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Federal Register

10–24–01 Wednesday
Vol. 66 No. 206 Oct. 24, 2001
Pages 53711–53942

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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 HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 99F–2533]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Change in Specifications for Gum or Wood Rosin Derivatives in Chewing Gum Base; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of July 23, 2001 (66 FR 38152). The document amended the food additive regulations in § 172.615 (21 CFR 172.615) to provide for their safe use as plasticizing materials (softeners) in chewing gum base. A word in the specification for glycerol ester of gum rosin was inadvertently misspelled. This document corrects that error.

EFFECTIVE DATE: July 23, 2001.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, Washington, DC 20204–0001, 202–418–3072.

SUPPLEMENTARY INFORMATION: In the FR Doc. 01–18221, appearing in the **Federal Register** of Monday, July 23, 2001, the following correction is made:

§ 172.615 [Corrected]

On page 38153, in § 172.615 *Chewing gum base*, in paragraph (a), in the table entitled ''Plasticizing Materials (Softeners)'' in the entry for ''Glycerol ester of gum rosin,'' the word ''striping'' is corrected to read ''stripping.''

Dated: October 15, 2001.

L. Robert Lake,

Director of Regulations Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–26708 Filed 10–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 3811]

Visas—Visa Classification Symbols: Corrections

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Correcting amendments.

SUMMARY: The Department of State (the Department) is publishing this document to correct an error in a final rule published in the **Federal Register** [66 FR 32740] on June 18, 2001. The Department is also taking this opportunity to include the dependents of the SN categories to the N8 and N9 categories in accordance with the provisions of Pub. L. 105–277.

DATES: This rule takes effect on October 24, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Chavez, Legislation and Regulations Division, Visa Office, (202) 663–1206.

SUPPLEMENTARY INFORMATION: On June 18, 2001, the Department amended section 41.12 of part 22 of the Code of Federal Regulations by adding the new nonimmigrant ''T'' classifications and the new nonimmigrant U classifications. The new T1 classification symbol would be used to classify victims of a severe form of trafficking in persons and the T2 classification for the spouse, child and parent of the T1. The rule also created two new U visa classification symbols; the U1 classification symbol for victims of criminal activity and the U2 for the spouse, child or parent of a U1.

The Immigration and Naturalization Service (INS), however, has decided there should be separate visa classifications for the spouses, the children and the parents of the T1 and U1 principals. This rule corrects section 41.12 by revising the T2 and U2 classification symbols and creating additional classification symbols T3, T4, U3, and U4.

This rule also amends the N8 and N9 categories to include dependents of the SN categories (NATO special immigrants) to comply with the provisions of Pub. L. 105–277. This rule corrects section 41.12 to read as follows:

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports, and Visas.

Accordingly, 22 CFR part 41 is corrected by making the following correcting amendments:

PART 41—VISAS: DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681 *et. seq.*

§ 41.12 (Amended)

2. In the table in § 41.12, revise the entries for N8 and N9, correct the entries for T2 and U2 and add the new visa classification symbols T3 and T4 and U3 and U4 to read as follows:

NONIMMIGRANTS

Symbol and class	Section of law
* * * * *	
N8 Parent of an Alien Classified SK3 or SN3.	101(a)(15)(N)(i)
N9 Child of N8 or of an SK1, SK2, SK4, SN1, SN2 or SN4.	101(a)(15)(N)(ii)
* * * * *	
T2 Spouse of T1	101(a)(15)(T)(ii)
T3 Child of T1	101(a)(15)(T)(ii)
T4 Parent of T1	101(a)(15)(T)(ii)
* * * * *	
U2 Spouse of U1	101(a)(15)(U)(ii)
U3 Child of U1	101(a)(15)(U)(ii)
U4 Parent of U1	101(a)(15)(U)(ii)
* * * * *	

Dated: October 2, 2001.

Mary A. Ryan,

Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 01–26772 Filed 10–23–01; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD05–01–066]

RIN 2115–AE84

Regulated Navigation Area; Chesapeake Bay Entrance and Hampton Roads, VA and Adjacent Waters

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Commander, Fifth Coast Guard District is adding vessel speed limits, for certain vessels operating in the vicinity of Naval Station Norfolk, to the existing regulated navigation area for the Chesapeake Bay entrance and Hampton Roads, VA and adjacent waters. This temporary rule is necessary to ensure the safety and security of naval vessels that are moored at Naval Station Norfolk. The temporary rule will require all vessels of 300 gross tons (GT) and greater to reduce speed to eight knots (as over ground) in the vicinity of Naval Station Norfolk, in order to improve security measures and reduce the potential threat to Naval Station Norfolk security that may be posed by these vessels.

