenville, NC Greene County, NC Pitt County, NC	0.9071
24780	Greenville-Mauldin-Easley, SC Greenville County, SC Laurens County, SC Pickens County, SC	0.9940
25020	Guayama, PR Arroyo Municipio, PR Guayama Municipio, PR Patillas Municipio, PR	0.3540
25060	Gulfport-Biloxi, MS Hancock County, MS Harrison County, MS Stone County, MS	0.8791
25180	Hagerstown-Martinsburg, MD-WV Washington County, MD Berkeley County, WV Morgan County, WV	0.8973

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22540	Fond du Lac, WI Fond du Lac County, WI	0.9669
22660	Fort Collins-Loveland, CO Larimer County, CO	1.0184
22744	Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Broward County, FL	1.0393
22900	Fort Smith, AR-OK Crawford County, AR Franklin County, AR Sebastian County, AR Le Flore County, OK Sequoyah County, OK	0.7868
23020	Fort Walton Beach-Crestview-Destin, FL Okaloosa County, FL	0.8766
23060	Fort Wayne, IN Allen County, IN Wells County, IN Whitley County, IN	0.9020
23104	Fort Worth-Arlington, TX Johnson County, TX Parker County, TX Tarrant County, TX Wise County, TX	0.9508
23420	Fresno, CA Fresno County, CA	1.1252
23460	Gadsden, AL Etowah County, AL	0.8274
23540	Gainesville, FL Alachua County, FL Gilchrist County, FL	0.8987
23580	Gainesville, GA Hall County, GA	0.9131
23844	Gary, IN Jasper County, IN Lake County, IN Newton County, IN Porter County, IN	0.9309
24020	Glens Falls, NY Warren County, NY Washington County, NY	0.8464
24140	Goldsboro, NC Wayne County, NC	0.9064

CBSA Code	Urban Area (Constituent Counties)	Wage Index
25260	Hanford-Corcoran, CA Kings County, CA	1.1020
25420	Harrisburg-Carlisle, PA Cumberland County, PA Dauphin County, PA Perry County, PA	0.9294
25500	Harrisonburg, VA Rockingham County, VA Harrisonburg City, VA	0.9033
25540	Hartford-West Hartford-East Hartford, CT Hartford County, CT Middlesex County, CT Tolland County, CT	1.1190
25620	Hattiesburg, MS Forrest County, MS Lamar County, MS Perry County, MS	0.7669
25860	Hickory-Lenoir-Morganton, NC Alexander County, NC Burke County, NC Caldwell County, NC Catawba County, NC	0.9005
25980 ²	Hinesville-Fort Stewart, GA Liberty County, GA Long County, GA	0.9029
26100	Holland-Grand Haven, MI Ottawa County, MI	0.8704
26180	Honolulu, HI Honolulu County, HI	1.1664
26300	Hot Springs, AR Garland County, AR	0.9013
26380	Houma-Bayou Cane-Thibodaux, LA Lafourche Parish, LA Terrebonne Parish, LA	0.7882

CBSA Code	Urban Area (Constituent Counties)	Wage Index
26420	Houston-Sugar Land-Baytown, TX Austin County, TX Brazoria County, TX Chambers County, TX Fort Bend County, TX Galveston County, TX Harris County, TX Liberty County, TX Montgomery County, TX San Jacinto County, TX Waller County, TX	0.9842
26580	Huntington-Ashland, WV-KY-OH Boyd County, KY Greenup County, KY Lawrence County, OH Cabell County, WV Wayne County, WV	0.9105
26620	Huntsville, AL Limestone County, AL Madison County, AL	0.9073
26820	Idaho Falls, ID Bonneville County, ID Jefferson County, ID	0.9445
26900	Indianapolis-Carmel, IN Boone County, IN Brown County, IN Hamilton County, IN Hancock County, IN Hendricks County, IN Johnson County, IN Marion County, IN Morgan County, IN Putnam County, IN Shelby County, IN	0.9930
26980	Iowa City, IA Johnson County, IA Washington County, IA	0.9557
27060	Ithaca, NY Tompkins County, NY	1.0121
27100	Jackson, MI Jackson County, MI	0.8728

CBSA Code	Urban Area (Constituent Counties)	Wage Index
27140	Jackson, MS Copiah County, MS Hinds County, MS Madison County, MS Rankin County, MS Simpson County, MS	0.8193
27180	Jackson, TN Chester County, TN Madison County, TN	0.8589
27260	Jacksonville, FL Baker County, FL Clay County, FL Duval County, FL Nassau County, FL St. Johns County, FL	0.9114
27340	Jacksonville, NC Onslow County, NC	0.8033
27500	Janesville, WI Rock County, WI	0.9209
27620	Jefferson City, MO Callaway County, MO Cole County, MO Moniteau County, MO Osage County, MO	0.8717
27740	Johnson City, TN Carter County, TN Unicoi County, TN Washington County, TN	0.7481
27780	Johnstown, PA Cambria County, PA	0.8241
27860	Jonesboro, AR Craighead County, AR Poinsett County, AR	0.7729
27900	Joplin, MO Jasper County, MO Newton County, MO	0.8292
28020	Kalamazoo-Portage, MI Kalamazoo County, MI Van Buren County, MI	1.0273
28100	Kankakee-Bradley, IL Kankakee County, IL	1.0183

CBSA Code	Urban Area (Constituent Counties)	Wage Index
28140	Kansas City, MO-KS Franklin County, KS Johnson County, KS Leavenworth County, KS Linn County, KS Miami County, KS Wyandotte County, KS Bates County, MO Caldwell County, MO Cass County, MO Clay County, MO Clinton County, MO Jackson County, MO Lafayette County, MO Platte County, MO Ray County, MO	0.9701
28420	Kennewick-Pasco-Richland, WA Benton County, WA Franklin County, WA	1.0458
28660	Killeen-Temple-Fort Hood, TX Bell County, TX Coryell County, TX Lampasas County, TX	0.8710
28700	Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN Sullivan County, TN Bristol City, VA Scott County, VA Washington County, VA	0.7974
28740	Kingston, NY Ulster County, NY	0.9375
28940	Knoxville, TN Anderson County, TN Blount County, TN Knox County, TN Loudon County, TN Union County, TN	0.7888
29020	Kokomo, IN Howard County, IN Tipton County, IN	0.9825
29100	Ia Crosse, WI-MN Houston County, MN	0.9924

CBSA Code	Urban Area (Constituent Counties)	Wage Index
	La Crosse County, WI	
29140	Lafayette, IN Benton County, IN Carroll County, IN Tippecanoe County, IN	0.9189
29180	Lafayette, LA Lafayette Parish, LA St. Martin Parish, LA	0.8524
29340	Lake Charles, LA Calcasieu Parish, LA Cameron Parish, LA	0.7993
29404	Lake County-Kenosha County, IL-WI Lake County, IL Kenosha County, WI	1.0485
29420	Lake Havasu City-Kingman, AZ Mohave County, AZ	1.0577
29460	Lakeland-Winter Haven, FL Polk County, FL	0.8398
29540	Lancaster, PA Lancaster County, PA	0.9212
29620	Lansing-East Lansing, MI Clinton County, MI Eaton County, MI Ingham County, MI	0.9659
29700	Laredo, TX Webb County, TX	0.8082
29740	Las Cruces, NM Dona Ana County, NM	0.8947
29820	Las Vegas-Paradise, NV Clark County, NV	1.2133
29940	Lawrence, KS Douglas County, KS	0.8588
30020	Lawton, OK Comanche County, OK	0.7854
30140	Lebanon, PA Lebanon County, PA	0.8127
30300	Lewiston, ID-WA Nez Perce County, ID Asotin County, WA	0.9579

CBSA Code	Urban Area (Constituent Counties)	Wage Index
30340	Lewiston-Auburn, ME Androscoggin County, ME	0.9093
30460	Lexington-Fayette, KY Bourbon County, KY Clark County, KY Fayette County, KY Jessamine County, KY Scott County, KY Woodford County, KY	0.8897
30620	Lima, OH Allen County, OH	0.9371
30700	Lincoln, NE Lancaster County, NE Seward County, NE	0.9572
30780	Little Rock-North Little Rock-Conway, AR Faulkner County, AR Grant County, AR Lonoke County, AR Perry County, AR Pulaski County, AR Saline County, AR	0.8550
30860	Logan, UT-ID Franklin County, ID Cache County, UT	0.9001
30980	Longview, TX Gregg County, TX Rusk County, TX Upshur County, TX	0.8056
31020	Longview, WA Cowlitz County, WA	1.0716
31084	Los Angeles-Long Beach-Santa Ana, CA Los Angeles County, CA	1.2025

CBSA Code	Urban Area (Constituent Counties)	Wage Index
31140	Louisville-Jefferson County, KY-IN Clark County, IN Floyd County, IN Harrison County, IN Washington County, IN Bullitt County, KY Henry County, KY Jefferson County, KY Meade County, KY Nelson County, KY Oldham County, KY Shelby County, KY Spencer County, KY Trimble County, KY	0.8972
31180	Lubbock, TX Crosby County, TX Lubbock County, TX	0.8759
31340	Lynchburg, VA Amherst County, VA Appomattox County, VA Bedford County, VA Campbell County, VA Bedford City, VA Lynchburg City, VA	0.8529
31420	Macon, GA Bibb County, GA Crawford County, GA Jones County, GA Monroe County, GA Twiggs County, GA	0.9835
31460	Madera-Chowchilla, CA Madera County, CA	0.7965
31540	Madison, WI Columbia County, WI Dane County, WI Iowa County, WI	1.1245
31700	Manchester-Nashua, NH Hillsborough County, NH	1.0180
31740	Manhattan, KS Geary County, KS Pottawatomie County, KS Riley County, KS	0.7885

CBSA Code	Urban Area (Constituent Counties)	Wage Index
31860	Mankato-North Mankato, MN Blue Earth County, MN Niccollet County, MN	0.9185
31900	Mansfield, OH Richland County, OH	0.9108
32420	Mayaguez, PR Hormigueros Municipio, PR Mayaguez Municipio, PR	0.3708
32580	McAllen-Edinburg-Mission, TX Hidalgo County, TX	0.8828
32780	Medford, OR Jackson County, OR	1.0093
32820	Memphis, TN-MS-AR Crittenden County, AR DeSoto County, MS Marshall County, MS Tate County, MS Tunica County, MS Fayette County, TN Shelby County, TN Tipton County, TN	0.9277
32900	Merced, CA Merced County, CA	1.0452
33124	Miami-Miami Beach-Kendall, FL Miami-Dade County, FL	0.9964
33140	Michigan City-La Porte, IN LaPorte County, IN	0.9320
33260	Midland, TX Midland County, TX	0.9555
33340	Milwaukee-Waukesha-West Allis, WI Milwaukee County, WI Ozaukee County, WI Washington County, WI Waukesha County, WI	1.0160

CBSA Code	Urban Area (Constituent Counties)	Wage Index
33460	Minneapolis-St. Paul-Bloomington, MN-WI Anoka County, MN Carver County, MN Chisago County, MN Dakota County, MN Hennepin County, MN Isanti County, MN Ramsey County, MN Scott County, MN Sherburne County, MN Washington County, MN Wright County, MN Pierce County, WI St. Croix County, WI	1.1108
33540	Missoula, MT	0.9215
33660	Missoula County, MT	
33700	Mobile, AL Mobile County, AL	0.7792
33740	Modesto, CA Stanislaus County, CA	1.2514
33780	Monroe, LA Ouachita Parish, LA Union Parish, LA	0.7759
33860	Monroe, MI Monroe County, MI	0.8893
34060	Montgomery, AL Autauga County, AL Elmore County, AL Lowndes County, AL Montgomery County, AL	0.8312
34100	Morgantown, WV Monongalia County, WV Preston County, WV	0.8467
34580	Morristown, TN Grainger County, TN Hamblen County, TN Jefferson County, TN	0.7208
34620	Mount Vernon-Anacortes, WA Skagit County, WA	1.0462
	Muncie, IN	0.8247
	Delaware County, IN	

CBSA Code	Urban Area (Constituent Counties)	Wage Index
34740	Muskegon-Norton Shores, MI Muskegon County, MI	0.9832
34820	Myrtle Beach-North Myrtle Beach-Conway, SC Horry County, SC	0.8736
34900	Napa, CA Napa County, CA	1.4449
34940	Naples-Marco Island, FL Collier County, FL	0.9671
34980	Nashville-Davidson-Murfreesboro-Franklin, TN Cannon County, TN Cheatham County, TN Davidson County, TN Dickson County, TN Hickman County, TN Macon County, TN Robertson County, TN Rutherford County, TN Smith County, TN Sumner County, TN Trousdale County, TN Williamson County, TN Wilson County, TN	0.9700
35004	Nassau-Suffolk, NY Nassau County, NY Suffolk County, NY	1.2471
35084	Newark-Union, NJ-PA Essex County, NJ Hunterdon County, NJ Morris County, NJ Sussex County, NJ Union County, NJ Pike County, PA	1.1420
35300	New Haven-Milford, CT New Haven County, CT	1.1496
35380	New Orleans-Metairie-Kenner, LA Jefferson Parish, LA Orleans Parish, LA Plaquemines Parish, LA St. Bernard Parish, LA St. Charles Parish, LA St. John the Baptist Parish, LA St. Tammany Parish, LA	0.9100

CBSA Code	Urban Area (Constituent Counties)	Wage Index
35644	New York-Wayne-White Plains, NY-NJ Bergen County, NJ Hudson County, NJ Passaic County, NJ Bronx County, NY Kings County, NY New York County, NY Putnam County, NY Queens County, NY Richmond County, NY Rockland County, NY Westchester County, NY	1.2982
35660	Niles-Benton Harbor, MI Berrien County, MI	0.8911
35980	Norwich-New London, CT New London County, CT	1.1409
36084	Oakland-Fremont-Hayward, CA Alameda County, CA Contra Costa County, CA	1.6331
36100	Ocala, FL Marion County, FL	0.8564
36140	Ocean City, NJ Cape May County, NJ	1.0169
36220	Odessa, TX Ector County, TX	0.9871
36260	Ogden-Clearfield, UT Davis County, UT Morgan County, UT Weber County, UT	0.9369
36420	Oklahoma City, OK Canadian County, OK Cleveland County, OK Grady County, OK Lincoln County, OK Logan County, OK McCain County, OK Oklahoma County, OK	0.8909
36500	Olympia, WA Thurston County, WA	1.1541

CBSA Code	Urban Area (Constituent Counties)	Wage Index
36540	Omaha-Council Bluffs, NE-IA Harrison County, IA Mills County, IA Pottawattamie County, IA Cass County, NE Douglas County, NE Sarpy County, NE Saunders County, NE Washington County, NE	0.9617
36740	Orlando-Kissimmee, FL Lake County, FL Orange County, FL Osceola County, FL Seminole County, FL	0.8964
36780	Oshkosh-Neenah, WI Winnebago County, WI	0.9160
36980	Owensboro, KY Davies County, KY Hancock County, KY McLean County, KY	0.8365
37100	Oxnard-Thousand Oaks-Ventura, CA Ventura County, CA	1.2299
37340	Palm Bay-Melbourne-Titusville, FL Brevard County, FL	0.9069
37380	Palm Coast, FL Flagler County, FL	0.9612
37460	Panama City-Lynn Haven-Panama City Beach, FL Bay County, FL	0.8332
37620	Parkersburg-Marietta, WV-OH Washington County, OH Pleasants County, WV Wirt County, WV Wood County, WV	0.7723
37700	Pascagoula, MS George County, MS Jackson County, MS	0.8441
37764	Peabody, MA Essex County, MA	1.0881
37860	Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL	0.8311

CBSA Code	Urban Area (Constituent Counties)	Wage Index
37900	Peoria, IL Marshall County, IL Peoria County, IL Stark County, IL Tazewell County, IL Woodford County, IL	0.9122
37964	Philadelphia, PA Bucks County, PA Chester County, PA Delaware County, PA Montgomery County, PA Philadelphia County, PA	1.0735
38060	Phoenix-Mesa-Scottsdale, AZ Maricopa County, AZ Pinal County, AZ	1.0640
38220	Fine Bluff, AR Cleveland County, AR Jefferson County, AR Lincoln County, AR	0.7288
38300	Pittsburgh, PA Allegheny County, PA Armstrong County, PA Beaver County, PA Butler County, PA Fayette County, PA Washington County, PA Westmoreland County, PA	0.8604
38340	Pittsfield, MA Berkshire County, MA	1.0668
38540	Pocatello, ID Bannock County, ID Power County, ID	0.9247
38660	Ponce, PR Juana Díaz Municipio, PR Ponce Municipio, PR Villalba Municipio, PR	0.4224
38860	Portland-South Portland-Biddeford, ME Cumberland County, ME Sagadahoc County, ME York County, ME	1.0196

CBSA Code	Urban Area (Constituent Counties)	Wage Index
38900	Portland-Vancouver-Beaverton, OR-WA Clackamas County, OR Columbia County, OR Multnomah County, OR Washington County, OR Yamhill County, OR Clark County, WA Skamania County, WA	1.1502
38940	Port St. Lucie, FL Martin County, FL St. Lucie County, FL	0.9906
39100	Poughkeepsie-Newburgh-Middletown, NY Dutchess County, NY Orange County, NY	1.1238
39140	Prescott, AZ Yavapai County, AZ	1.0130
39300	Providence-New Bedford-Fall River, RI-MA Bristol County, MA Bristol County, RI Kent County, RI Newport County, RI Providence County, RI Washington County, RI	1.0792
39340	Provo-Orem, UT Juab County, UT Utah County, UT	0.9556
39380	Pueblo, CO Pueblo County, CO	0.8578
39460	Punta Gorda, FL Charlotte County, FL	0.8782
39540	Racine, WI Racine County, WI	0.9381
39580	Raleigh-Cary, NC Franklin County, NC Johnston County, NC Wake County, NC	0.9656
39660	Rapid City, SD Meade County, SD Pennington County, SD Reading, PA Berks County, PA	1.0055
39740		0.9271

CBSA Code	Urban Area (Constituent Counties)	Wage Index
40340	Rochester, MN Dodge County, MN Olmsted County, MN Wabasha County, MN	1.1146
40380	Rochester, NY Livingston County, NY Monroe County, NY Ontario County, NY Orleans County, NY Wayne County, NY	0.8652
40420	Rockford, IL Boone County, IL Winnebago County, IL	1.0162
40484	Rockingham County--Strafford County, NH Rockingham County, NH Strafford County, NH	1.0134
40580	Rocky Mount, NC Edgecombe County, NC Nash County, NC	0.8853
40660	Rome, GA Floyd County, GA	0.8923
40900	Sacramento--Arden-Arcade--Roseville, CA El Dorado County, CA Placer County, CA Sacramento County, CA Yolo County, CA	1.4031
40980	Saginaw--Saginaw Township North, MI Saginaw County, MI	0.9127
41060	St. Cloud, MN Benton County, MN Stearns County, MN	1.1117
41100	St. George, UT	0.9245
41140	Washington County, UT St. Joseph, MO-KS Doniphan County, KS Andrew County, MO Buchanan County, MO DeKalb County, MO	1.0198