DATES: This temporary final rule is effective from October 24, 2001 to June 15, 2002.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–01–066 and are available for inspection or copying at USCG Marine Safety Office Hampton Roads, 200 Granby Street, Norfolk, Virginia 23510 between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Monica Acosta, USCG, project officer, USCG Marine Safety Office Hampton Roads, telephone number (757) 441–3453.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this rulemaking, and the rule takes effective immediately. The changes made by this temporary rule are specifically authorized under 33 U.S.C. 1223(a)(4) and 1226 as a response to the terrorist acts that occurred on September 11, 2001, and to prevent similar occurrences. In response to an October 9, 2001 request by the Navy, immediate action is necessary to ensure the safety and security of naval vessels moored at Naval Station Norfolk during large merchant vessel transits of the Elizabeth River. Due to their large size and substantial momentum while underway, and considering the close proximity of the shipping channel to Naval Station Norfolk, merchant vessels greater than 300 GT pose a potential threat to Naval Station Norfolk's security. Imposing this speed limit will help provide better security alongside Naval Station Norfolk as well as reduce the potential threat. Therefore, delay in implementing these changes is contrary to the public interest, and the Coast Guard finds under 5 U.S.C. 553(b)(B) and (d)(3) that notice and comment rulemaking and advance publication are not required.

Background and Purpose

The Commander Naval Station Norfolk requested this rule to reduce the potential threat to national security that may be posed by vessels of 300 gross tons or greater as they pass the naval station. This temporary modification of the RNA is necessary to ensure the safety and security of naval vessels in the vicinity of Naval Station Norfolk. The U.S. Navy or other federal agencies may assist the U.S. Coast Guard in the enforcement of this rule.

No vessel of 300 gross tons or greater may proceed at a speed over eight knots between Elizabeth River Channel Lighted Gong Buoy 5 (LL 9470) of Norfolk Harbor Reach and gated Elizabeth River Channel Lighted Buoys 17 (LL 9595) and 18 (LL 9600) of Craney Island Reach. All vessels less than 300 gross tons are exempt from this rule, as well as all Public vessels as defined in 33 U.S.C. 1321, which states that a public vessel means a vessel owned or bareboat-chartered and operated by the United States, or by a State or political subdivision thereof, or by a foreign nation, except when such vessel is engaged in commerce.

Regulatory Evaluation

This temporary 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. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040; February 26, l979). This temporary final rule will be in effect for less than nine months. During this period, it is estimated to affect 3988 vessel transits. However, the speed limit restrictions are only in effect for less than four miles, and typical vessel speed is 10 knots, so the actual delay for each vessel will be less than 6 minutes in each direction. Therefore, this delay caused by the two-knot reduction in speed will be minimal.

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 temporary rule will not have a significant economic impact on a substantial number of small entities. This rule will only affect the following entities, some of which may be small entities: The owners or operators of vessels 300 gross tons or greater intending to transit Norfolk Harbor Reach at speeds greater than eight knots. This rule will only affect a limited portion of a vessel's total transit, and for only a length of less than four miles. Deep-draft vessels typically transit this area at approximately 10 knots, and therefore the eight-knot speed limit will not cause significant delays. The actual delay for each vessel is less than 6 min. in each direction and the impact on small entities should be minimal. Additionally, we believe that very few small entities operate vessels of greater than 300 gross tons on a regular basis. Further, the rule is only in effect for nine months.

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

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they 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).

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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this temporary rule and concluded that under figure 2–1, paragraph (34)(g) of Commandant Instruction M16475.lC, this temporary rule is categorically excluded from further environmental documentation. This temporary rule seeks to modify a well-established Regulated Navigation Area, and will be in effect for less than nine months. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C 1231; 50 U.S.C 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. From October 24, 2001 until June 15, 2002, in § 165.501, add new paragraph (d)(14) to read as follows:

§ 165.501 Chesapeake Bay entrance and Hampton Roads, Va. and adjacent waters—regulated navigation area.