CBSA Code	Urban Area (Constituent Counties)	Wage Index
39820	Redding, CA Shasta County, CA	1.4027
39900	Reno-Sparks, NV Storey County, NV Washoe County, NV	1.0295
40060	Richmond, VA Amelia County, VA Caroline County, VA Charles City County, VA Chesterfield County, VA Cumberland County, VA Dinwiddie County, VA Goochland County, VA Hanover County, VA Henrico County, VA King and Queen County, VA King William County, VA Louisa County, VA New Kent County, VA Powhatan County, VA Prince George County, VA Sussex County, VA Colonial Heights City, VA Hopewell City, VA Petersburg City, VA Richmond City, VA	0.9530
40140	Riverside-San Bernardino-Ontario, CA Riverside County, CA San Bernardino County, CA	1.1234
40220	Roanoke, VA Botetourt County, VA Craig County, VA Franklin County, VA Roanoke County, VA Roanoke City, VA Salem City, VA	0.8642

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41180	St. Louis, MO-IL Bond County, IL Calhoun County, IL Clinton County, IL Jersey County, IL Macoupin County, IL Madison County, IL Monroe County, IL St. Clair County, IL Crawford County, MO Franklin County, MO Jefferson County, MO Lincoln County, MO St. Charles County, MO St. Louis County, MO Warren County, MO Washington County, MO St. Louis City, MO	0.9110
41420	Salem, OR Marion County, OR Polk County, OR	1.0985
41500	Salinas, CA Monterey County, CA	1.5221
41540	Salisbury, MD Somerset County, MD Wicomico County, MD	0.9119
41620	Salt Lake City, UT Salt Lake County, UT Summit County, UT Tooele County, UT	0.9387
41660	San Angelo, TX Irion County, TX Tom Green County, TX	0.7921
41700	San Antonio, TX Atascosa County, TX Bandera County, TX Bexar County, TX Comal County, TX Guadalupe County, TX Kendall County, TX Medina County, TX Wilson County, TX	0.8853

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41740	San Diego-Carlsbad-San Marcos, CA San Diego County, CA	1.1759
41780	Sandusky, OH Erie County, OH	0.8896
41884	San Francisco-San Mateo-Redwood City, CA Marin County, CA San Francisco County, CA San Mateo County, CA	1.5963
41900	San Germán-Cabo Rojo, PR Cabo Rojo Municipio, PR Lajas Municipio, PR Sabana Grande Municipio, PR San Germán Municipio, PR	0.4745
41940	San Jose-Sunnyvale-Santa Clara, CA San Benito County, CA Santa Clara County, CA	1.6399

CBSA Code	Urban Area (Constituent Counties)	Wage Index
41980	San Juan-Caguas-Guaynabo, PR Agua Buenas Municipio, PR Aibonito Municipio, PR Arecibo Municipio, PR Barceloneta Municipio, PR Barranquitas Municipio, PR Bayamón Municipio, PR Caguas Municipio, PR Camuy Municipio, PR Canóvanas Municipio, PR Carolina Municipio, PR Cataño Municipio, PR Cayey Municipio, PR Ciales Municipio, PR Cidra Municipio, PR Comerio Municipio, PR Corozal Municipio, PR Dorado Municipio, PR Florida Municipio, PR Guaynabo Municipio, PR Gurabo Municipio, PR Hatillo Municipio, PR Humacao Municipio, PR Juncos Municipio, PR Las Piedras Municipio, PR Loíza Municipio, PR Manatí Municipio, PR Maunabo Municipio, PR Morovis Municipio, PR Naguabo Municipio, PR Naranjito Municipio, PR Orocovis Municipio, PR Quebradillas Municipio, PR Río Grande Municipio, PR San Juan Municipio, PR San Lorenzo Municipio, PR Toa Alta Municipio, PR Toa Baja Municipio, PR Trujillo Alto Municipio, PR Vega Alta Municipio, PR Vega Baja Municipio, PR Yabucoa Municipio, PR	0.4367

CBSA Code	Urban Area (Constituent Counties)	Wage Index
42020	San Luis Obispo-Paso Robles, CA San Luis Obispo County, CA	1.2561
42044	Santa Ana-Anaheim-Irvine, CA Orange County, CA	1.1977
42060	Santa Barbara-Santa Maria-Goleta, CA Santa Barbara County, CA	1.2333
42100	Santa Cruz-Watsonville, CA Santa Cruz County, CA	1.6749
42140	Santa Fe, NM	1.0704
42220	Santa Fe County, NM Santa Rosa-Petaluma, CA	1.5914
42340	Sonoma County, CA Savannah, GA Bryan County, GA Chatham County, GA Effingham County, GA	0.9051
42540	Scranton--Wilkes-Barre, PA Lackawanna County, PA Luzerne County, PA Wyoming County, PA	0.8382
42644	Seattle--Bellevue--Everett, WA King County, WA Snohomish County, WA	1.1587
42680	Sebastian-Vero Beach, FL Indian River County, FL	0.9370
43100	Sheboygan, WI Sheboygan County, WI	0.9174
43300	Sherman-Denison, TX Grayson County, TX	0.8071
43340	Shreveport-Bossier City, LA Bossier Parish, LA Caddo Parish, LA De Soto Parish, LA	0.8391
43580	Sioux City, IA-NE-SD Woodbury County, IA Dakota County, NE Dixon County, NE Union County, SD	0.9103

CBSA Code	Urban Area (Constituent Counties)	Wage Index
43620	Sioux Falls, SD Lincoln County, SD McCook County, SD Minnehaha County, SD Turner County, SD	0.8991
43780	South Bend-Mishawaka, IN-MI St. Joseph County, IN Cass County, MI	0.9699
43900	Spartanburg, SC	0.9350
44060	Spokane, WA Spokane County, WA	1.0453
44100	Springfield, IL Menard County, IL Sangamon County, IL	0.9554
44140	Springfield, MA Franklin County, MA Hampden County, MA Hampshire County, MA	1.0384
44180	Springfield, MO Christian County, MO Dallas County, MO Greene County, MO Polk County, MO Webster County, MO	0.8058
44220	Springfield, OH Clark County, OH	0.9203
44300	State College, PA Centre County, PA	0.9104
44700	Stockton, CA San Joaquin County, CA	1.2306
44940	Sumter, SC Sumter County, SC	0.8159
45060	Syracuse, NY Madison County, NY Onondaga County, NY Oswego County, NY	0.9790

CBSA Code	Urban Area (Constituent Counties)	Wage Index
45104	Tacoma, WA Pierce County, WA	1.1206
45220	Tallahassee, FL Gadsden County, FL Jefferson County, FL Leon County, FL Wakulla County, FL	0.8414
45300	Tampa-St. Petersburg-Clearwater, FL Hernando County, FL Hillsborough County, FL Pasco County, FL Pinellas County, FL	0.8990
45460	Terre Haute, IN Clay County, IN Sullivan County, IN Vermillion County, IN Vigo County, IN	0.8967
45500	Texarkana, TX-Texarkana, AR Miller County, AR Bowie County, TX	0.8121
45780	Toledo, OH Fulton County, OH Lucas County, OH Ottawa County, OH Wood County, OH	0.9549
45820	Topeka, KS Jackson County, KS Jefferson County, KS Osage County, KS Shawnee County, KS Wabaunsee County, KS	0.8838
45940	Trenton-Ewing, NJ Mercer County, NJ	1.0561

CBSA Code	Urban Area (Constituent Counties)	Wage Index
46060	Tucson, AZ Pima County, AZ	0.9514
46140	Tulsa, OK Creek County, OK Okmulgee County, OK Osage County, OK Pawnee County, OK Rogers County, OK Tulsa County, OK Wagoner County, OK	0.8670
46220	Tuscaloosa, AL Greene County, AL Hale County, AL Tuscaloosa County, AL	0.8706
46340	Tyler, TX Smith County, TX	0.8320
46540	Utica-Rome, NY Herkimer County, NY Oneida County, NY	0.8492
46660	Valdosta, GA Brooks County, GA Echols County, GA Lanier County, GA Lowndes County, GA	0.7952
46700	Vallejo-Fairfield, CA Solano County, CA	1.4948
47020	Victoria, TX Calhoun County, TX Goliad County, TX Victoria County, TX	0.8062
47220	Vineland-Millville-Bridgeton, NJ Cumberland County, NJ	1.0216
47260	Virginia Beach-Norfolk-Newport News, VA-NC Currituck County, NC Gloucester County, VA Isle of Wight County, VA James City County, VA Mathews County, VA Surry County, VA York County, VA Chesapeake City, VA Hampton City, VA Newport News City, VA Norfolk City, VA Poquoson City, VA Portsmouth City, VA Suffolk City, VA Virginia Beach City, VA Williamsburg City, VA	0.8969
47300	Visalia-Porterville, CA Tulare County, CA	1.0231
47380	Waco, TX McLennan County, TX	0.8384
47580	Warner Robins, GA Houston County, GA	0.8762
47644	Warren-Troy-Farmington Hills, MI Lapeer County, MI Livingston County, MI Macomb County, MI Oakland County, MI St. Clair County, MI	0.9825

CBSA Code	Urban Area (Constituent Counties)	Wage Index
48620	Wichita, KS Butler County, KS Harvey County, KS Sedwick County, KS Sumner County, KS	0.8978
48660	Wichita Falls, TX Archer County, TX Clay County, TX Wichita County, TX	0.9205
48700	Williamsport, PA Lycoming County, PA	0.7885
48864	Wilmington, DE-MD-NJ New Castle County, DE Cecil County, MD Salem County, NJ	1.0558
48900	Wilmington, NC Brunswick County, NC New Hanover County, NC Pender County, NC	0.8994
49020	Winchester, VA-WV Frederick County, VA Winchester City, VA Hampshire County, WV	0.9786
49180	Winston-Salem, NC Davie County, NC Forsyth County, NC Stokes County, NC Yadkin County, NC	0.8942
49340	Worcester, MA Worcester County, MA	1.1099
49420	Yakima, WA Yakima County, WA	0.9958
49500	Yauco, PR Guánica Municipio, PR Guayanilla Municipio, PR Peñuelas Municipio, PR Yauco Municipio, PR	0.3351
49620	York-Hanover, PA York County, PA	0.9308

CBSA Code	Urban Area (Constituent Counties)	Wage Index
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV District of Columbia, DC Calvert County, MD Charles County, MD Prince George's County, MD Arlington County, VA Clarke County, VA Fairfax County, VA Fauquier County, VA Loudoun County, VA Prince William County, VA Spotsylvania County, VA Stafford County, VA Warren County, VA Alexandria City, VA Fairfax City, VA Falls Church City, VA Fredericksburg City, VA Manassas City, VA Manassas Park City, VA Jefferson County, WV	1.0891
47940	Waterloo-Cedar Falls, IA Black Hawk County, IA Bremer County, IA Grundy County, IA	0.8526
48140	Wausau, WI Marathon County, WI	0.9449
48260	Weirton-Steubenville, WV-OH Jefferson County, OH Brooke County, WV Hancock County, WV	0.7375
48300	Wenatchee-East Wenatchee, WA Chelan County, WA Douglas County, WA	0.9728
48424	West Palm Beach-Boca Raton-Boynton Beach, FL Palm Beach County, FL	0.9888
48540	Wheeling, WV-OH Belmont County, OH Marshall County, WV Ohio County, WV	0.6876

CBSA Code	Urban Area (Constituent Counties)	Wage Index
49660	Youngstown-Warren-Boardman, OH-PA Mahoning County, OH Trumbull County, OH Mercer County, PA	0.8615
49700	Yuba City, CA Sutter County, CA Yuba County, CA	1.1100
49740	Yuma, AZ Yuma County, AZ	0.9152

²At this time, there are no hospitals in these urban areas on which to base a wage index. Therefore, the urban wage index value is based on the average wage index of all urban areas within the State.

[FR Doc. E9-18587 Filed 7-30-09; 4:15 pm]

Editorial Note: Federal Register proposed rule document E9-18587, originally

published at pages 39436 to 39496 in the issue of Thursday, August 6, 2009, included incorrect tables from pages 39471 to 39496.

This document, along with the correct tables, is being republished in its entirety.

[FR Doc. R9-18587 Filed 8-12-09; 8:45 am]

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Federal Register

**Thursday,
August 13, 2009**

Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

**Migratory Bird Hunting; Proposed
Framework for Late-Season Migratory
Bird Hunting Regulations; Proposed Rule**

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****50 CFR Part 20**

[FWS-R9-MB-2008-0124; 91200-1231-9BPP-L2]

RIN 1018-AW31

Migratory Bird Hunting; Proposed Frameworks for Late-Season Migratory Bird Hunting Regulations**AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Proposed rule; supplemental.

SUMMARY: The Fish and Wildlife Service (hereinafter Service or we) is proposing to establish the 2009–10 late-season hunting regulations for certain migratory game birds. We annually prescribe frameworks, or outer limits, for dates and times when hunting may occur and the number of birds that may be taken and possessed in late seasons. These frameworks are necessary to allow State selections of seasons and limits and to allow recreational harvest at levels compatible with population and habitat conditions.

DATES: You must submit comments on the proposed migratory bird hunting late-season frameworks by August 24, 2009.

ADDRESSES: You may submit comments on the proposals by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- U.S. mail or hand-delivery: Public Comments Processing, Attn: FWS–R9–MB–2008–0124; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the **Public Comments** section below for more information).

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS MBSP-4107-ARLSQ, 1849 C Street, NW, Washington, DC 20240; (703) 358-1714.

SUPPLEMENTARY INFORMATION:**Regulations Schedule for 2009**

On April 10, 2009, we published in the **Federal Register** (74 FR 16339) 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, 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 2009–10 regulatory cycle relating to open public meetings and **Federal Register** notifications were also identified in the April 10 proposed rule. Further, we explained that all sections of subsequent documents outlining hunting frameworks and guidelines were organized under numbered headings.

On May 27, 2009, we published in the **Federal Register** (74 FR 25209) a second document providing supplemental proposals for early- and late-season migratory bird hunting regulations. The May 27 supplement also provided detailed information on the 2009–10 regulatory schedule and announced the Service Migratory Bird Regulation Committee (SRC) and Flyway Council meetings.

On June 24 and 25, 2009, 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 2009–10 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 2009–10 regular waterfowl seasons. On July 24, 2009, we published in the **Federal Register** (74 FR 36870) a third document specifically dealing with the proposed frameworks for early-season regulations. In late August 2009, we will publish a rulemaking establishing final frameworks for early-season migratory bird hunting regulations for the 2009–10 season.

On July 29–30, 2009, we held open meetings with the Flyway Council Consultants, at which the participants reviewed the status of waterfowl and developed recommendations for the 2009–10 regulations for these species. This document deals specifically with proposed frameworks for the late-season migratory bird hunting regulations. It will lead to final frameworks from which States may select season dates, shooting hours, areas, and limits.

We have considered all pertinent comments received through August 1, 2009, in developing this document. In

addition, new proposals for certain late-season regulations are provided for public comment. The comment period is specified above under **DATES**. We will publish final regulatory frameworks for late-season migratory game bird hunting in the **Federal Register** on or around September 22, 2009.

Population Status and Harvest

The following paragraphs provide a brief summary of information on the status and harvest of waterfowl excerpted from various reports. For more detailed information on methodologies and results, you may obtain complete copies of the various reports at the address indicated under **FOR FURTHER INFORMATION CONTACT** or from our website <http://www.fws.gov/migratorybirds/NewsPublicationsReports.html>.

Status of Ducks

Federal, provincial, and State agencies conduct surveys each spring to estimate the size of breeding populations and to evaluate the conditions of the habitats. These surveys are conducted using fixed-wing aircraft and helicopters and encompass principal breeding areas of North America, and cover over 2.0 million square miles. The Traditional survey area comprises Alaska, Canada, and the northcentral United States, and includes approximately 1.3 million square miles. The Eastern survey area includes parts of Ontario, Quebec, Labrador, Newfoundland, Nova Scotia, Prince Edward Island, New Brunswick, New York, and Maine, an area of approximately 0.7 million square miles.

Breeding Ground Conditions

Habitat conditions during the 2009 Waterfowl Breeding Population and Habitat Survey were characterized by above-average moisture across the southern portions of the traditional survey area, good habitat in the eastern survey area, and late spring conditions across northern survey areas. The total pond estimate (prairie Canada and U.S. combined) was 6.4 ± 0.2 million. This was 45 percent above last year's estimate of 4.4 ± 0.2 million ponds and 31 percent above the long-term average of 4.9 ± 0.03 million ponds. The 2009 estimate of ponds in prairie Canada was 3.6 ± 0.1 million. This was a 17 percent increase from last year's estimate (3.1 ± 0.1 million) and was similar to the long-term average (3.4 ± 0.03 million). The 2009 pond estimate for the northcentral U.S. of 2.9 ± 0.1 million was 108 percent above last year's estimate (1.4 ± 0.07 million) and 87 percent above the long-term average (1.5 ± 0.02 million).

Breeding population status

In the Waterfowl Breeding Population and Habitat Survey traditional survey area (strata 1–18, 20–50, and 75–77), the total duck population estimate was 42.0 ± 0.7 [SE] million birds. This estimate represents a 13 percent increase over last year's estimate of 37.3 ± 0.6 million birds and was 25 percent above the long-term average (1955–2008). Estimated mallard (*Anas platyrhynchos*) abundance was 8.5 ± 0.2 million birds, which was a 10 percent increase over last year's estimate of 7.7 ± 0.3 million birds and 13 percent above the long-term average. Estimated abundance of gadwall (*A. strepera*; 3.1 ± 0.2 million) was similar to the 2008 estimate and 73 percent above the long-term average. Estimated American wigeon abundance (*A. americana*; 2.5 ± 0.1 million) was similar to 2008 and the long-term average. Estimated abundances of green-winged teal (*A. crecca*; 3.4 ± 0.2 million) and blue-winged teal (*A. discors*; 7.4 ± 0.4 million) were similar to last year's estimates and well above their long-term averages (+79 percent and +60 percent, respectively). Northern shovelers (*A. clypeata*; 4.4 ± 0.2 million) were 25 percent above the 2008 estimate and remain well above their long-term average (+92 percent). The estimate for northern pintails (*A. acuta*) was 3.2 ± 0.2 million, which was 23 percent above the 2008 estimate of 2.6 ± 0.1 million, and 20 percent below the long-term average. Estimated abundance of redheads (*Aythya americana*; 1.0 ± 0.1 million) was similar to last year and 62 percent above the long-term average. The canvasback estimate (*A. valisineria*; 0.7 ± 0.06 million) was 35 percent above the 2008 estimate (0.5 ± 0.05 million) and similar to the long-term average. The scaup estimate (*A. affinis* and *A. marila* combined; 4.2 ± 0.2 million) was similar to that of 2008 and 18 percent below the long-term average of 5.1 ± 0.05 million.

The eastern survey area was restratified in 2005 and is now composed of strata 51–72. Estimates of mallards, scaup, scoters (black [*Melanitta nigra*], white-winged [*M. fusca*], and surf [*M. perspicillata*]), green-winged teal, American wigeon, bufflehead (*Bucephala albeola*), American black duck (*Anas rubripes*), ring-necked duck (*Aythya collaris*), mergansers (red-breasted [*Mergus serrator*], common [*M. merganser*], and hooded [*Lophodytes cucullatus*]), and goldeneye (common [*B. clangula*] and Barrow's [*B. islandica*]) all were similar to their 2008 estimates and long-term averages.