* * * * *

(d) * * *

(14) Speed restrictions on Norfolk Harbor Reach. Vessels of 300 gross tons or more may not proceed at a speed over eight knots between the Elizabeth River Channel Lighted Gong Buoy 5 (LL 9470) of Norfolk Harbor Reach (northwest of Sewells Point) at approximately 36°58′00″ N, 76°20′00″ W and gated Elizabeth River Channel Lighted Buoys 17 (LL 9595) and 18 (LL 9600) of Craney Island Reach (southwest of Norfolk International Terminal) at approximately 36°54′17″ N, 76°20′11″ W. All vessels less than 300 gross tons are exempt from this rule. All coordinates reference Datum NAD 1983. This speed restriction does not apply to Public vessels as defined in 33 U.S.C. 1321(a)(4). The U.S. Navy or other Federal agencies may assist the U.S. Coast Guard in the enforcement of this paragraph.

* * * * *

Dated: October 10, 2001.

T.W. Allen,

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

[FR Doc. 01–26817 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Los Angeles-Long Beach 01–008]

RIN 2115–AA97

Security Zones; Los Angeles Harbor, Los Angeles, CA and Avila Beach, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing three temporary security zones—one in the waters surrounding the Coast Guard Base-ISC San Pedro at Reservation Point in the Los Angeles Harbor, the second one in the waters surrounding the Los Angeles Cruise Ship Terminal in the Los Angeles Harbor and the third zone is in the waters adjacent to the Diablo Canyon Nuclear Power Plant in Avila Beach, CA. These actions are necessary to ensure public safety and prevent sabotage or terrorist acts against the public and commercial structures and individuals near or in these structures. These security zones will prohibit all persons and vessels from entering,

transiting through or anchoring within the security zones unless authorized by the Captain of the Port (COTP), or his designated representative.

DATES: This rule is effective from 4 p.m. (PDT) on September 28, 2001 to 3:59 p.m. (PDT) March 29, 2002.

ADDRESSES: Any comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket COTP Los Angeles-Long Beach 01–008, and are available for inspection or copying at U.S. Coast Guard Marine Safety Office/Group Los Angeles-Long Beach, 1001 S. Seaside Avenue, Bldg 20, San Pedro, California, 90731, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: BM1 George Kirk, Waterways Management Division, Marine Safety Office/Group Los Angeles-Long Beach, at (310) 732–2020.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. In keeping with the requirements of 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. In keeping with the requirements of 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**.

On September 11, 2001, two commercial aircraft were hijacked from Logan Airport in Boston, Massachusetts and flown into the World Trade Center in New York, New York inflicting catastrophic human casualties and property damage. A similar attack was conducted on the Pentagon in Arlington, Virginia on the same day. National security officials warn that future terrorist attacks against civilian targets may be anticipated. A heightened level of security has been established concerning all vessels transiting in the Los Angeles Harbor and Diablo Canyon Nuclear Power Plant areas. These security zones are needed to protect the United States and more specifically the people, ports, waterways, and properties of the Los Angeles Harbor and Diablo Canyon Nuclear Power Plant areas.

The delay inherent in the NPRM process, and any delay in the effective date of this rule, is contrary to the public interest insofar as it may render individuals and facilities within and adjacent to the Coast Guard Base-ISC San Pedro, Los Angeles Cruise Ship Terminal and the Diablo Canyon Nuclear Power Plant vulnerable to subversive activity, sabotage or terrorist attack. The measures contemplated by the rule are intended to prevent future terrorist attacks against individuals and facilities within or adjacent to these Los Angeles Harbor and Diablo Canyon Nuclear Power Plant area facilities. Immediate action is required to accomplish these objectives. Any delay in the effective date of this rule is impracticable and contrary to the public interest.

Background and Purpose

On September 11, 2001, terrorists launched attacks on civilian and military targets within the United States killing large numbers of people and damaging properties of national significance. Vessels operating near these installations within Los Angeles Harbor and the Diablo Canyon Nuclear Power Plant present possible platforms from which individuals may gain unauthorized access to these installations, or launch terrorist attacks upon the waterfront structures and adjacent population centers.

As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress amended The Ports and Waterways Safety Act (PWSA) to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. 33 U.S.C. 1226. The terrorist acts against the United States on September 11, 2001 have increased the need for safety and security measures on U.S. ports and waterways. In response to these terrorist acts, and in order to prevent similar occurrences, the Coast Guard is establishing three temporary security zones in the navigable waters of the United States within Los Angeles Harbor and the navigable waters of the United States adjacent to the Diablo Canyon Nuclear Power Plant.