Fall Flight Estimate

The mid-continent mallard population is composed of mallards from the traditional survey area (revised in 2008 to exclude Alaska mallards), Michigan, Minnesota, and Wisconsin, and was estimated to be 10.3 ± 0.9 million in 2009. This was similar to the 2008 estimate of 9.2 ± 0.8 million.

See section 1.A. **Harvest Strategy** **Considerations** for further discussion of the implications of this information for this year's selection of the appropriate hunting regulations.

Status of Geese and Swans

We provide information on the population status and productivity of North American Canada geese (*Branta canadensis*), brant (*B. bernicla*), snow geese (*Chen caerulescens*), Ross' geese (*C. rossii*), emperor geese (*C. canagica*), white-fronted geese (*Anser albifrons*), and tundra swans (*Cygnus columbianus*). In May of 2009, temperatures were 1–5 degrees Celsius colder than average throughout the central region of subarctic and Arctic Canada. In some locales harsh spring conditions persisted into June. In areas near Hudson Bay and the Queen Maud Gulf, goose and swan nesting activities were delayed by 1 to 3 weeks. In contrast, nesting conditions were favorable near Wrangel Island, Alaska's North Slope and eastern interior regions, parts of the Canadian high Arctic, and Newfoundland. Improved wetland abundance in the Canadian and U.S. prairies, and other temperate regions, will likely improve the production of Canada geese that nest at southern latitudes. Primary abundance indices decreased for 15 goose populations and increased for 10 goose populations in 2009 compared to 2008. Primary abundance indices for both populations of tundra swans increased in 2009 from 2008 levels. The following populations displayed significant positive trends during the most recent 10-year period ($P < 0.05$): Mississippi Flyway Giant, Aleutian, Atlantic, and Eastern Prairie Canada geese; Greater, Western Arctic/Wrangel Island, and Western Central Flyway light geese; and Pacific white-fronted geese. No populations showed a significant negative 10-year trend. The forecast for the production of geese and swans in North America for 2009 is regionally variable, but production for many populations will be reduced this year due to harsh spring conditions in much of central Canada.

Waterfowl Harvest and Hunter Activity

National surveys of migratory bird hunters were conducted during the 2007 and 2008 hunting seasons. About 1.2 million waterfowl hunters harvested 14,578,900 ($\pm 4\%$) ducks and 3,666,100 ($\pm 6\%$) geese in 2007, and harvested 13,635,700 ($\pm 4\%$) ducks and 3,792,600 ($\pm 5\%$) geese in 2008. Mallard, green-winged teal, gadwall, wood duck (*Aix sponsa*), and American wigeon were the 5 most-harvested duck species in the United States, and Canada goose was the predominant goose species in the goose harvest. Coot hunters (about 33,700 in 2007 and 31,100 in 2008) harvested 198,300 ($\pm 29\%$) coots in 2007 and 275,900 ($\pm 43\%$) in 2008.

Review of Public Comments and Flyway Council Recommendations

The preliminary proposed rulemaking, which appeared in the April 10, 2009, **Federal Register**, opened the public comment period for migratory game bird hunting regulations. The supplemental proposed rule, which appeared in the May 27, 2009, **Federal Register**, discussed the regulatory alternatives for the 2009–10 duck hunting season. Late-season comments are summarized below and numbered in the order used in the April 10 and May 27 **Federal Register** documents. We have included only the numbered items pertaining to late-season issues for which we received written comments. Consequently, the issues do not follow in successive numerical or alphabetical order.

We received recommendations from all four Flyway Councils. Some recommendations supported continuation of last year's frameworks. Due to the comprehensive nature of the annual review of the frameworks performed by the Councils, support for continuation of last year's frameworks is assumed for items for which no recommendations were received. Council recommendations for changes in the frameworks are summarized below.

We seek additional information and comments on the recommendations in this supplemental proposed rule. New proposals and modifications to previously described proposals are discussed below. Wherever possible, they are discussed under headings corresponding to the numbered items in the April 10 and May 27, 2009, **Federal Register** documents.

General

Written Comments: An individual commenter protested the entire migratory bird hunting regulations

process, the killing of all migratory birds, and the Flyway Council process.

Service Response: Our long-term objectives continue to include providing opportunities to harvest portions of certain migratory game bird populations and to limit annual harvests to levels compatible with each population's ability to maintain healthy, viable numbers. Having taken into account the zones of temperature and the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory birds, we believe that the hunting seasons provided herein are compatible with the current status of migratory bird populations and long-term population goals. Additionally, we are obligated to, and do, give serious consideration to all information received as public comment. While there are problems inherent with any type of representative management of public-trust resources, we believe that the Flyway Council system of migratory bird management has been a long-standing example of State-Federal cooperative management since its establishment in 1952. However, as always, we continue to explore new ways to streamline and improve the process.

1. Ducks

Categories used to discuss issues related to duck harvest management are: (A) Harvest Strategy Considerations, (B) Regulatory Alternatives, (C) Zones and Split Seasons, and (D) Special Seasons/Species Management. The categories correspond to previously published issues/discussion, and only those containing substantial recommendations are discussed below.

A. Harvest Strategy Considerations

Council Recommendations: The Atlantic, Central, and Pacific Flyway Councils and the Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended the adoption of the "liberal" regulatory alternative.

Service Response: We are continuing development of an Adaptive Harvest Management (AHM) protocol that would allow hunting regulations to vary among Flyways in a manner that recognizes each Flyway's unique breeding-ground derivation of mallards. Last year, we described and adopted a protocol for regulatory decision-making for the newly defined stock of western mallards (73 FR 43290). For the 2009 hunting season, we continue to believe that the prescribed regulatory choice for the Pacific Flyway should be based on the status of this western mallard breeding stock, while the regulatory

choice for the Mississippi and Central Flyways should depend on the status of the recently redefined mid-continent mallard stock. We also recommend that the regulatory choice for the Atlantic Flyway continue to depend on the status of eastern mallards.

For the 2009 hunting season, we are continuing to consider the same regulatory alternatives as those used last year. The nature of the "restrictive," "moderate," and "liberal" alternatives has remained essentially unchanged since 1997, except that extended framework dates have been offered in the "moderate" and "liberal" regulatory alternatives since 2002. Also, in 2003, we agreed to place a constraint on closed seasons in the western three Flyways whenever the midcontinent mallard breeding-population size (as defined prior to 2008; traditional survey area plus Minnesota, Michigan, and Wisconsin) was ≥ 5.5 million.

Optimal AHM strategies for the 2009–10 hunting season were calculated using: (1) Harvest-management objectives specific to each mallard stock; (2) the 2009 regulatory alternatives; and (3) current population models and associated weights for midcontinent, western, and eastern mallards. Based on this year's survey results of 8.71 million midcontinent mallards (traditional survey area minus Alaska plus Minnesota, Wisconsin, and Michigan), 3.57 million ponds in Prairie Canada, 884,000 western mallards (381,000 and 503,000 respectively in California-Oregon and Alaska), and 908,000 eastern mallards, the prescribed regulatory choice for all four Flyways is the "liberal" alternative.

Therefore, we concur with the recommendations of the Atlantic, Mississippi, Central, and Pacific Flyway Councils regarding selection of the "liberal" regulatory alternative and propose to adopt the liberal regulatory alternative, as described in the July 24, 2009 **Federal Register**.

D. Special Seasons/Species Management

iii. Black Ducks

In 2008, U.S. and Canadian waterfowl managers developed an interim harvest strategy that will be employed by both countries until a formal strategy based on the principles of AHM is completed. We detailed this interim strategy in the July 24, 2008, **Federal Register** (73 FR 43290). The interim harvest strategy is prescriptive, in that it calls for no substantive changes in hunting regulations unless the black duck breeding population, averaged over the most recent 3 years, exceeds or falls

below the long-term average breeding population by 15 percent or more. The strategy is designed to share the black duck harvest equally between the two countries; however, recognizing incomplete control of harvest through regulations, it will allow realized harvest in either country to vary between 40 and 60 percent.

Each year in November, Canada publishes its proposed migratory bird hunting regulations for the upcoming hunting season. Thus, last fall the Canadian Wildlife Service (CWS) used the interim strategy to establish its proposed black duck regulations for the 2009–10 season based on the most current data available at that time: breeding population estimates for 2006, 2007, and 2008, and an assessment of parity based on harvest estimates for the 2003–07 hunting seasons. Although updates of both breeding population estimates and harvest estimates are now available, the United States will base its 2009–10 black duck regulations on the same data CWS used, to ensure comparable application of the strategy. The long-term (1998–2007) breeding population mean estimate is 713,800 and the 2006–08 3-year running mean estimate is 721,600. Based on these estimates, no restriction or liberalization of black duck harvest is warranted. The average proportion of the harvest during the 5-year period 2003–2007 was 0.56 in the United States and 0.44 in Canada, and this falls within the established parity bounds of 40 and 60 percent.

iv. Canvasbacks

Council Recommendations: The Atlantic, Central, and Pacific Flyway Councils recommended a full season for canvasbacks with a 1-bird daily bag limit. Season lengths would be 60 days in the Atlantic Flyway, 74 days in the Central Flyway, and 107 days in the Pacific Flyway.

The Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended use of their alternative canvasback harvest management strategy that uses threshold levels based on breeding population size in order to determine bag limits (detailed in the June 18, 2008, **Federal Register** (73 FR 34692)). Their strategy results in a Council recommendation for a 1-bird daily bag limit and a 60-day season in the Mississippi Flyway.

Service Response: Since 1994, we have followed a canvasback harvest strategy that if canvasback population status and production are sufficient to permit a harvest of one canvasback per day nationwide for the entire length of the regular duck season, while still

attaining a projected spring population objective of 500,000 birds, the season on canvasbacks should be opened. A partial season would be permitted if the estimated allowable harvest was within the projected harvest for a shortened season. If neither of these conditions can be met, the harvest strategy calls for a closed season on canvasbacks nationwide. Last year (73 FR 43290), we announced our decision to modify the Canvasback Harvest Strategy to incorporate the option for a 2-bird daily bag limit for canvasbacks when the predicted breeding population the subsequent year exceeds 725,000 birds.

This year's spring survey resulted in an estimate of 662,000 canvasbacks. This was 35 percent above the 2008 estimate of 489,000 canvasbacks and 16 percent above the 1955–2008 average. The estimate of ponds in Prairie Canada was 3.6 million, which was 17 percent above last year and 5 percent above the long-term average. The canvasback harvest strategy predicts a 2010 canvasback population of 602,000 birds under a “liberal” duck season with a 1-bird daily bag limit and 565,000 with a 2-bird daily bag limit. Because the predicted 2010 population under the 1-bird daily bag limit is greater than 500,000, while the prediction under the 2-bird daily bag limit is less than 725,000, the canvasback harvest strategy stipulates a full canvasback season with a 1-bird daily bag limit for the upcoming season.

v. Pintails

Council Recommendations: The Atlantic, Central and Pacific Flyway Councils and the Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended a full season for pintails consisting of a 1-bird daily bag limit and a 60-day season in the Atlantic and Mississippi Flyways and a 74-day season in the Central Flyway, and a 2-bird daily bag limit with a 107-day season in the Pacific Flyway.

The Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council also recommended that the Service evaluate the performance of the prescribed strategy for managing harvest of northern pintails and explain the reasons for implementing the derived strategy despite a Council recommendation to continue using the prescribed strategy.

Service Response: Based on the current strategy last modified in 2007, along with an observed spring breeding population of 3.22 million, an overflight-bias-corrected breeding population of 3.73 million and a

projected fall flight of 5.13 million pintails, the pintail harvest strategy prescribes a full season and a 1-bird daily bag limit in the Atlantic, Mississippi, and Central Flyways. In the Pacific Flyway a 2-bird daily bag limit and a full season is prescribed. Under the “liberal” season length, this regulation is expected to result in a harvest of 643,388 pintails and an expected breeding population estimate (corrected scale) of 4.02 million in 2010.

Regarding the Mississippi Flyway Council's recommendation to evaluate the performance of the prescribed strategy for managing harvest of northern pintails, we have previously provided such information and remain committed to implementation of a derived strategy for pintail harvest management next year. This strategy would replace the current prescriptive strategy that has been used for pintails since 1997. In order for the implementation of the new derived strategy to be successful, the Service and Flyway Councils must reach agreement on several key issues. These issues include: (1) determination of the harvest management objective, (2) identification of any constraints that would be included in the strategy (e.g., closure constraint), and (3) a decision regarding specific inclusion of a harvest allocation process. We will make technical information regarding these three aspects of the derived strategy available at the December 2009 AHM Working Group Meeting, with additional discussion at the 2010 February SRC meeting in Denver, followed by Flyway Council consideration at their 2010 winter meetings.

vi. Scaup

Council Recommendations: The Atlantic Flyway Council and the Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended use of the “moderate” regulation package consisting of a 60-day season with a 2-bird daily bag.

The Central Flyway Council recommended use of the “moderate” regulation package consisting of a 74-day season with a 2-bird daily bag limit.

The Pacific Flyway Council recommended the adoption of the “moderate” regulation package for the Pacific Flyway consisting of an 86-day season with a 3-bird daily bag limit.

Service Response: Last year, we adopted and implemented a new scaup harvest strategy (73 FR 43290 and 73 FR 51124). Initial “restrictive,” “moderate,” and “liberal” regulatory packages were adopted for each Flyway in 2008.

Further opportunity to revise these packages was afforded prior to the 2009–10 season and modifications that were recommended by the Mississippi and Central Flyway Councils were endorsed by the Service in June 2009 (74 FR 36870). These packages will remain in effect for at least 3 years prior to their re-evaluation.

The 2009 breeding population estimate for scaup is 4.17 million, up 12 percent from, but similar to, the 2008 estimate of 3.74 million. Total estimated scaup harvest for the 2008–09 season was 229,000 birds. Based on updated model parameter estimates, the optimal regulatory choice for scaup is the “moderate” package recommended by the Councils in all four Flyways.

vii. Mottled Ducks

Council Recommendations: The Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended reducing the daily bag limit for mottled ducks from 3 to 1 bird per day.

The Central Flyway Council initially recommended that no further harvest reductions were warranted. However, at the July SRC meeting, they subsequently amended their Council recommendation by agreeing to delay the opening of the mottled duck season for the first 5 days of the regular duck season.

Service Response: For many years, we have expressed concern about the long-term status of mottled ducks, especially the Western Gulf Coast Population. After consideration of long-term trends for this population, recent harvest levels, and this year's breeding habitat conditions, we believe that a reduction in harvest levels for this population is necessary.

The Mississippi Flyway Council's recommendation to reduce the daily bag limit of mottled ducks to one bird is projected to result in a harvest reduction of about 20 percent. The Central Flyway Council's amended recommendation to delay the opening of the mottled duck season is expected to result in a similar harvest reduction. We believe that this level of reduction is necessary across the entire range of Western Gulf Coast Population this year. Accordingly, we support the Mississippi Flyway Council's recommendation and the Central Flyway Council's amended recommendation with the goal of achieving approximately a 20 percent reduction in mottled duck harvest.

We also urge that an assessment be conducted of whether desired reductions in harvest are achieved as a result of the proposed restrictions. Furthermore, the status of mottled ducks and their breeding habitat should

be closely monitored and a determination made whether further restrictions are warranted. Should additional restrictions be needed, we will consider all regulatory options, including the potential for a closed season.

viii. Wood Ducks

Council Recommendations: The Atlantic and Central Flyway Councils and the Upper- and Lower-Region Regulations Committees of the Mississippi Flyway Council recommended that the Service's timetable for implementing a wood duck harvest strategy in the Atlantic, Mississippi, and Central Flyways be extended to allow additional data collection and evaluation of wood duck harvest rates from seasons with a 3-bird daily limit.

Service Response: Last year, we indicated that we would like the Flyways to develop a wood duck harvest strategy for implementation during the 2010–11 hunting season (73 FR 55602). However, upon further review, this date will only allow information from two hunting seasons (2008–09 and 2009–10) to be considered for any assessment of wood duck harvest rates and other parameters useful in making management decisions under a wood duck harvest strategy. Further, we would not have any wood duck recovery information available from this year's hunting season. We believe that an additional year(s) would provide more information for assessing the effect of the 3-bird bag limit and incorporation of this information into the harvest strategy development process. Thus, we agree with the Councils and support such an extension.

4. Canada Geese

B. Regular Seasons

Council Recommendations: The Atlantic Flyway Council forwarded two recommendations concerning Canada geese. First, the Council recommended the establishment of an operational season in Back Bay, Virginia. The season frameworks would be aligned with the harvest regulations in the adjacent Atlantic Population (AP) Zone (currently a 45-day season with a 2-bird daily bag limit). The Council also recommended that the Service allow a 7-day season with a 1-bird daily bag limit in the Northeast Goose Zone of North Carolina with framework dates of the Saturday prior to December 25 to January 31.

The Upper- and Lower-Region Regulations Committees of the

Mississippi Flyway Council recommended that the season length in Louisiana be extended from 16 to 44 days and that the daily bag limit of 1 per day be included in an aggregate dark goose bag of 2 per day, with no more than 1 Canada goose. The Committees also recommended extending the goose season in Ohio from 70 to 74 days.

The Pacific Flyway Council recommended reducing quotas for dusky Canada geese in Washington to 45 (from 85) and in Oregon to 90 (from 165) and lengthening the season in California's Sacramento Valley Special Management Area (West) to allow it to begin concurrently with the general goose season and change the name by removing the "(West)".

Service Response: We support the Atlantic Flyway's recommendations for operational Canada goose seasons in Back Bay, Virginia, and the Northeast Goose Zone in North Carolina. Although results of the recent experimental seasons show that migrant goose harvest was greater than 10 percent, we recognize that both of those experimental seasons were within the existing frameworks for AP, North Atlantic Population (NAP), and Southern James Bay Population (SJB) goose regular seasons. We also recognize that these proposed seasons, and the harvest expected to result from them, are allowable under the current hunt plan guidelines established in the Flyway Management Plans for AP, NAP, SJB, and resident Canada geese.

We also support the Mississippi Flyway Council's proposals to lengthen the season in Louisiana and Ohio. With regard to the goose population involved in Louisiana, the 2009 mid-winter estimate for the Tall Grass Prairie Population (TGPP) was 310,000, which, although much lower than previous years, remains above the 250,000 population objective. We note that harvest rate on this population is relatively low and Louisiana harvest is very small, averaging 1,710 in 1999–2005 during 9-day seasons and 1,480 in 2006–08 during 16-day seasons. Louisiana further estimates that extending the season length to 44 days will likely increase the harvest to possibly twice current levels. However, while the extended season would allow increased opportunity to take Canada geese, Louisiana believes that aggregating the daily bag limit with white-fronted geese would moderate the increased harvest of Canada geese and possibly reduce the harvest pressure on white-fronted geese.

Regarding dusky Canada geese, the annual population index based on the breeding pair survey on the Copper

River Delta is 6,709, a decrease from the previous year's index of 9,152. The 3-year average index is 8,682. This decline triggers implementation of further measures of protection for this population as described under Action level 2 in the management plan. Based on the harvest strategy in the management plan, we support the Council recommendations to further reduce the quotas assigned to Washington (to 45) and Oregon (to 90) and institution of the other management actions identified for Action level 2. We note that the status of dusky Canada geese continues to be a matter of concern, which has resulted in harvest restrictions throughout their range in recent years. However, we continue to support the harvest strategy described in the 2008 management plan for this population.

We also concur with the Pacific Flyway Council's recommendation regarding the Sacramento Valley Special Management Area (West) in California. Created in 1975, the zone was a closure area for Canada geese to protect the then-endangered Aleutian Canada goose. Over the decades, the boundaries and specifics of the zone evolved to manage harvest of cackling Canada geese and Pacific white-fronted geese when those populations were at low levels. Given the current status of Aleutian and cackling Canada geese and Pacific white-fronted geese, we view this change as relatively minor and administrative in nature and do not expect the proposed change to impact populations (see further discussion under **5. White-fronted Geese**).

5. White-fronted Geese

Council Recommendations: The Pacific Flyway Council recommended increasing the overall daily bag limit for geese in the Klamath County Zone of Oregon in the portion of the season after the last Sunday in January from 4 to 6 geese per day. Specific to white-fronted geese, the Council recommended increasing the daily bag limit from 1 to 2 per day within the proposed overall goose daily bag limit of 6 birds. In California's Sacramento Valley Special Management Area (West), the Council also recommended lengthening the season to allow it to begin concurrently with the general goose season and changing the name by removing the "(West)".

Service Response: We concur with the Pacific Flyway Council's recommended changes in the Oregon's Klamath County Zone and California's Sacramento Valley Special Management Area (West). In the Klamath County Zone, of the five recognized goose

populations affected by this proposal, all three light goose and Pacific greater white-fronted geese are currently above identified management plan objectives. Additionally, Tule goose population estimates have remained stable over the last 6 years at nearly 12,000 geese. Increasing the white-fronted goose daily bag limit from 1 to 2 is expected to increase white-fronted goose harvest to levels observed during late-winter hunts in 2007 and 2008 and the proposed change is not expected to appreciably increase Tule goose harvest beyond that currently occurring in other areas of California and Oregon.

6. Brant

Council Recommendations: The Atlantic Flyway Council recommended a 50-day season with a 2-bird daily bag limit for Atlantic brant.

Service Response: We concur with the Atlantic Flyway Council's recommendation. The 2009 Mid-Winter Index (MWI) for Atlantic brant decreased to 151,300 from 160,618 brant in 2008. While the Brant Management Plan prescribes the continuation of a 60-day season with a 3-bird daily bag limit when the MWI estimate is above 150,000, we note that spring was 2-3 weeks later than normal in portions of Atlantic brant staging and breeding areas this year and these conditions have usually resulted in poor brant production in the past. Thus, we agree with the Council that a decrease of 10 days with the associated daily bag limit decrease is the proper approach for the upcoming season.

7. Snow and Ross's (Light) Geese

Council Recommendations: The Pacific Flyway Council recommended increasing the overall daily bag limit for geese in the Klamath County Zone of Oregon in the portion of the season after the last Sunday in January from 4 to 6 geese per day. Specific to light geese, the Council recommended increasing the daily bag limit from 3 to 4 per day within the proposed overall goose daily bag limit of 6 birds. In California's Sacramento Valley Special Management Area (West), the Council also recommended lengthening the season to allow it to begin concurrently with the general goose season and changing the name by removing the "(West)."

Service Response: We support the proposed changes for light geese in the Pacific Flyway. In 2007, the Flyway's December goose count exceeded 1 million for the first time, representing a doubling of this index since 1999. Light goose indices (Snow and Ross' geese combined) indicate that all recognized populations currently exceed

management plan goals. In some areas of the Pacific Flyway, these goose populations are leading to increasing depredation complaints. In addition, numbers of light geese breeding on Wrangel Island, Russia, a colony that has been of concern in the past, has recovered to near record levels in the past few years. We support efforts to increase harvest of these geese to limit further population growth and perhaps the overabundance problems associated with the species that have been documented in several of the mid-continent regions.

Public Comments

The Department of the Interior's policy is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, we invite interested persons to submit written comments, suggestions, or recommendations regarding the proposed regulations. Before promulgation of final migratory game bird hunting regulations, we will take into consideration all comments received. Such comments, and any additional information received, may lead to final regulations that differ from these proposals.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section. Finally, we will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post your entire comment—including your personal identifying information—on <http://www.regulations.gov>. If you provide personal identifying information in your comment, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on <http://www.regulations.gov>, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, Room 4107, 4501 North Fairfax Drive, Arlington, VA 22203.

For each series of proposed rulemakings, we will establish specific comment periods. We will consider, but possibly may not respond in detail to, each comment. As in the past, we will summarize all comments received

during the comment period and respond to them after the closing date in any final rules.

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 (FSER 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 **FOR FURTHER INFORMATION CONTACT**.

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, as detailed in a March 9, 2006, **Federal Register** (71 FR 12216). We have prepared a scoping report summarizing the scoping comments and scoping meetings. The report is available by either writing to the address indicated under **FOR FURTHER INFORMATION CONTACT** or by viewing on our website at <http://www.fws.gov/migratorybirds/>.

Endangered Species Act Consideration

Prior to issuance of the 2009-10 migratory game bird hunting regulations, we will comply with provisions of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531-1543; hereinafter, the Act), to ensure that hunting is not likely to jeopardize the continued existence of any species designated as endangered or threatened, or modify or destroy its critical habitat, and is consistent with conservation programs for those species. Consultations under section 7 of the Act may cause us to change proposals in this and future supplemental rulemaking documents.

Executive Order 12866

The Office of Management and Budget has determined that this rule is significant and has reviewed this rule under Executive Order 12866. A regulatory cost-benefit analysis has been prepared and is available at <http://www.fws.gov/migratorybirds/>

NewReportsPublications/SpecialTopics/SpecialTopics.html#HuntingRegs or at <http://www.regulations.gov>. OMB bases its determination of regulatory significance upon the following four criteria:

(a) Whether the rule will have an annual effect of \$100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Flexibility Act

The 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. 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, 2004, and 2008. 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 2008 Analysis was based on the 2006 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 approximately \$1.2 billion at small businesses in 2008.

Copies of the Analysis are available upon request from the address indicated under **FOR FURTHER INFORMATION CONTACT** or from our website at <http://www.fws.gov/migratorybirds/NewReportsPublications/SpecialTopics/SpecialTopics.html#HuntingRegs> or at <http://www.regulations.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.

Paperwork Reduction Act

We examined these regulations under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). 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 our Migratory Bird Surveys and assigned control number 1018–0023 (expires 2/28/2011). 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 Alaska Subsistence Household Survey, an associated voluntary annual household survey used to determine levels of subsistence take in Alaska, and assigned control number 1018–0124 (expires 1/31/2010).

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

The Department, in promulgating this proposed rule, has determined that this proposed rule 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 proposed 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

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. While this proposed 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

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 10 **Federal Register**, 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 2009–10 migratory bird hunting season. The resulting proposals will be contained in a separate proposed rule. By virtue of these actions, we have consulted with 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 Indian 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.

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 2009–10 hunting season are authorized under 16 U.S.C. 703-712 and 16 U.S.C. 742 a-j.

Dated: August 5, 2009

Jane Lyder

Deputy Assistant Secretary for Fish and Wildlife and Parks.

Proposed Regulations Frameworks for 2009–10 Late Hunting Seasons on Certain Migratory Game Birds

Pursuant to the Migratory Bird Treaty Act and delegated authorities, the Department has approved frameworks for season lengths, shooting hours, bag and possession limits, and outside dates within which States may select seasons for hunting waterfowl and coots between the dates of September 1, 2009, and March 10, 2010.

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:

High Plains Mallard Management Unit—roughly defined as that portion of the Central Flyway that lies west of the 100th meridian.

Definitions:

For the purpose of hunting regulations listed below, the collective terms “dark” and “light” geese include the following species:

Dark geese: Canada geese, white-fronted geese, brant (except in California, Oregon, Washington, and the Atlantic Flyway), and all other goose species except light geese.

Light geese: snow (including blue) geese and Ross’ geese.

Area, Zone, and Unit Descriptions:

Geographic descriptions related to late-season regulations are contained in a later portion of this document.

Area-Specific Provisions:

Frameworks for open seasons, season lengths, bag and possession limits, and other special provisions are listed below by Flyway.

Waterfowl Seasons 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 Youth Waterfowl Hunting Days

Outside Dates: States may select 2 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, holiday, or other non-school day 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, tundra swans, 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. Tundra swans may only be taken by participants possessing applicable tundra swan permits.

Atlantic Flyway

Ducks, Mergansers, and Coots

Outside Dates: Between the Saturday nearest September 24 (September 26) and the last Sunday in January (January 31).

Hunting Seasons and Duck Limits: 60 days. The daily bag limit is 6 ducks, including no more than 4 mallards (2 hens), 1 black duck, 1 pintail, 1 mottled duck, 1 fulvous whistling duck, 3 wood ducks, 2 redheads, 2 scaup, 1 canvasback, and 4 scoters.

Closures: The season on harlequin ducks is closed.

Sea Ducks: 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.

Merganser Limits: The daily bag limit of mergansers is 5, only 2 of which may be hooded mergansers. In States that include mergansers in the duck bag limit, the daily limit is the same as the duck bag limit, only two of which may be hooded mergansers.

Coot Limits: The daily bag limit is 15 coots.

Lake Champlain Zone, New York: The waterfowl seasons, limits, and shooting hours shall be the same as those selected for the Lake Champlain Zone of Vermont.

Connecticut River Zone, Vermont: The waterfowl seasons, limits, and shooting hours shall be the same as those selected for the Inland Zone of New Hampshire.

Zoning and Split Seasons: Delaware, Florida, Georgia, Maryland, North Carolina, Rhode Island, South Carolina, and Virginia may split their seasons into three segments; Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Vermont, and West Virginia may select hunting seasons by zones and may split their seasons into two segments in each zone.

Canada Geese

Season Lengths, Outside Dates, and Limits: Specific regulations for Canada geese are shown below by State. These seasons also include white-fronted geese. Unless specified otherwise, seasons may be split into two segments. In areas within States where the framework closing date for Atlantic Population (AP) goose seasons overlaps with special late-season frameworks for resident geese, the framework closing date for AP goose seasons is January 14.

Connecticut:

North Atlantic Population (NAP) Zone: Between October 1 and January 31, a 60-day season may be held with a 2-bird daily bag limit.

Atlantic Population (AP) Zone: A 45-day season may be held between the fourth Saturday in October (October 24) and January 31, with a 3-bird daily bag limit.

South Zone: A special season may be held between January 15 and February 15, with a 5-bird daily bag limit.

Resident Population (RP) Zone: An 80-day season may be held between October 1 and February 15, with a 5-bird daily bag limit. The season may be split into 3 segments.

Delaware: A 45-day season may be held between November 15 and January 31, with a 2-bird daily bag limit.

Florida: An 80-day season may be held between November 15 and February 15, with a 5-bird daily bag limit. The season may be split into 3 segments.

Georgia: In specific areas, an 80-day season may be held between November 15 and February 15, with a 5-bird daily bag limit. The season may be split into 3 segments.

Maine: A 60-day season may be held Statewide between October 1 and January 31, with a 2-bird daily bag limit.

Maryland:

RP Zone: An 80-day season may be held between November 15 and March 10, with a 5-bird daily bag limit. The season may be split into 3 segments.

AP Zone: A 45-day season may be held between November 15 and January 31, with a 2-bird daily bag limit.

Massachusetts:

NAP Zone: A 60-day season may be held between October 1 and January 31, with a 2-bird daily bag limit.

Additionally, a special season may be held from January 15 to February 15, with a 5-bird daily bag limit.

AP Zone: A 45-day season may be held between October 20 and January 31, with a 3-bird daily bag limit.

New Hampshire: A 60-day season may be held statewide between October 1 and January 31, with a 2-bird daily bag limit.

New Jersey:

Statewide: A 45-day season may be held between the fourth Saturday in October (October 24) and January 31, with a 3-bird daily bag limit.

Special Late Goose Season Area: An experimental season may be held in designated areas of North and South New Jersey from January 15 to February 15, with a 5-bird daily bag limit.

New York:

NAP Zone: Between October 1 and January 31, a 60-day season may be held, with a 2-bird daily bag limit in the High Harvest areas; and between October 1 and February 15, a 70-day season may be held, with a 3-bird daily bag limit in the Low Harvest areas.

Special Late Goose Season Area: An experimental season may be held between January 15 and February 15, with a 5-bird daily bag limit in designated areas of Chemung, Delaware, Tioga, Broome, Sullivan, Westchester, Nassau, Suffolk, Orange, Dutchess, Putnam, and Rockland Counties.

AP Zone: A 45-day season may be held between the fourth Saturday in October (October 24), except in the Lake Champlain Area where the opening date is October 20, and January 31, with a 3-bird daily bag limit.

Western Long Island RP Zone: An 80-day season may be held between October 1 and February 15, with a 5-bird daily bag limit. The season may be split into 3 segments.

Rest of State RP Zone: An 80-day season may be held between the fourth Saturday in October (October 24) and March 10, with a 5-bird daily bag limit. The season may be split into 3 segments.

North Carolina:

SJBZ Zone: A 70-day season may be held between October 1 and December 31, with a 5-bird daily bag limit.

RP Zone: An 80-day season may be held between October 1 and March 10, with a 5-bird daily bag limit. The season may be split into 3 segments.

Northeast Hunt Unit: A 7-day season may be held between the Saturday prior to December 25 (December 19) and January 31, with a 1-bird daily bag limit.

Pennsylvania:

SJBZ Zone: A 70-day season may be held between the second Saturday in October (October 10) and February 15, with a 3-bird daily bag limit.

RP Zone: An 80-day season may be held between the fourth Saturday in October (October 24) and March 10, with a 5-bird daily bag limit. The season may be split into 3 segments.

AP Zone: A 45-day season may be held between the fourth Saturday in October (October 24) and January 31, with a 3-bird daily bag limit.

Rhode Island: A 60-day season may be held between October 1 and January 31, with a 2-bird daily bag limit. An experimental season may be held in designated areas from January 15 to February 15, with a 5-bird daily bag limit.

South Carolina: In designated areas, an 80-day season may be held during November 15 to February 15, with a 5-bird daily bag limit. The season may be split into 3 segments.

Vermont: A 45-day season may be held between the fourth Saturday in October (October 24), except in the Lake Champlain Zone and Interior Zone where the opening date is October 20, and January 31, with a 3-bird daily bag limit.

Virginia:

SJBZ Zone: A 40-day season may be held between November 15 and January 14, with a 3-bird daily bag limit.

Additionally, an experimental season may be held between January 15 and February 15, with a 5-bird daily bag limit.

AP Zone: A 45-day season may be held between November 15 and January 31, with a 2-bird daily bag limit.

RP Zone: An 80-day season may be held between November 15 and March

10, with a 5-bird daily bag limit. The season may be split into 3 segments.

West Virginia: An 80-day season may be held between October 1 and January 31, with a 5-bird daily bag limit. The season may be split into 2 segments in each zone.

Light Geese

Season Lengths, Outside Dates, and Limits: States may select a 107-day season between October 1 and March 10, with a 15-bird daily bag limit and no possession limit. States may split their seasons into three segments.

Brant

Season Lengths, Outside Dates, and Limits: States may select a 50-day season between the Saturday nearest September 24 (September 26) and January 31, with a 2-bird daily bag limit. States may split their seasons into two segments.

Mississippi Flyway

Ducks, Mergansers, and Coots

Outside Dates: Between the Saturday nearest September 24 (September 26) and the last Sunday in January (January 31).

Hunting Seasons and Duck Limits: The season may not exceed 60 days, with a daily bag limit of 6 ducks, including no more than 4 mallards (no more than 2 of which may be females), 1 mottled duck, 1 black duck, 1 pintail, 3 wood ducks, 1 canvasback, 2 scaup, and 2 redheads.

Merganser Limits: The daily bag limit is 5, only 2 of which may be hooded mergansers. In States that include mergansers in the duck bag limit, the daily limit is the same as the duck bag limit, only 2 of which may be hooded mergansers.

Coot Limits: The daily bag limit is 15 coots.

Zoning and Split Seasons: Alabama, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Ohio, Tennessee, and Wisconsin may select hunting seasons by zones.

In Alabama, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Ohio, Tennessee, and Wisconsin, the season may be split into two segments in each zone.

In Arkansas and Mississippi, the season may be split into three segments.

Geese

Split Seasons: Seasons for geese may be split into three segments.

Season Lengths, Outside Dates, and Limits: States may select seasons for light geese not to exceed 107 days, with 20 geese daily between the Saturday

nearest September 24 (September 26) and March 10; for white-fronted geese not to exceed 72 days with 2 geese daily or 86 days with 1 goose daily between the Saturday nearest September 24 (September 26) and the Sunday nearest February 15 (February 14); and for brant not to exceed 70 days, with 2 brant daily or 107 days with 1 brant daily between the Saturday nearest September 24 (September 26) and January 31. There is no possession limit for light geese. Specific regulations for Canada geese and exceptions to the above general provisions are shown below by State. Except as noted below, the outside dates for Canada geese are the Saturday nearest September 24 (September 26) and January 31.

Alabama: In the SJB Goose Zone, the season for Canada geese may not exceed 70 days. Elsewhere, the season for Canada geese may extend for 70 days in the respective duck-hunting zones. The daily bag limit is 2 Canada geese.

Arkansas: In the Northwest Zone, the season for Canada geese may extend for 50 days. In the remainder of the State, the season may not exceed 40 days. The season may extend to February 15. The daily bag limit is 2 Canada geese.

Illinois: The season for Canada geese may extend for 85 days in the North and Central Zones and 66 days in the South Zone. The daily bag limit is 2 Canada geese.

Indiana: The season for Canada geese may extend for 74 days. The daily bag limit is 2 Canada geese.

Late Canada Goose Season Zone—an experimental special Canada goose season of up to 15 days may be held during February 1–15. During this special season the daily bag limit cannot exceed 5 Canada geese.

Iowa: The season for Canada geese may extend for 90 days. The daily bag limit is 2 Canada geese.

Kentucky:

(a) *Western Zone*—The season for Canada geese may extend for 70 days (85 days in Fulton County). The season in Fulton County may extend to February 15. The daily bag limit is 2 Canada geese.

(b) *Pennyroyal/Coalfield Zone*—The season may extend for 70 days. The daily bag limit is 2 Canada geese.

(c) *Remainder of the State*—The season may extend for 70 days. The daily bag limit is 2 Canada geese.

Louisiana: The season for Canada geese may extend for 44 days. The daily bag limit is 1 Canada goose.

Michigan:

(a) *North Zone*—The framework opening date for all geese is September 16 and the season for Canada geese may

extend for 45 days. The daily bag limit is 2 Canada geese.

(b) *Middle Zone*—The framework opening date for all geese is September 16 and the season for Canada geese may extend for 45 days. The daily bag limit is 2 Canada geese.

(c) *South Zone*—The framework opening date for all geese is September 16 and the season for Canada geese may extend for 45 days. The daily bag limit is 2 Canada geese.

(1) *Allegan County and Muskegon Wastewater GMU*—The framework opening date for all geese is September 16 and the season for Canada geese may extend for 45 days. The daily bag limit is 2 Canada geese.

(2) *Saginaw County and Tuscola/Huron GMUs*—The framework opening date for all geese is September 16 and the season for Canada geese may extend for 45 days through December 30 and an additional 30 days may be held between December 31 and February 7. The daily bag limit is 2 Canada geese.

(d) *Southern Michigan Late Season Canada Goose Zone*—A 30-day special Canada goose season may be held between December 31 and February 7. The daily bag limit may not exceed 5 Canada geese.

Minnesota:

(a) *West Zone*

(1) *West Central Zone*—The season for Canada geese may extend for 41 days. The daily bag limit is 2 Canada geese.

(2) *Remainder of West Zone*—The season for Canada geese may extend for 60 days. The daily bag limit is 2 Canada geese.

(b) *Remainder of the State*—The season for Canada geese may extend for 70 days. The daily bag limit is 2 Canada geese.

(c) *Special Late Canada Goose Season*—A special Canada goose season of up to 10 days may be held in December, except in the West Central Goose zone. During the special season, the daily bag limit is 5 Canada geese, except in the Southeast Goose Zone, where the daily bag limit is 2.

Mississippi: The season for Canada geese may extend for 70 days. The daily bag limit is 3 Canada geese.

Missouri: The season for Canada geese may extend for 79 days and may be split into 3 segments provided that at least 1 segment of at least 9 days occurs prior to October 16. The daily bag limit is 3 Canada geese through October 15 and 2 Canada geese thereafter.

Ohio:

(a) *Lake Erie Zone*—The season may extend for 74 days. The daily bag limit is 2 Canada geese.

(b) *North Zone*—The season may extend for 74 days. The daily bag limit is 2 Canada geese.

(c) South Zone – The season may extend for 74 days. The daily bag limit is 2 Canada geese.

Tennessee:

(a) Northwest Zone—The season for Canada geese may not exceed 72 days, and may extend to February 15. The daily bag limit is 2 Canada geese.

(b) Southwest Zone—The season for Canada geese may extend for 72 days. The daily bag limit is 2 Canada geese.

(c) Kentucky/Barkley Lakes Zone—The season for Canada geese may extend for 72 days. The daily bag limit is 2 Canada geese.

(d) Remainder of the State—The season for Canada geese may extend for 72 days. The daily bag limit is 2 Canada geese.

Wisconsin:

(a) Horicon Zone—The framework opening date for all geese is September 16. The season may not exceed 92 days. All Canada geese harvested must be tagged. The season limit will be 6 Canada geese per permittee.

(b) Collins Zone—The framework opening date for all geese is September 16. The season may not exceed 70 days. All Canada geese harvested must be tagged. The season limit will be 6 Canada geese per permittee.

(c) Exterior Zone—The framework opening date for all geese is September 16. The season may not exceed 85 days. The daily bag limit is 2 Canada geese.

Additional Limits: In addition to the harvest limits stated for the respective zones above, an additional 4,500 Canada geese may be taken in the Horicon Zone under special agricultural permits.

Central Flyway

Ducks, Mergansers, and Coots

Outside Dates: Between the Saturday nearest September 24 (September 26) and the last Sunday in January (January 31).

Hunting Seasons:

(1) High Plains Mallard Management Unit (roughly defined as that portion of the Central Flyway which lies west of the 100th meridian): 97 days. The last 23 days may start no earlier than the Saturday nearest December 10 (December 12).

(2) Remainder of the Central Flyway: 74 days.

Bag Limits: The daily bag limit is 6 ducks, with species and sex restrictions as follows: 5 mallards (no more than 2 of which may be females), 2 redheads, 2 scaup, 3 wood ducks, 1 pintail, 1 mottled duck (except for the first 5 days of the season when it is closed), and 1 canvasback.

Merganser Limits: The daily bag limit is 5 mergansers, only 2 of which may be

hooded mergansers. In States that include mergansers in the duck daily bag limit, the daily limit may be the same as the duck bag limit, only two of which may be hooded mergansers.

Coot Limits: The daily bag limit is 15 coots.

Zoning and Split Seasons: Kansas (Low Plains portion), Montana, Nebraska (Low Plains portion), New Mexico, Oklahoma (Low Plains portion), South Dakota (Low Plains portion), Texas (Low Plains portion), and Wyoming may select hunting seasons by zones.

In Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming, the regular season may be split into two segments.

In Colorado, the season may be split into three segments.

Geese

Split Seasons: Seasons for geese may be split into three segments. Three-way split seasons for Canada geese require Central Flyway Council and U.S. Fish and Wildlife Service approval, and a 3-year evaluation by each participating State.

Outside Dates: For dark geese, seasons may be selected between the outside dates of the Saturday nearest September 24 (September 26) and the Sunday nearest February 15 (February 14). For light geese, outside dates for seasons may be selected between the Saturday nearest September 24 (September 26) and March 10. In the Rainwater Basin Light Goose Area (East and West) of Nebraska, temporal and spatial restrictions that are consistent with the late-winter snow goose hunting strategy cooperatively developed by the Central Flyway Council and the Service are required.

Season Lengths and Limits:

Light Geese: States may select a light goose season not to exceed 107 days. The daily bag limit for light geese is 20 with no possession limit.

Dark Geese: In Kansas, Nebraska, North Dakota, Oklahoma, South Dakota, and the Eastern Goose Zone of Texas, States may select a season for Canada geese (or any other dark goose species except white-fronted geese) not to exceed 107 days with a daily bag limit of 3. Additionally, in the Eastern Goose Zone of Texas, an alternative season of 107 days with a daily bag limit of 1 Canada goose may be selected. For white-fronted geese, these States may select either a season of 72 days with a bag limit of 2 or an 86-day season with a bag limit of 1.

In Montana, New Mexico and Wyoming, States may select seasons not to exceed 107 days. The daily bag limit for dark geese is 5 in the aggregate.

In Colorado, the season may not exceed 107 days. The daily bag limit is 4 dark geese in the aggregate.

In the Western Goose Zone of Texas, the season may not exceed 95 days. The daily bag limit for Canada geese (or any other dark goose species except white-fronted geese) is 4. The daily bag limit for white-fronted geese is 1.

Pacific Flyway

Ducks, Mergansers, Coots, Common Moorhens, and Purple Gallinules

Hunting Seasons and Duck Limits: Concurrent 107 days. The daily bag limit is 7 ducks and mergansers, including no more than 2 female mallards, 1 pintails, 1 scaup, 1 canvasback, and 2 redheads. For scaup, the season length would be 86 days, which may be split according to applicable zones/split duck hunting configurations approved for each State.

The season on coots and common moorhens may be between the outside dates for the season on ducks, but not to exceed 107 days.

Coot, Common Moorhen, and Purple Gallinule Limits: The daily bag and possession limits of coots, common moorhens, and purple gallinules are 25, singly or in the aggregate.

Outside Dates: Between the Saturday nearest September 24 (September 26) and the last Sunday in January (January 31).

Zoning and Split Seasons: Arizona, California, Idaho, Nevada, Oregon, Utah, Washington, and Wyoming may select hunting seasons by zones. Arizona, California, Idaho, Nevada, Oregon, Utah, Washington, and Wyoming may split their seasons into two segments.

Colorado, Montana, and New Mexico may split their seasons into three segments.

Colorado River Zone, California: Seasons and limits shall be the same as seasons and limits selected in the adjacent portion of Arizona (South Zone).

Geese

Season Lengths, Outside Dates, and Limits:

California, Oregon, and Washington:

Dark geese: Except as subsequently noted, 100-day seasons may be selected, with outside dates between the Saturday nearest October 1 (October 3), and the last Sunday in January (January 31). The basic daily bag limit is 4 dark geese, except the dark goose bag limit does not include brant.

Light geese: Except as subsequently noted, 107-day seasons may be selected, with outside dates between the Saturday nearest October 1 (October 3), and March 10. The daily bag limit is 6 light geese.

Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming:

Dark geese: Except as subsequently noted, 107-day seasons may be selected, with outside dates between the Saturday nearest September 24 (September 26), and the last Sunday in January (January 31). The basic daily bag limit is 4 dark geese.

Light geese: Except as subsequently noted, 107-day seasons may be selected, with outside dates between the Saturday nearest September 24 (September 26), and March 10. The basic daily bag limit is 10 light geese.

Split Seasons: Unless otherwise specified, seasons for geese may be split into up to 3 segments. Three-way split seasons for Canada geese and white-fronted geese require Pacific Flyway Council and U.S. Fish and Wildlife Service approval and a 3-year evaluation by each participating State.

Brant Season

Oregon may select a 16-day season, Washington a 16-day season, and California a 30-day season. Days must be consecutive. Washington and California may select hunting seasons by up to two zones. The daily bag limit is 2 brant and is in addition to dark goose limits. In Oregon and California, the brant season must end no later than December 15.

Arizona: The daily bag limit for dark geese is 3.

California:

Northeastern Zone: The daily bag limit is 6 dark geese and may include no more than 1 cackling Canada goose or 1 Aleutian Canada goose.

Balance-of-the-State Zone: Limits may not include more than 6 dark geese per day. In the Sacramento Valley Special Management Area, the season on white-fronted geese must end on or before December 14, and the daily bag limit shall contain no more than 2 white-fronted geese. In the North Coast Special Management Area, 107-day seasons may be selected, with outside dates between the Saturday nearest October 1 (October 3) and March 10. Hunting days that occur after the last Sunday in January shall be concurrent with Oregon's South Coast Zone.

Colorado: The daily bag limit for dark geese is 3 geese.

Nevada: The daily bag limit for dark geese is 3.

New Mexico: The daily bag limit for dark geese is 3.

Oregon:

Except as subsequently noted, the dark goose daily bag limit is 4, including not more than 1 cackling or Aleutian goose.

Harney, Lake, and Malheur County Zone: For Lake County only, the daily dark goose bag limit may not include more than 1 white-fronted goose.

Klamath County Zone: A 107-day season may be selected, with outside dates between the Saturday nearest October 1 (October 3), and March 10. A 3-way split season may be selected. The daily goose bag limit is 4 dark geese and 4 white geese except for hunting days that occur after the last Sunday in January when only light geese and white-fronted geese may be taken. The daily bag limit of geese is 6 of which only 4 may be light geese and only 2 may be white-fronted geese.

Northwest Special Permit Zone:

Outside dates are between the Saturday nearest October 1 (October 3), and the Sunday closest to March 1 (February 28). The daily bag limit of dark geese is 4 including not more than 2 cackling or Aleutian geese and daily bag limit of light geese is 4. In those designated areas of Tillamook County open to hunting, the daily bag limit of dark geese is 2.

South Coast Zone: The daily dark goose bag limit is 4 including cackling and Aleutian geese. In Oregon's South Coast Zone 107-day seasons may be selected, with outside dates between the Saturday nearest October 1 (October 3) and March 10. Hunting days that occur after the last Sunday in January shall be concurrent with California's North Coast Special Management Area. A 3-way split season may be selected.

Southwest Zone: The daily dark goose bag limit is 4 including cackling and Aleutian geese.

Utah: The daily bag limit for dark geese is 3.

Washington: The daily bag limit is 4 geese.

Area 1: Outside dates are between the Saturday nearest October 1 (October 3), and the last Sunday in January (January 31).

Areas 2A and 2B (Southwest Quota Zone): Except for designated areas, there will be no open season on Canada geese. See section on quota zones. In this area, the daily bag limit may include 2 cackling geese. In Southwest Quota Zone Area 2B (Pacific County), the daily bag limit may include 1 Aleutian goose.

Areas 4 and 5: A 107-day season may be selected for dark geese.

Wyoming: The daily bag limit for dark geese is 3.

Quota Zones

Seasons on geese must end upon attainment of individual quotas of dusky geese allotted to the designated areas of Oregon (90) and Washington (45). The September Canada goose season, the regular goose season, any special late dark goose season, and any extended falconry season, combined, must not exceed 107 days, and the established quota of dusky geese must not be exceeded. Hunting of geese in those designated areas will only be by hunters possessing a State-issued permit authorizing them to do so. In a Service-approved investigation, the State must obtain quantitative information on hunter compliance of those regulations aimed at reducing the take of dusky geese. If the monitoring program cannot be conducted, for any reason, the season must immediately close. In the designated areas of the Washington Southwest Quota Zone, a special late goose season may be held between the Saturday following the close of the general goose season and March 10. In the Northwest Special Permit Zone of Oregon, the framework closing date is extended to the Sunday closest to March 1 (February 28). Regular goose seasons may be split into 3 segments within the Oregon and Washington quota zones.

Swans

In portions of the Pacific Flyway (Montana, Nevada, and Utah), an open season for taking a limited number of swans may be selected. Permits will be issued by the State and will authorize each permittee to take no more than 1 swan per season with each permit. Nevada may issue up to 2 permits per hunter. Montana and Utah may only issue 1 permit per hunter. Each State's season may open no earlier than the Saturday nearest October 1 (October 3). These seasons are also subject to the following conditions:

Montana: No more than 500 permits may be issued. The season must end no later than December 1. The State must implement a harvest-monitoring program to measure the species composition of the swan harvest and should use appropriate measures to maximize hunter compliance in reporting bill measurement and color information.

Utah: No more than 2,000 permits may be issued. During the swan season, no more than 10 trumpeter swans may be taken. The season must end no later than the second Sunday in December (December 13) or upon attainment of 10 trumpeter swans in the harvest, whichever occurs earliest. The Utah season remains subject to the terms of

the Memorandum of Agreement entered into with the Service in August 2001, regarding harvest monitoring, season closure procedures, and education requirements to minimize the take of trumpeter swans during the swan season.

Nevada: No more than 650 permits may be issued. During the swan season, no more than 5 trumpeter swans may be taken. The season must end no later than the Sunday following January 1 (January 3) or upon attainment of 5 trumpeter swans in the harvest, whichever occurs earliest.

In addition, the States of Utah and Nevada must implement a harvest-monitoring program to measure the species composition of the swan harvest. The harvest-monitoring program must require that all harvested swans or their species-determinant parts be examined by either State or Federal biologists for the purpose of species classification. The States should use appropriate measures to maximize hunter compliance in providing bagged swans for examination. Further, the States of Montana, Nevada, and Utah must achieve at least an 80-percent compliance rate, or subsequent permits will be reduced by 10 percent. All three States must provide to the Service by June 30, 2010, a report detailing harvest, hunter participation, reporting compliance, and monitoring of swan populations in the designated hunt areas.

Tundra Swans

In portions of the Atlantic Flyway (North Carolina and Virginia) and the Central Flyway (North Dakota, South Dakota [east of the Missouri River], and that portion of Montana in the Central Flyway), an open season for taking a limited number of tundra swans may be selected. Permits will be issued by the States that authorize the take of no more than 1 tundra swan per permit. A second permit may be issued to hunters from unused permits remaining after the first drawing. The States must obtain harvest and hunter participation data. These seasons are also subject to the following conditions:

In the Atlantic Flyway:

- The season may be 90 days, from October 1 to January 31.
- In North Carolina, no more than 5,000 permits may be issued.
- In Virginia, no more than 600 permits may be issued.

In the Central Flyway:

- The season may be 107 days, from the Saturday nearest October 1 (October 3) to January 31.

—In the Central Flyway portion of Montana, no more than 500 permits may be issued.

—In North Dakota, no more than 2,200 permits may be issued.

—In South Dakota, no more than 1,300 permits may be issued.

Area, Unit, and Zone Descriptions

Ducks (Including Mergansers) and Coots

Atlantic Flyway

Connecticut

North Zone: That portion of the State north of I-95.

South Zone: Remainder of the State.

Maine

North Zone: That portion north of the line extending east along Maine State Highway 110 from the New Hampshire and Maine State line to the intersection of Maine State Highway 11 in Newfield; then north and east along Route 11 to the intersection of U.S. Route 202 in Auburn; then north and east on Route 202 to the intersection of Interstate Highway 95 in Augusta; then north and east along I-95 to Route 15 in Bangor; then east along Route 15 to Route 9; then east along Route 9 to Stony Brook in Baileyville; then east along Stony Brook to the United States border.

South Zone: Remainder of the State.

Massachusetts

Western Zone: That portion of the State west of a line extending south from the Vermont State line 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 State line.

Central Zone: That portion of the State east of the Berkshire Zone and west of a line extending south from the New Hampshire State line 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 State line; 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 shall be in the Coastal Zone.

Coastal Zone: That portion of Massachusetts east and south of the Central Zone.

New Hampshire

Coastal Zone: That portion of the State east of a line extending west from the Maine State line in Rollinsford on NH 4 to the city of Dover, south to NH 108, south along NH 108 through Madbury, Durham, and Newmarket to NH 85 in Newfields, south to NH 101 in Exeter, east to NH 51 (Exeter-Hampton Expressway), east to I-95

(New Hampshire Turnpike) in Hampton, and south along I-95 to the Massachusetts State line.

Inland Zone: That portion of the State north and west of the above boundary and along the Massachusetts State line crossing the Connecticut River to Interstate 91 and northward in Vermont to Route 2, east to 102, northward to the Canadian border.

New Jersey

Coastal Zone: That portion of the State seaward of a line beginning at the New York State line in Raritan Bay and extending west along the New York State line to NJ 440 at Perth Amboy; west on NJ 440 to the Garden State Parkway; south on the Garden State Parkway to the shoreline at Cape May and continuing to the Delaware State line in Delaware Bay.

North Zone: That portion of the State west of the Coastal Zone and north of a line extending west from the Garden State Parkway on NJ 70 to the New Jersey Turnpike, north on the turnpike to U.S. 206, north on U.S. 206 to U.S. 1 at Trenton, west on U.S. 1 to the Pennsylvania State line in the Delaware River.

South Zone: That portion of the State not within the North Zone or the Coastal 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 State line.

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 State line.

Northeastern Zone: That area north of a line extending from Lake Ontario east along the north shore of the Salmon River to I-81 to NY 31, east along NY 31 to NY 13, north along NY 13 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 State line, exclusive of the Lake Champlain Zone.

Southeastern Zone: The remaining portion of New York.

Pennsylvania

Lake Erie Zone: The Lake Erie waters of Pennsylvania and a shoreline margin along Lake Erie from New York on the east to Ohio on the west extending 150 yards inland, but including all of Presque Isle Peninsula.

Northwest Zone: The area bounded on the north by the Lake Erie Zone and including all of Erie and Crawford Counties and those portions of Mercer and Venango Counties north of I-80.

North Zone: That portion of the State east of the Northwest Zone and north of a line extending east on I-80 to U.S. 220, Route 220 to I-180, I-180 to I-80, and I-80 to the Delaware River.

South Zone: The remaining portion of Pennsylvania.

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 State line 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 State line at Interstate 91; north along Interstate 91 to US 2; east along US 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.

West Virginia

Zone 1: That portion outside the boundaries in Zone 2.

Zone 2 (Allegheny Mountain Upland): That area bounded by a line extending south along U.S. 220 through Keyser to U.S. 50; U.S. 50 to WV 93; WV 93 south to WV 42; WV 42 south to Petersburg; WV 28 south to Minnehaha Springs; WV 39 west to U.S. 219; U.S. 219 south to I-64; I-64 west to U.S. 60; U.S. 60 west to U.S. 19; U.S. 19 north to I-79, I-79 north to I-68; I-68 east to the Maryland State line; and along the State line to the point of beginning.

Mississippi Flyway*Alabama*

South Zone: Mobile and Baldwin Counties.

North Zone: The remainder of Alabama.

Illinois

North Zone: That portion of the State 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 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.

Indiana

North Zone: That portion of the State north of a line extending east from the Illinois State line 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 State line.

Ohio River Zone: That portion of the State south of a line extending east from the Illinois State line along Interstate Highway 64 to New Albany, east along State Road 62 to State Road 56, east along State Road 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 State line.

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.

Kentucky

West Zone: All counties west of and including Butler, Daviess, Ohio, Simpson, and Warren Counties.

East Zone: The remainder of Kentucky.

Louisiana

West Zone: That portion of the State west and south of a line extending south from the Arkansas State line along Louisiana Highway 3 to Bossier City, east along Interstate Highway 20 to Minden, south along Louisiana 7 to Ringgold, east along Louisiana 4 to Jonesboro, south along U.S. Highway 167 to Lafayette, southeast along U.S. 90 to the Mississippi State line.

East Zone: The remainder of Louisiana.

Michigan

North Zone: The Upper Peninsula.

Middle Zone: That portion of the Lower Peninsula north of a line beginning at the Wisconsin State line 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, easterly along U.S. 10 BR to U.S. 10, easterly along U.S. 10 to Interstate Highway 75/U.S. Highway 23, northerly along I-75/U.S. 23 to the U.S. 23 exit at Standish, easterly along 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.

South Zone: The remainder of Michigan.

Minnesota

North Duck Zone: That portion of the State north of a line extending east from the North Dakota State line along State Highway 210 to State Highway 23, east along State Highway 23 to State Highway 39, then east along State Highway 39 to the Wisconsin State line at the Oliver Bridge.

South Duck Zone: The remainder of Minnesota.

Missouri

North Zone: That portion of Missouri north of a line running west from the Illinois State line (Lock and Dam 25) on Lincoln County Highway N to Missouri Highway 79; south on Missouri Highway 79 to Missouri Highway 47; west on Missouri Highway 47 to Interstate 70; west on Interstate 70 to the Kansas State line.

South Zone: That portion of Missouri south of a line running west from the Illinois State line on Missouri Highway 34 to Interstate 55; south on Interstate

55 to U.S. Highway 62; west on U.S. Highway 62 to Missouri Highway 53; north on Missouri Highway 53 to Missouri Highway 51; north on Missouri Highway 51 to U.S. Highway 60; west on U.S. Highway 60 to Missouri Highway 21; north on Missouri Highway 21 to Missouri Highway 72; west on Missouri Highway 72 to Missouri Highway 32; west on Missouri Highway 32 to U.S. Highway 65; north on U.S. Highway 65 to U.S. Highway 54; west on U.S. Highway 54 to the Kansas State line.

Middle Zone: The remainder of Missouri.

Ohio

North Zone: That portion of the State north of a line extending east from the Indiana State line along U.S. Highway 33 to State Route 127, south along SR 127 to SR 703, south along SR 703 to SR 219, east along SR 219 to SR 364, north along SR 364 to SR 703, east along SR 703 to SR 66, north along SR 66 to U.S. 33, east along U.S. 33 to SR 385, east along SR 385 to SR 117, south along SR 117 to SR 273, east along SR 273 to SR 31, south along SR 31 to SR 739, east along SR 739 to SR 4, north along SR 4 to SR 95, east along SR 95 to SR 13, southeast along SR 13 to SR 3, northeast along SR 3 to SR 60, north along SR 60 to U.S. 30, east along U.S. 30 to SR 3, south along SR 3 to SR 226, south along SR 226 to SR 514, southwest along SR 514 to SR 754, south along SR 754 to SR 39/60, east along SR 39/60 to SR 241, north along SR 241 to U.S. 30, east along U.S. 30 to SR 39, east along SR 39 to the Pennsylvania State line.

South Zone: The remainder of Ohio.

Tennessee

Reelfoot Zone: All or portions of Lake and Obion Counties.

State Zone: The remainder of Tennessee.

Wisconsin

North Zone: That portion of the State north of a line extending east from the Minnesota State line along U.S. Highway 10 to U.S. Highway 41, then north on U.S. Highway 41 to the Michigan State line.

South Zone: The remainder of Wisconsin.

Central Flyway

Colorado (Central Flyway Portion)

Eastern Plains Zone: That portion of the State east of Interstate 25, and all of El Paso, Pueblo, Huerfano, and Las Animas Counties.

Mountain/Foothills Zone: That portion of the State west of Interstate 25 and east of the Continental Divide, except El Paso, Pueblo, Huerfano, and Las Animas Counties.

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 border 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; southwest on U.S. 56 to KS 19; east on KS 19 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; southwest on U.S. 56 to Ford Co. Road 126; south on Ford Co. Road 126 to U.S. 400; northwest on U.S. 400 to U.S. 283.

Low Plains Late Zone: The remainder of Kansas.

Montana (Central Flyway Portion)

Zone 1: The Counties of Blaine, Carbon, Carter, Daniels, Dawson, Fallon, Fergus, Garfield, Golden Valley, Judith Basin, McCone, Musselshell, Petroleum, Phillips, Powder River, Richland, Roosevelt, Sheridan, Stillwater, Sweet Grass, Valley, Wheatland, Wibaux, and Yellowstone.

Zone 2: The remainder of Montana.

Nebraska

High Plains Zone: That portion of Nebraska lying west of a line beginning at the South Dakota-Nebraska border on U.S. 183, south on U.S. 183 to U.S. 20, west on U.S. 20 to NE 7, south on NE 7 to NE 91, southwest on NE 91 to NE 2, southeast on NE 2 to NE 92, west on NE 92 to NE 40, south on NE 40 to NE 47, south on NE 47 to NE 23, east on NE 23 to U.S. 283 and south on U.S. 283 to the Kansas-Nebraska border.

Low Plains Zone 1: That portion of Dixon County west of NE 26E Spur and north of NE 12; those portions of Cedar County north of NE 12 to intersection of Niobrara River; all of Boyd County; Keya Paha County east of U.S. 183. Both banks of the Niobrara River in Keya Paha, Boyd, and Knox Counties east of U.S. 183 shall be included in Zone 1.

Low Plains Zone 2: Area bounded by designated Federal and State highways and political boundaries beginning at the Kansas-Nebraska border on U.S. 75 to U.S. 136; east to the intersection of

U.S. 136 and the Steamboat Trace (Trace); north along the Trace to the intersection with Federal Levee R-562; north along Federal Levee R-562 to the intersection with the Trace; north along the Trace/Burlington Northern Railroad right-of-way to NE 2; west to U.S. 75; north to NE 2; west to NE 43; north to U.S. 34; east to NE 63; north and west to U.S. 77; north to NE 92; west to U.S. 81; south to NE 66; west to NE 14; south to County Road 22 (Hamilton County); west to County Road M; south to County Road 21; west to County Road K; south U.S. 34; west to NE 2; south to U.S. I-80; west to Gunbarrel Road (Hall/Hamilton county line); south to Giltner Road; west to U.S. 281; south to U.S. 34; west to NE 10; north to County Road "R" (Kearney County) and County Road #742 (Phelps County); west to County Road #438 (Gosper County line); south along County Road #438 (Gosper County line) to County Road #726 (Furnas County line); east to County Road #438 (Harlan County line); south to U.S. 34; south and west to U.S. 136; east to NE 14; south to the Kansas-Nebraska border; west to U.S. 283; north to NE 23; west to NE 47; north to U.S. 30; east to NE 14; north to NE 52; west and north to NE 91 to U.S. 281; south to NE 22; west to NE 11; northwest to NE 91; west to Loup County Line; north to Loup-Brown County line; east along northern boundaries of Loup, Garfield, and Wheeler Counties; south on the Wheeler-Antelope county line to NE 70; east to NE 14; south to NE 39; southeast to NE 22; east to U.S. 81; southeast to U.S. 30; east to U.S. 75; north to the Washington County line; east to the Iowa-Nebraska border; south along the Iowa-Nebraska border; to the beginning at U.S. 75 and the Kansas-Nebraska border.

Low Plains Zone 3: The area east of the High Plains Zone, excluding Low Plains Zone 1, north of Low Plains Zone 2.

Low Plains Zone 4: The area east of the High Plains Zone and south of Zone 2.

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.

North Dakota

High Plains Unit: That portion of the State south and west of a line from the South Dakota State line along U.S. 83 and I-94 to ND 41, north to U.S. 2, west to the Williams/Divide County line, then north along the County line to the Canadian border.

Low Plains Unit: The remainder of North Dakota.

Oklahoma

High Plains Zone: The Counties of Beaver, Cimarron, and Texas.

Low Plains Zone 1: That portion of the State east of the High Plains Zone and north of a line extending east from the Texas State line along OK 33 to OK 47, east along OK 47 to U.S. 183, south along U.S. 183 to I-40, east along I-40 to U.S. 177, north along U.S. 177 to OK 33, east along OK 33 to OK 18, north along OK 18 to OK 51, west along OK 51 to I-35, north along I-35 to U.S. 412, west along U.S. 412 to OK 132, then north along OK 132 to the Kansas State line.

Low Plains Zone 2: The remainder of Oklahoma.

South Dakota

High Plains Zone: That portion of the State west of a line beginning at the North Dakota State line and extending south along U.S. 83 to U.S. 14, east on U.S. 14 to Blunt, south on the Blunt-Canning road to SD 34, east and south on SD 34 to SD 50 at Lee's Corner, south on SD 50 to I-90, east on I-90 to SD 50, south on SD 50 to SD 44, west on SD 44 across the Platte-Winner bridge to SD 47, south on SD 47 to U.S. 18, east on U.S. 18 to SD 47, south on SD 47 to the Nebraska State line.

North Zone: That portion of northeastern South Dakota east of the High Plains Unit and north of a line extending east along U.S. 212 to the Minnesota State line.

South Zone: That portion of Gregory County east of SD 47 and south of SD 44; Charles Mix County south of SD 44 to the Douglas County line; south on SD 50 to Geddes; east on the Geddes Highway to U.S. 281; south on U.S. 281 and U.S. 18 to SD 50; south and east on SD 50 to the Bon Homme County line; the Counties of Bon Homme, Yankton, and Clay south of SD 50; and Union County south and west of SD 50 and I-29.

Middle Zone: The remainder of South Dakota.

Texas

High Plains Zone: That portion of the State west of a line extending south from the Oklahoma State line along U.S. 183 to Vernon, south along U.S. 283 to Albany, south along TX 6 to TX 351 to Abilene, south along U.S. 277 to Del Rio, then south along the Del Rio International Toll Bridge access road to the Mexico border.

Low Plains North Zone: That portion of northeastern Texas east of the High Plains Zone and north of a line beginning at the International Toll Bridge south of Del Rio, then extending east on U.S. 90 to San Antonio, then continuing east on I-10 to the Louisiana State line at Orange, Texas.

Low Plains South Zone: The remainder of Texas.

Wyoming (Central Flyway Portion)

Zone 1: The Counties of Converse, Goshen, Hot Springs, Natrona, Platte, and Washakie; and the portion of Park County east of the Shoshone National Forest boundary and south of a line beginning where the Shoshone National Forest boundary meets Park County Road 8VC, east along Park County Road 8VC to Park County Road 1AB, continuing east along Park County Road 1AB to Wyoming Highway 120, north along WY Highway 120 to WY Highway 294, south along WY Highway 294 to Lane 9, east along Lane 9 to Powel and WY Highway 14A, and finally east along WY Highway 14A to the Park County and Big Horn County line.

Zone 2: The remainder of Wyoming.

Pacific Flyway

Arizona

Game Management Units (GMU) as follows:

South Zone: Those portions of GMUs 6 and 8 in Yavapai County, and GMUs 10 and 12B-45.

North Zone: GMUs 1-5, those portions of GMUs 6 and 8 within Coconino County, and GMUs 7, 9, 12A.

California

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 State line 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 State line 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 State line.

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.

Idaho

Zone 1: Includes all lands and waters within the Fort Hall Indian Reservation, including private inholdings; Bannock County; Bingham County, except that portion within the Blackfoot Reservoir drainage; and Power County east of ID 37 and ID 39.

Zone 2: Includes the following Counties or portions of Counties: Adams; Bear Lake; Benewah; Bingham within the Blackfoot Reservoir drainage; Blaine; Bonner; Bonneville; Boundary; Butte; Camas; Caribou except the Fort Hall Indian Reservation; Cassia within the Minidoka National Wildlife Refuge; Clark; Clearwater; Custer; Elmore within the Camas Creek drainage; Franklin; Fremont; Idaho; Jefferson; Kootenai; Latah; Lemhi; Lewis; Madison; Nez Perce; Oneida; Power within the Minidoka National Wildlife Refuge; Shoshone; Teton; and Valley Counties.

Zone 3: Includes the following Counties or portions of Counties: Ada;

Boise; Canyon; Cassia except within the Minidoka National Wildlife Refuge; Elmore except the Camas Creek drainage; Gem; Gooding; Jerome; Lincoln; Minidoka; Owyhee; Payette; Power west of ID 37 and ID 39 except that portion within the Minidoka National Wildlife Refuge; Twin Falls; and Washington Counties.

Nevada

Lincoln and Clark County Zone: All of Clark and Lincoln Counties.

Remainder-of-the-State Zone: The remainder of Nevada.

Oregon

Zone 1: Clatsop, Tillamook, Lincoln, Lane, Douglas, Coos, Curry, Josephine, Jackson, Linn, Benton, Polk, Marion, Yamhill, Washington, Columbia, Multnomah, Clackamas, Hood River, Wasco, Sherman, Gilliam, Morrow and Umatilla Counties.

Columbia Basin Mallard Management Unit: Gilliam, Morrow, and Umatilla Counties.

Zone 2: The remainder of the State.

Utah

Zone 1: All of Box Elder, Cache, Daggett, Davis, Duchesne, Morgan, Rich, Salt Lake, Summit, Uintah, Utah, Wasatch, and Weber Counties, and that part of Toole County north of I-80.

Zone 2: The remainder of Utah.

Washington

East Zone: All areas east of the Pacific Crest Trail and east of the Big White Salmon River in Klickitat County.

Columbia Basin Mallard Management Unit: Same as East Zone.

West Zone: All areas to the west of the East Zone.

Wyoming

Snake River Zone: Beginning at the south boundary of Yellowstone National Park and the Continental Divide; south along the Continental Divide to Union Pass and the Union Pass Road (U.S.F.S. Road 600); west and south along the Union Pass Road to U.S. F.S. Road 605; south along U.S.F.S. Road 605 to the Bridger-Teton National Forest boundary; along the national forest boundary to the Idaho State line; north along the Idaho State line to the south boundary of Yellowstone National Park; east along the Yellowstone National Park boundary to the Continental Divide.

Balance of Flyway Zone: Balance of the Pacific Flyway in Wyoming outside the Snake River Zone.

Geese

Atlantic Flyway

Connecticut

AP Unit: Litchfield County and the portion of Hartford County west of a line beginning at the Massachusetts border in Suffield and extending south

along Route 159 to its intersection with Route 91 in Hartford, and then extending south along Route 91 to its intersection with the Hartford/Middlesex County line.

AFRP Unit: Starting at the intersection of I-95 and the Quinnipiac River, north on the Quinnipiac River to its intersection with I-91, north on I-91 to I-691, west on I-691 to the Hartford County line, and encompassing the rest of New Haven County and Fairfield County in its entirety.

NAP H-Unit: All of the rest of the State not included in the AP or AFRP descriptions above.

South Zone: Same as for ducks.

North Zone: Same as for ducks.

Maryland

Resident Population (RP) Zone:

Garrett, Allegany, Washington, Frederick, and Montgomery Counties; that portion of Prince George's County west of Route 3 and Route 301; that portion of Charles County west of Route 301 to the Virginia State line; and that portion of Carroll County west of Route 31 to the intersection of Route 97, and west of Route 97 to the Pennsylvania line.

AP Zone: Remainder of the State.

Massachusetts

NAP Zone: Central and Coastal Zones (see duck zones).

AP Zone: The Western Zone (see duck zones).

Special Late Season Area: The Central Zone and that portion of the Coastal Zone (see duck zones) that lies north of the Cape Cod Canal, north to the New Hampshire line.

New Hampshire

Same zones as for ducks.

New Jersey

North: That portion of the State within a continuous line that runs east along the New York State boundary line to the Hudson River; then south along the New York State boundary to its intersection with Route 440 at Perth Amboy; then west on Route 440 to its intersection with Route 287; then west along Route 287 to its intersection with Route 206 in Bedminster (Exit 18); then north along Route 206 to its intersection with Route 94; then west along Route 94 to the tollbridge in Columbia; then north along the Pennsylvania State boundary in the Delaware River to the beginning point.

South: That portion of the State within a continuous line that runs west from the Atlantic Ocean at Ship Bottom along Route 72 to Route 70; then west along Route 70 to Route 206; then south along Route 206 to Route 536; then west along Route 536 to Route 322; then west along Route 322 to Route 55; then south along Route 55 to Route 553 (Buck

Road); then south along Route 553 to Route 40; then east along Route 40 to Route 55; then south along Route 55 to Route 552 (Sherman Avenue); then west along Route 552 to Carmel Road; then south along Carmel Road to Route 49; then east along Route 49 to Route 555; then south along Route 555 to Route 553; then east along Route 553 to Route 649; then north along Route 649 to Route 670; then east along Route 670 to Route 47; then north along Route 47 to Route 548; then east along Route 548 to Route 49; then east along Route 49 to Route 50; then south along Route 50 to Route 9; then south along Route 9 to Route 625 (Sea Isle City Boulevard); then east along Route 625 to the Atlantic Ocean; then north to the beginning point.

New York

Lake Champlain Goose Area: That area of New York State lying east and north of a continuous line extending along Route 11 from the New York-Canada International boundary south to Route 9B, south along Route 9B to Route 9, south along Route 9 to Route 22 south of Keeseville, south along Route 22 to the west shore of South Bay along and around the shoreline of South Bay to Route 22 on the east shore of South Bay, southeast along Route 22 to Route 4, northeast along Route 4 to the New York-Vermont boundary.

Northeast Goose Area: The same as the Northeastern Waterfowl Hunting Zone, which is that area of New York State lying north of a continuous line extending from Lake Ontario east along the north shore of the Salmon River to Interstate 81, south along Interstate Route 81 to Route 31, east along Route 31 to Route 13, north along Route 13 to Route 49, east along Route 49 to Route 365, east along Route 365 to Route 28, east along Route 28 to Route 29, east along Route 29 to Interstate Route 87, north along Interstate Route 87 to Route 9 (at Exit 20), north along Route 9 to Route 149, east along Route 149 to Route 4, north along Route 4 to the New York-Vermont boundary, exclusive of the Lake Champlain Zone.

East Central Goose Area: That area of New York State lying inside of a continuous line extending from Interstate Route 81 in Cicero, east along Route 31 to Route 13, north along Route 13 to Route 49, east along Route 49 to Route 365, east along Route 365 to Route 28, east along Route 28 to Route 29, east along Route 29 to Route 147 at Kimball Corners, south along Route 147 to Schenectady County Route 40 (West Glenville Road), west along Route 40 to Touareuna Road, south along Touareuna Road to Schenectady County Route 59, south along Route 59 to State Route 5,

east along Route 5 to the Lock 9 bridge, southwest along the Lock 9 bridge to Route 5S, southeast along Route 5S to Schenectady County Route 58, southwest along Route 58 to the NYS Thruway, south along the Thruway to Route 7, southwest along Route 7 to Schenectady County Route 103, south along Route 103 to Route 406, east along Route 406 to Schenectady County Route 99 (Windy Hill Road), south along Route 99 to Dunnsville Road, south along Dunnsville Road to Route 397, southwest along Route 397 to Route 146 at Altamont, west along Route 146 to Albany County Route 252, northwest along Route 252 to Schenectady County Route 131, north along Route 131 to Route 7, west along Route 7 to Route 10 at Richmondville, south on Route 10 to Route 23 at Stamford, west along Route 23 to the south bank of the Susquehanna River, southwest along the south bank of the Susquehanna River to Interstate Route 88 near Harpursville, west along Route 88 to Route 79, northwest along Route 79 to Route 26 in Whitney Point, southwest along Route 26 to Interstate Route 81, north along Route 81 to the point of beginning.

West Central Goose Area: That area of New York State lying within a continuous line beginning at the point where the northerly extension of Route 269 (County Line Road on the Niagara-Orleans County boundary) meets the International boundary with Canada, south to the shore of Lake Ontario at the eastern boundary of Golden Hill State Park, south along the extension of Route 269 and Route 269 to Route 104 at Jeddo, west along Route 104 to Niagara County Route 271, south along Route 271 to Route 31E at Middleport, south along Route 31E to Route 31, west along Route 31 to Griswold Street, south along Griswold Street to Ditch Road, south along Ditch Road to Foot Road, south along Foot Road to the north bank of Tonawanda Creek, west along the north bank of Tonawanda Creek to Route 93, south along Route 93 to Route 5, east along Route 5 to Crittenden-Murrays Corners Road, south on Crittenden-Murrays Corners Road to the NYS Thruway, east along the Thruway 90 to Route 98 (at Thruway Exit 48) in Batavia, south along Route 98 to Route 20, east along Route 20 to Route 19 in Pavilion Center, south along Route 19 to Route 63, southeast along Route 63 to Route 246, south along Route 246 to Route 39 in Perry, northeast along Route 39 to Route 20A, northeast along Route 20A to Route 20, east along Route 20 to Route 364 (near Canandaigua), south and east along Route 364 to Yates County Route 18 (Italy Valley Road),

southwest along Route 18 to Yates County Route 34, east along Route 34 to Yates County Route 32, south along Route 32 to Steuben County Route 122, south along Route 122 to Route 53, south along Route 53 to Steuben County Route 74, east along Route 74 to Route 54A (near Pulteney), south along Route 54A to Steuben County Route 87, east along Route 87 to Steuben County Route 96, east along Route 96 to Steuben County Route 114, east along Route 114 to Schuyler County Route 23, east and southeast along Route 23 to Schuyler County Route 28, southeast along Route 28 to Route 409 at Watkins Glen, south along Route 409 to Route 14, south along Route 14 to Route 224 at Montour Falls, east along Route 224 to Route 228 in Odessa, north along Route 228 to Route 79 in Mecklenburg, east along Route 79 to Route 366 in Ithaca, northeast along Route 366 to Route 13, northeast along Route 13 to Interstate Route 81 in Cortland, north along Route 81 to the north shore of the Salmon River to shore of Lake Ontario, extending generally northwest in a straight line to the nearest point of the International boundary with Canada, south and west along the International boundary to the point of beginning.

Hudson Valley Goose Area: That area of New York State lying within a continuous line extending from Route 4 at the New York-Vermont boundary, west and south along Route 4 to Route 149 at Fort Ann, west on Route 149 to Route 9, south along Route 9 to Interstate Route 87 (at Exit 20 in Glens Falls), south along Route 87 to Route 29, west along Route 29 to Route 147 at Kimball Corners, south along Route 147 to Schenectady County Route 40 (West Glenville Road), west along Route 40 to Touareuna Road, south along Touareuna Road to Schenectady County Route 59, south along Route 59 to State Route 5, east along Route 5 to the Lock 9 bridge, southwest along the Lock 9 bridge to Route 5S, southeast along Route 5S to Schenectady County Route 58, southwest along Route 58 to the NYS Thruway, south along the Thruway to Route 7, southwest along Route 7 to Schenectady County Route 103, south along Route 103 to Route 406, east along Route 406 to Schenectady County Route 99 (Windy Hill Road), south along Route 99 to Dunnsville Road, south along Dunnsville Road to Route 397, southwest along Route 397 to Route 146 at Altamont, southeast along Route 146 to Main Street in Altamont, west along Main Street to Route 156, southeast along Route 156 to Albany County Route 307, southeast along Route 307 to Route 85A, southwest along Route 85A

to Route 85, south along Route 85 to Route 443, southeast along Route 443 to Albany County Route 301 at Clarksville, southeast along Route 301 to Route 32, south along Route 32 to Route 23 at Cairo, west along Route 23 to Joseph Chadderdon Road, southeast along Joseph Chadderdon Road to Hearts Content Road (Greene County Route 31), southeast along Route 31 to Route 32, south along Route 32 to Greene County Route 23A, east along Route 23A to Interstate Route 87 (the NYS Thruway), south along Route 87 to Route 28 (Exit 19) near Kingston, northwest on Route 28 to Route 209, southwest on Route 209 to the New York-Pennsylvania boundary, southeast along the New York-Pennsylvania boundary to the New York-New Jersey boundary, southeast along the New York-New Jersey boundary to Route 210 near Greenwood Lake, northeast along Route 210 to Orange County Route 5, northeast along Orange County Route 5 to Route 105 in the Village of Monroe, east and north along Route 105 to Route 32, northeast along Route 32 to Orange County Route 107 (Quaker Avenue), east along Route 107 to Route 9W, north along Route 9W to the south bank of Moodna Creek, southeast along the south bank of Moodna Creek to the New Windsor-Cornwall town boundary, northeast along the New Windsor-Cornwall town boundary to the Orange-Dutchess County boundary (middle of the Hudson River), north along the county boundary to Interstate Route 84, east along Route 84 to the Dutchess-Putnam County boundary, east along the county boundary to the New York-Connecticut boundary, north along the New York-Connecticut boundary to the New York-Massachusetts boundary, north along the New York-Massachusetts boundary to the New York-Vermont boundary, north to the point of beginning.

Eastern Long Island Goose Area (NAP High Harvest Area): That area of Suffolk County lying east of a continuous line extending due south from the New York-Connecticut boundary to the northernmost end of Roanoke Avenue in the Town of Riverhead; then south on Roanoke Avenue (which becomes County Route 73) to State Route 25; then west on Route 25 to Peconic Avenue; then south on Peconic Avenue to County Route (CR) 104 (Riverleigh Avenue); then south on CR 104 to CR 31 (Old Riverhead Road); then south on CR 31 to Oak Street; then south on Oak Street to Potunk Lane; then west on Stevens Lane; then south on Jessup Avenue (in Westhampton Beach) to

Dune Road (CR 89); then due south to international waters.

Western Long Island Goose Area (RP Area): That area of Westchester County and its tidal waters southeast of Interstate Route 95 and that area of Nassau and Suffolk Counties lying west of a continuous line extending due south from the New York-Connecticut boundary to the northernmost end of the Sunken Meadow State Parkway; then south on the Sunken Meadow Parkway to the Sagtikos State Parkway; then south on the Sagtikos Parkway to the Robert Moses State Parkway; then south on the Robert Moses Parkway to its southernmost end; then due south to international waters.

Central Long Island Goose Area (NAP Low Harvest Area): That area of Suffolk County lying between the Western and Eastern Long Island Goose Areas, as defined above.

South Goose Area: The remainder of New York State, excluding New York City.

Special Late Canada Goose Area: That area of the Central Long Island Goose Area lying north of State Route 25A and west of a continuous line extending northward from State Route 25A along Randall Road (near Shoreham) to North Country Road, then east to Sound Road and then north to Long Island Sound and then due north to the New York-Connecticut boundary.

North Carolina

SJBP Hunt Zone: Includes the following Counties or portions of Counties: Anson, Cabarrus, Chatham, Davidson, Durham, Halifax (that portion east of NC 903), Montgomery (that portion west of NC 109), Northampton, Richmond (that portion south of NC 73 and west of US 220 and north of US 74), Rowan, Stanly, Union, and Wake.

RP Hunt Zone: Includes the following Counties or portions of Counties: Alamance, Alleghany, Alexander, Ashe, Avery, Beaufort, Bertie (that portion south and west of a line formed by NC 45 at the Washington Co. line to US 17 in Midway, US 17 in Midway to US 13 in Windsor, US 13 in Windsor to the Hertford Co. line), Bladen, Brunswick, Buncombe, Burke, Caldwell, Carteret, Caswell, Catawba, Cherokee, Clay, Cleveland, Columbus, Craven, Cumberland, Davie, Duplin, Edgecombe, Forsyth, Franklin, Gaston, Gates, Graham, Granville, Greene, Guilford, Halifax (that portion west of NC 903), Harnett, Haywood, Henderson, Hertford, Hoke, Iredell, Jackson, Johnston, Jones, Lee, Lenoir, Lincoln, McDowell, Macon, Madison, Martin, Mecklenburg, Mitchell, Montgomery (that portion that is east of NC 109), Moore, Nash, New Hanover, Onslow, Orange, Pamlico,

Pender, Person, Pitt, Polk, Randolph, Richmond (all of the county with exception of that portion that is south of NC 73 and west of US 220 and north of US 74), Robeson, Rockingham, Rutherford, Sampson, Scotland, Stokes, Surry, Swain, Transylvania, Vance, Warren, Watauga, Wayne, Wilkes, Wilson, Yadkin, and Yancey.

Northeast Hunt Unit: Includes the following Counties or portions of Counties: Bertie (that portion north and east of a line formed by NC 45 at the Washington County line to US 17 in Midway, US 17 in Midway to US 13 in Windsor, US 13 in Windsor to the Hertford Co. line), Camden, Chowan, Currituck, Dare, Hyde, Pasquotank, Perquimans, Tyrrell, and Washington.

Pennsylvania

Resident Canada Goose Zone: All of Pennsylvania except for SJBP Zone and the area east of route SR 97 from the Maryland State Line to the intersection of SR 194, east of SR 194 to intersection of US Route 30, south of US Route 30 to SR 441, east of SR 441 to SR 743, east of SR 743 to intersection of I-81, east of I-81 to intersection of I-80, and south of I-80 to the New Jersey State line.

SJBP Zone: The area north of I-80 and west of I-79 including in the city of Erie west of Bay Front Parkway to and including the Lake Erie Duck zone (Lake Erie, Presque Isle, and the area within 150 yards of the Lake Erie Shoreline).

AP Zone: The area east of route SR 97 from Maryland State Line to the intersection of SR 194, east of SR 194 to intersection of US Route 30, south of US Route 30 to SR 441, east of SR 441 to SR 743, east of SR 743 to intersection of I-81, east of I-81 to intersection of I-80, south of I-80 to New Jersey State line.

Rhode Island

Special Area for Canada Geese: Kent and Providence Counties and portions of the towns of Exeter and North Kingston within Washington County (see State regulations for detailed descriptions).

South Carolina

Canada Goose Area: Statewide except for Clarendon County, that portion of Orangeburg County north of SC Highway 6, and that portion of Berkeley County north of SC Highway 45 from the Orangeburg County line to the junction of SC Highway 45 and State Road S-8-31 and that portion west of the Santee Dam.

Vermont

Same zones as for ducks.

Virginia

AP Zone: The area east and south of the following line the Stafford County line from the Potomac River west to Interstate 95 at Fredericksburg, then south along Interstate 95 to Petersburg,

then Route 460 (SE) to City of Suffolk, then south along Route 32 to the North Carolina line.

SJBP Zone: The area to the west of the AP Zone boundary and east of the following line: the "Blue Ridge" (mountain spine) at the West Virginia-Virginia Border (Loudoun County-Clarke County line) south to Interstate 64 (the Blue Ridge line follows county borders along the western edge of Loudoun-Fauquier-Rappahannock-Madison-Greene-Albemarle and into Nelson Counties), then east along Interstate Rt. 64 to Route 15, then south along Rt. 15 to the North Carolina line.

RP Zone: The remainder of the State west of the SJBP Zone.

West Virginia

Same zones as for ducks.

Mississippi Flyway

Alabama

Same zones as for ducks, but in addition:

SJBP Zone: That portion of Morgan County east of U.S. Highway 31, north of State Highway 36, and west of U.S. 231; that portion of Limestone County south of U.S. 72; and that portion of Madison County south of Swancott Road and west of Triana Road.

Arkansas

Northwest Zone: Baxter, Benton, Boone, Carroll, Conway, Crawford, Faulkner, Franklin, Johnson, Logan, Madison, Marion, Newton, Perry, Pope, Pulaski, Searcy, Sebastian, Scott, Van Buren, Washington, and Yell Counties.

Illinois

Same zones as for ducks.

Indiana

Same zones as for ducks but in addition:

Special Canada Goose Seasons

Indiana Late Canada Goose Season Zone: That part of the state encompassed by the following Counties: Steuben, Lagrange, Elkhart, St. Joseph, La Porte, Starke, Marshall, Kosciusko, Noble, De Kalb, Allen, Whitley, Huntington, Wells, Adams, Boone, Hamilton, Madison, Hendricks, Marion, Hancock, Morgan, Johnson, Shelby, Vermillion, Parke, Vigo, Clay, Sullivan, and Greene.

Iowa

North Zone: That portion of the State north of U.S. Highway 20.

South Zone: The remainder of Iowa.

Kentucky

Western Zone: That portion of the State west of a line beginning at the Tennessee State line at Fulton and extending north along the Purchase Parkway to Interstate Highway 24, east along I-24 to U.S. Highway 641, north along U.S. 641 to U.S. 60, northeast

along U.S. 60 to the Henderson County line, then south, east, and northerly along the Henderson County line to the Indiana State line.

Ballard Reporting Area: That area encompassed by a line beginning at the northwest city limits of Wickliffe in Ballard County and extending westward to the middle of the Mississippi River, north along the Mississippi River and along the low-water mark of the Ohio River on the Illinois shore to the Ballard-McCracken County line, south along the county line to Kentucky Highway 358, south along Kentucky 358 to U.S. Highway 60 at LaCenter, then southwest along U.S. 60 to the northeast city limits of Wickliffe.

Henderson-Union Reporting Area: Henderson County and that portion of Union County within the Western Zone.

Pennyroyal/Coalfield Zone: Butler, Daviess, Ohio, Simpson, and Warren Counties and all counties lying west to the boundary of the Western Goose Zone.

Michigan

(a) North Zone – Same as North duck zone.

(b) Middle Zone – Same as Middle duck zone.

(c) South Zone – Same as South duck zone.

Tuscola/Huron Goose Management Unit (GMU): Those portions of Tuscola and Huron Counties bounded on the south by Michigan Highway 138 and Bay City Road, on the east by Colwood and Bay Port Roads, on the north by Kilmanagh Road and a line extending directly west off the end of Kilmanagh Road into Saginaw Bay to the west boundary, and on the west by the Tuscola-Bay County line and a line extending directly north off the end of the Tuscola-Bay County line into Saginaw Bay to the north boundary.

Allegan County GMU: That area encompassed by a line beginning at the junction of 136th Avenue and Interstate Highway 196 in Lake Town Township and extending easterly along 136th Avenue to Michigan Highway 40, southerly along Michigan 40 through the city of Allegan to 108th Avenue in Trowbridge Township, westerly along 108th Avenue to 46th Street, northerly along 46th Street to 109th Avenue, westerly along 109th Avenue to I-196 in Casco Township, then northerly along I-196 to the point of beginning.

Saginaw County GMU: That portion of Saginaw County bounded by Michigan Highway 46 on the north; Michigan 52 on the west; Michigan 57 on the south; and Michigan 13 on the east.

Muskegon Wastewater GMU: That portion of Muskegon County within the

boundaries of the Muskegon County wastewater system, east of the Muskegon State Game Area, in sections 5, 6, 7, 8, 17, 18, 19, 20, 29, 30, and 32, T10N R14W, and sections 1, 2, 10, 11, 12, 13, 14, 24, and 25, T10N R15W, as posted.

Special Canada Goose Seasons

Southern Michigan Late Season Canada Goose Zone: Same as the South Duck Zone excluding Tuscola/Huron Goose Management Unit (GMU), Allegan County GMU, Saginaw County GMU, and Muskegon Wastewater GMU.

Minnesota

West Zone: That portion of the State encompassed by a line beginning at the junction of State Trunk Highway (STH) 60 and the Iowa State line, 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 State line.

West Central Zone: That area encompassed by a line beginning at the intersection of State Trunk Highway (STH) 29 and U.S. Highway 212 and extending west along U.S. 212 to U.S. 59, south along U.S. 59 to STH 67, west along STH 67 to U.S. 75, north along U.S. 75 to County State Aid Highway (CSAH) 30 in Lac qui Parle County, west along CSAH 30 to the western boundary of the State, north along the western boundary of the State to a point due south of the intersection of STH 7 and CSAH 7 in Big Stone County, and continuing due north to said intersection, then north along CSAH 7 to CSAH 6 in Big Stone County, east along CSAH 6 to CSAH 21 in Big Stone County, south along CSAH 21 to CSAH 10 in Big Stone County, east along CSAH 10 to CSAH 22 in Swift County, east along CSAH 22 to CSAH 5 in Swift County, south along CSAH 5 to U.S. 12, east along U.S. 12 to CSAH 17 in Swift County, south along CSAH 17 to CSAH 9 in Chippewa County, south along CSAH 9 to STH 40, east along STH 40 to STH 29, then south along STH 29 to the point of beginning.

Special Canada Goose Seasons

Southeast 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.

Missouri

Same zones as for ducks but in addition:

Middle Zone

Southeast Zone: That portion of the State encompassed by a line beginning at the intersection of Missouri Highway (MO) 34 and Interstate 55 and extending south along I-55 to U.S. Highway 62, west along U.S. 62 to MO 53, north along MO 53 to MO 51, north along MO 51 to U.S. 60, west along U.S. 60 to MO 21, north along MO 21 to MO 72, east along MO 72 to MO 34, then east along MO 34 to I-55.

Ohio

Same zones as for ducks but in addition:

North Zone

Lake Erie Zone: That portion of the North Duck Zone encompassed by and north and east of a line beginning in Lucas County at the Michigan State line on I-75, and extending south along I-75 to I-280, south along I-280 to I-80, and east along I-80 to the Pennsylvania State line in Trumbull County.

Tennessee

Southwest Zone: That portion of the State south of State Highways 20 and 104, and west of U.S. Highways 45 and 45W.

Northwest Zone: Lake, Obion, and Weakley Counties and those portions of Gibson and Dyer Counties not included in the Southwest Tennessee Zone.

Kentucky/Barkley Lakes Zone: That portion of the State bounded on the west by the eastern boundaries of the Northwest and Southwest Zones and on the east by State Highway 13 from the Alabama State line to Clarksville and U.S. Highway 79 from Clarksville to the Kentucky State line.

Wisconsin

Same zones as for ducks but in addition:

Horicon Zone: That area encompassed by a line beginning at the intersection of State Highway 21 and the Fox River in Winnebago County and extending westerly along State 21 to the west boundary of Winnebago County, southerly along the west boundary of Winnebago County to the north boundary of Green Lake County, westerly along the north boundaries of Green Lake and Marquette Counties to State 22, southerly along State 22 to State 33, westerly along State 33 to Interstate Highway 39, southerly along

Interstate Highway 39 to Interstate Highway 90/94, southerly along I-90/94 to State 60, easterly along State 60 to State 83, northerly along State 83 to State 175, northerly along State 175 to State 33, easterly along State 33 to U.S. Highway 45, northerly along U.S. 45 to the east shore of the Fond Du Lac River, northerly along the east shore of the Fond Du Lac River to Lake Winnebago, northerly along the western shoreline of Lake Winnebago to the Fox River, then westerly along the Fox River to State 21.

Collins Zone: That area encompassed by a line beginning at the intersection of Hilltop Road and Collins Marsh Road in Manitowoc County and extending westerly along Hilltop Road to Humpty Dumpty Road, southerly along Humpty Dumpty Road to Poplar Grove Road, easterly along Poplar Grove Road to Rockea Road, southerly along Rockea Road to County Highway JJ, southeasterly along County JJ to Collins Road, southerly along Collins Road to the Manitowoc River, southeasterly along the Manitowoc River to Quarry Road, northerly along Quarry Road to Einberger Road, northerly along Einberger Road to Moschel Road, westerly along Moschel Road to Collins Marsh Road, northerly along Collins Marsh Road to Hilltop Road.

Exterior Zone: That portion of the State not included in the Horicon or Collins Zones.

Mississippi River Subzone: That area encompassed by a line beginning at the intersection of the Burlington Northern & Santa Fe Railway and the Illinois State line in Grant County and extending northerly along the Burlington Northern & Santa Fe Railway to the city limit of Prescott in Pierce County, then west along the Prescott city limit to the Minnesota State line.

Rock Prairie Subzone: That area encompassed by a line beginning at the intersection of the Illinois State line and Interstate Highway 90 and extending north along I-90 to County Highway A, east along County A to U.S. Highway 12, southeast along U.S. 12 to State Highway 50, west along State 50 to State 120, then south along 120 to the Illinois State line.

Brown County Subzone: That area encompassed by a line beginning at the intersection of the Fox River with Green Bay in Brown County and extending southerly along the Fox River to State Highway 29, northwesterly along State 29 to the Brown County line, south, east, and north along the Brown County line to Green Bay, due west to the midpoint of the Green Bay Ship Channel, then southwesterly along the Green Bay Ship Channel to the Fox River.

Central Flyway

Colorado (Central Flyway Portion)

Northern Front Range Area: All areas in Boulder, Larimer and Weld Counties from the Continental Divide east along the Wyoming border to U.S. 85, south on U.S. 85 to the Adams County line, and all lands in Adams, Arapahoe, Broomfield, Clear Creek, Denver, Douglas, Gilpin, and Jefferson Counties.

North Park Area: Jackson County.

South Park and San Luis Valley Area: All of Alamosa, Chaffee, Conejos, Costilla, Custer, Fremont, Lake, Park, Rio Grande and Teller Counties, and those portions of Saguache, Mineral and Hinsdale Counties east of the Continental Divide.

Remainder: Remainder of the Central Flyway portion of Colorado.

Eastern Colorado Late Light Goose Area: That portion of the State east of Interstate Highway 25.

Nebraska

Dark Geese

Niobrara Unit: That area contained within and bounded by the intersection of the South Dakota State line and the Cherry County line, south along the Cherry County line to the Niobrara River, east to the Norden Road, south on the Norden Road to U.S. Hwy 20, east along U.S. Hwy 20 to NE Hwy 137, north along NE Hwy 137 to the Niobrara River, east along the Niobrara River to the Boyd County line, north along the Boyd County line to the South Dakota State line. Where the Niobrara River forms the boundary, both banks of the river are included in the Niobrara Unit.

East Unit: That area north and east of U.S. 281 at the Kansas-Nebraska State line, north to Giltner Road (near Doniphan), east to NE 14, north to NE 66, east to U.S. 81, north to NE 22, west to NE 14 north to NE 91, east to U.S. 275, south to U.S. 77, south to NE 91, east to U.S. 30, east to Nebraska-Iowa State line.

Platte River Unit: That area south and west of U.S. 281 at the Kansas-Nebraska State line, north to Giltner Road (near Doniphan), east to NE 14, north to NE 66, east to U.S. 81, north to NE 22, west to NE 14 north to NE 91, west along NE 91 to NE 11, north to the Holt County line, west along the northern border of Garfield, Loup, Blaine and Thomas Counties to the Hooker County line, south along the Thomas-Hooker County lines to the McPherson County line, east along the south border of Thomas County to the western line of Custer County, south along the Custer-Logan County line to NE 92, west to U.S. 83, north to NE 92, west to NE 61, north along NE 61 to NE

2, west along NE 2 to the corner formed by Garden-Grant-Sheridan Counties, west along the north border of Garden, Morrill, and Scotts Bluff Counties to the intersection of the Interstate Canal, west to Wyoming State line.

North-Central Unit: The remainder of the State.

Light Geese

Rainwater Basin Light Goose Area (West): The area bounded by the junction of U.S. 283 and U.S. 30 at Lexington, east on U.S. 30 to U.S. 281, south on U.S. 281 to NE 4, west on NE 4 to U.S. 34, continue west on U.S. 34 to U.S. 283, then north on U.S. 283 to the beginning.

Rainwater Basin Light Goose Area (East): The area bounded by the junction of U.S. 281 and U.S. 30 at Grand Island, north and east on U.S. 30 to NE 14, south to NE 66, east to US 81, north to NE 92, east on NE 92 to NE 15, south on NE 15 to NE 4, west on NE 4 to U.S. 281, north on U.S. 281 to the beginning.

Remainder of State: The remainder portion of Nebraska.

New Mexico (Central Flyway Portion)

Dark Geese

Middle Rio Grande Valley Unit: Sierra, Socorro, and Valencia Counties.

Remainder: The remainder of the Central Flyway portion of New Mexico.

North Dakota

Missouri River Canada Goose Zone: The area within and bounded by a line starting where ND Hwy 6 crosses the South Dakota border; thence north on ND Hwy 6 to I-94; thence west on I-94 to ND Hwy 49; thence north on ND Hwy 49 to ND Hwy 200; thence north on Mercer County Rd. 21 to the section line between sections 8 and 9 (T146N-R87W); thence north on that section line to the southern shoreline to Lake Sakakawea; thence east along the southern shoreline (including Mallard Island) of Lake Sakakawea to US Hwy 83; thence south on US Hwy 83 to ND Hwy 200; thence east on ND Hwy 200 to ND Hwy 41; thence south on ND Hwy 41 to US Hwy 83; thence south on US Hwy 83 to I-94; thence east on I-94 to US Hwy 83; thence south on US Hwy 83 to the South Dakota border; thence west along the South Dakota border to ND Hwy 6.

Rest of State: Remainder of North Dakota.

South Dakota

Canada Geese

Unit 1: Remainder of South Dakota.

Unit 2: Bon Homme, Brule, Buffalo, Charles Mix, Custer east of SD Hwy 79 and south of French Creek, Dewey south of US Hwy 212, Fall River east of SD

Hwy 71 and US Hwy 385, Gregory, Hughes, Hyde south of US Hwy 14, Lyman, Perkins, Potter west of US Hwy 83, Stanley, and Sully Counties.

Unit 3: Bennett County.

Texas

Northeast Goose Zone: That portion of Texas lying east and north of a line beginning at the Texas–Oklahoma border at U.S. 81, then continuing south to Bowie and then southeasterly along U.S. 81 and U.S. 287 to I–35W and I–35 to the juncture with I–10 in San Antonio, then east on I–10 to the Texas–Louisiana border.

Southeast Goose Zone: That portion of Texas lying east and south of a line beginning at the International Toll Bridge at Laredo, then continuing north following I–35 to the juncture with I–10 in San Antonio, then easterly along I–10 to the Texas–Louisiana border.

West Goose Zone: The remainder of the State.

Wyoming (Central Flyway Portion)

Dark Geese

Area 1: Converse, Hot Springs, Natrona, and Washakie Counties, and the portion of Park County east of the Shoshone National Forest boundary and south of a line beginning where the Shoshone National Forest boundary crosses Park County Road 8VC, easterly along said road to Park County Road 1AB, easterly along said road to Wyoming Highway 120, northerly along said highway to Wyoming Highway 294, southeasterly along said highway to Lane 9, easterly along said lane to the town of Powel and Wyoming Highway 14A, easterly along said highway to the Park County and Big Horn County Line.

Area 2: Albany, Campbell, Crook, Johnson, Laramie, Niobrara, Sheridan, and Weston Counties, and that portion of Carbon County east of the Continental Divide; that portion of Park County west of the Shoshone National Forest boundary, and that portion of Park County north of a line beginning where the Shoshone National Forest boundary crosses Park County Road 8VC, easterly along said road to Park County Road 1AB, easterly along said road to Wyoming Highway 120, northerly along said highway to Wyoming Highway 294, southeasterly along said highway to Lane 9, easterly along said lane to the town of Powel and Wyoming Highway 14A, easterly along said highway to the Park County and Big Horn County Line.

Area 3: Goshen and Platte Counties.

Area 4: Big Horn and Fremont Counties.

Pacific Flyway

Arizona

North Zone: Game Management Units 1-5, those portions of Game Management Units 6 and 8 within Coconino County, and Game Management Units 7, 9, and 12A.

South Zone: Those portions of Game Management Units 6 and 8 in Yavapai County, and Game Management Units 10 and 12B-45.

California

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 State line 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.

Imperial County Special Management Area: The area bounded by a line beginning at Highway 86 and the Navy Test Base Road; south on Highway 86 to the town of Westmoreland; continue through the town of Westmoreland to Route S26; east on Route S26 to Highway 115; north on Highway 115 to Weist Rd.; north on Weist Rd. to Flowing Wells Rd.; northeast on Flowing Wells Rd. to the Coachella Canal; northwest on the Coachella Canal to Drop 18; a straight line from Drop 18 to Frink Rd.; south on Frink Rd. to Highway 111; north on Highway 111 to Niland Marina Rd.; southwest on Niland Marina Rd. to the old Imperial County boat ramp and the water line of the Salton Sea; from the water line of the Salton Sea, a straight line across the Salton Sea to the Salinity Control Research Facility and the Navy Test Base Road; southwest on the Navy Test Base Road to the point of beginning.

Balance-of-the-State Zone: The remainder of California not included in the Northeastern, Southern, and the Colorado River Zones.

North Coast Special Management Area: The Counties of Del Norte and Humboldt.

Sacramento Valley Special Management Area: That area bounded by a line beginning at Willows south on I-5 to Hahn Road; easterly on Hahn Road and the Grimes–Arbuckle Road to Grimes; northerly on CA 45 to the junction with CA 162; northerly on CA 45/162 to Glenn; and westerly on CA 162 to the point of beginning in Willows.

Colorado (Pacific Flyway Portion)

West Central Area: Archuleta, Delta, Dolores, Gunnison, LaPlata, Montezuma, Montrose, Ouray, San Juan, and San Miguel Counties and those portions of Hinsdale, Mineral, and Saguache Counties west of the Continental Divide.

State Area: The remainder of the Pacific–Flyway Portion of Colorado.

Idaho

Zone 1: Adams, Benewah, Bonner, Boundary, Clearwater, Idaho, Kootenai, Latah, Lewis, Nez Perce, Shoshone, and Valley Counties.

Zone 2: The Counties of Ada; Boise; Canyon; those portions of Elmore north

and east of I-84, and south and west of I-84, west of ID 51, except the Camas Creek drainage; Gem; Owyhee west of ID 51; Payette; and Washington.

Zone 3: The Counties of Cassia except the Minidoka National Wildlife Refuge; those portions of Elmore south of I-84 east of ID 51, and within the Camas Creek drainage; Gooding; Jerome; Lincoln; Minidoka; Owyhee east of ID 51; and Twin Falls.

Zone 4: The Counties of Bear Lake; Bingham within the Blackfoot Reservoir drainage; Blaine; Bonneville, Butte; Camas; Caribou except the Fort Hall Indian Reservation; Cassia within the Minidoka National Wildlife Refuge; Clark; Custer; Franklin; Fremont; Jefferson; Lemhi; Madison; Oneida; and Teton.

Zone 5: All lands and waters within the Fort Hall Indian Reservation, including private inholdings; Bannock County; Bingham County, except that portion within the Blackfoot Reservoir drainage; and Power County.

Montana (Pacific Flyway Portion)

East of the Divide Zone: The Pacific Flyway portion of the State located east of the Continental Divide.

West of the Divide Zone: The remainder of the Pacific Flyway portion of Montana.

Nevada

Lincoln Clark County Zone: All of Lincoln and Clark Counties.

Remainder-of-the-State Zone: The remainder of Nevada.

New Mexico (Pacific Flyway Portion)

North Zone: The Pacific Flyway portion of New Mexico located north of I-40.

South Zone: The Pacific Flyway portion of New Mexico located south of I-40.

Oregon

Southwest Zone: Those portions of Douglas, Coos, and Curry Counties east of Highway 101, and Josephine and Jackson Counties.

South Coast Zone: Those portions of Douglas, Coos, and Curry Counties west of Highway 101.

Northwest Special Permit Zone: That portion of western Oregon west and north of a line running south from the Columbia River in Portland along I-5 to OR 22 at Salem; then east on OR 22 to the Stayton Cutoff; then south on the Stayton Cutoff to Stayton and due south to the Santiam River; then west along the north shore of the Santiam River to I-5; then south on I-5 to OR 126 at Eugene; then west on OR 126 to Greenhill Road; then south on Greenhill Road to Crow Road; then west on Crow Road to Territorial Hwy; then west on Territorial Hwy to OR 126; then west on OR 126 to Milepost 19; then north to the

intersection of the Benton and Lincoln County line; then north along the western boundary of Benton and Polk Counties to the southern boundary of Tillamook County; then west along the Tillamook County boundary to the Pacific Coast.

Lower Columbia/N. Willamette Valley Management Area: Those portions of Clatsop, Columbia, Multnomah, and Washington Counties within the Northwest Special Permit Zone.

Tillamook County Management Area: All of Tillamook County is open to goose hunting except for the following area—beginning in Cloverdale at Hwy 101, west on Old Woods Rd to Sand Lake Rd at Woods, north on Sand Lake Rd to the intersection with McPhillips Dr, due west (~200 yards) from the intersection to the Pacific coastline, south on the Pacific coastline to Neskowin Creek, east along the north shores of Neskowin Creeks and then Hawk Creeks to Salem Ave, east on Salem Ave in Neskowin to Hawk Ave, east on Hawk Ave to Hwy 101, north on Hwy 101 at Cloverdale, to the point of beginning.

Northwest Zone: Those portions of Clackamas, Lane, Linn, Marion, Multnomah, and Washington Counties outside of the Northwest Special Permit Zone and all of Lincoln County.

Eastern Zone: Hood River, Wasco, Sherman, Gilliam, Morrow, Umatilla, Deschutes, Jefferson, Crook, Wheeler, Grant, Baker, Union, and Walla Walla Counties.

Harney, Lake, and Malheur County Zone: All of Harney, Lake, and Malheur Counties.

Klamath County Zone: All of Klamath County.

Utah

Northern Utah Zone: All of Cache and Rich Counties, and that portion of Box Elder County beginning at I-15 and the Weber-Box Elder County line; east and north along this line to the Weber-Cache County line; east along this line to the Cache-Rich County line; east and south along the Rich County line to the Utah-Wyoming State line; north along this line to the Utah-Idaho State line; west on this line to Stone, Idaho-Snowville, Utah road; southwest on this road to Locomotive Springs Wildlife Management Area; east on the county road, past Monument Point and across Salt Wells Flat, to the intersection with Promontory Road; south on Promontory Road to a point directly west of the northwest corner of the Bear River Migratory Bird Refuge boundary; east along an imaginary line to the northwest corner of the Refuge boundary; south and east along the Refuge boundary to the southeast corner of the boundary;

northeast along the boundary to the Perry access road; east on the Perry access road to I-15; south on I-15 to the Weber-Box Elder County line.

Remainder-of-the-State Zone: The remainder of Utah.

Washington

Area 1: Skagit, Island, and Snohomish Counties.

Area 2A (SW Quota Zone): Clark County, except portions south of the Washougal River; Cowlitz County; and Wahkiakum County.

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.

Brant

Pacific Flyway

California

North Coast Zone: Del Norte, Humboldt and Mendocino Counties.

South Coast Zone: Balance of the State.

Washington

Puget Sound Zone: Skagit County.

Coastal Zone: Pacific County.

Swans

Central Flyway

South Dakota: Aurora, Beadle, Brookings, Brown, Brule, Buffalo, Campbell, Clark, Codington, Davison, Deuel, Day, Edmunds, Faulk, Grant, Hamlin, Hand, Hanson, Hughes, Hyde, Jerauld, Kingsbury, Lake, Marshall, McCook, McPherson, Miner, Minnehaha, Moody, Potter, Roberts, Sanborn, Spink, Sully, and Walworth Counties.

Pacific Flyway

Montana (Pacific Flyway Portion)

Open Area: Cascade, Chouteau, Hill, Liberty, and Toole Counties and those portions of Pondera and Teton Counties lying east of U.S. 287–89.

Nevada

Open Area: Churchill, Lyon, and Pershing Counties.

Utah

Open Area: Those portions of Box Elder, Weber, Davis, Salt Lake, and Toole Counties lying west of I-15, north of I-80, and south of a line beginning from the Forest Street exit to the Bear River National Wildlife Refuge

boundary; then north and west along the Bear River National Wildlife Refuge boundary to the farthest west boundary of the Refuge; then west along a line to Promontory Road; then north on

Promontory Road to the intersection of SR 83; then north on SR 83 to I-84; then north and west on I-84 to State Hwy 30; then west on State Hwy 30 to the

Nevada-Utah State line; then south on the Nevada-Utah State line to I-80.

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H.R. 2245/P.L. 111-44

New Frontier Congressional Gold Medal Act (Aug. 7, 2009; 123 Stat. 1966)

H.R. 3114/P.L. 111-45

To authorize the Director of the United States Patent and Trademark Office to use funds made available under the Trademark Act of 1946 for

patent operations in order to avoid furloughs and reductions-in-force, and for other purposes. (Aug. 7, 2009; 123 Stat. 1968)

H.R. 3357/P.L. 111-46

To restore sums to the Highway Trust Fund and for other purposes. (Aug. 7, 2009; 123 Stat. 1970)

H.R. 3435/P.L. 111-47

Making supplemental appropriations for fiscal year 2009 for the Consumer Assistance to Recycle and Save Program. (Aug. 7, 2009; 123 Stat. 1972)

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