These temporary security zones are necessary to provide for the safety and security of the United States of America and the people, ports, waterways and properties within the Los Angeles Harbor and Diablo Canyon Nuclear Power Plant area. These temporary security zones, prohibiting all vessel traffic from entering, transiting or anchoring within the above described areas, are necessary for the security and protection of the Coast Guard Base-ISC San Pedro, the Los Angeles Cruise Ship Terminal and any vessels moored there, as well as the Diablo Canyon Nuclear Power Plant. These zones will be enforced by Coast Guard patrol craft or any patrol craft enlisted by the COTP. Persons and vessels are prohibited from entering into these security zones unless authorized by the Captain of the Port or his designated representative. Each person and vessel in a security zone shall obey any direction or order of the COTP. The COTP may remove any person, vessel, article, or thing from a security zone. No person may board, or take or place any article or thing on board, any vessel in a security zone without the permission of the COTP.

Any violation of either security zone described herein, is punishable by, among other things, civil penalties (not to exceed $25,000 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment for not more than 12 years and a fine of not more than $250,000), in rem liability against the offending vessel, and license sanctions.

Regulatory Evaluation

This temporary final 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. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

Due to the recent terrorist actions against the United States the implementation of this security zone is necessary for the protection of the United States and its people. Because these security zones are established in an area of the Los Angeles Harbor that is seldom used by non-Coast Guard vessels and non-cruise ships; and in an area near the Diablo Canyon Nuclear Power Plant that is seldom used, the Coast Guard expects the economic impact of this rule to so minimal that full regulatory evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

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

These security zones will not have a significant impact on a substantial number of small entities because these security zones are only closing small portions of the navigable waters of the Los Angeles Main Channel. Vessels may still continue to transit other portions of the Los Angeles Main Channel. The portion of the security zone that affects the Diablo Canyon Nuclear Power Plant will also have an insignificant impact on small entities, because the area is infrequently transited. In addition, there are no small entities shoreward of any of these security zones, and no vessels other than Coast Guard vessels and/or cruise ships would normally transit these zones. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with § 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard offers to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact BM1 George Kirk, Waterways Management Division, Marine Safety Office/Group Los Angeles-Long Beach, at (310) 732–2020.

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).

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 and have determined that this rule 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (34), of Commandant Instruction M16475.lD, this rule, which establishes three security zones, is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying 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. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Add new § 165.T11–055 to read as follows:

§ 165.T11–055 Security Zones: Waters surrounding Coast Guard Base-ISC San Pedro, Reservation Point; Los Angeles Cruise Ship Terminal, Los Angeles Harbor; and Diablo Canyon Nuclear Power Plant, Avila Beach, CA.

(a) *Location.* (1) *Coast Guard Base-ISC San Pedro.* This security zone encompasses all waters of Los Angeles Harbor Main Channel within 100 yards of the western shore of Reservation Point including the small boat basin.

(2) *Los Angeles Cruise Ship Terminal.* This security zone encompasses all waters of Los Angeles Harbor Main Channel within 100 yards of the cruise ship terminal, including the entire basin at berth 93 to a point 100 yards east of the south end of berth 94.

(3) *Diablo Canyon Nuclear Power Plant.* This security zone encompasses waters within a one-nautical-mile radius of Diablo Canyon Nuclear Power Plant that is centered at the following coordinate: latitude 35°12′30″ N, longitude 120°51′30″ W.

(b) *Effective dates.* These security zones will be in effect from 4 p.m. (PDT) on September 28, 2001 to 3:59 p.m.

(PST) on March 29, 2002. If the need for these security zones ends before the scheduled termination time and date, the Captain of the Port will cease enforcement of the security zones and will also announce that fact via Broadcast Notice to Mariners and Local Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.33 of this part, no person or vessel may enter or remain in the security zone established by this temporary section, unless authorized by the Captain of the Port, or his designated representative. All other general regulations of § 165.33 of this part apply in the security zones established by this temporary section. Mariners requesting permission to transit through the security zones must request authorization to do so from the Captain of the Port, who may be contacted through Coast Guard Group Los Angeles—Long Beach on VHF–FM Channel 16.

Dated: October 2, 2001.

J.M. Holmes,

Captain, U.S. Coast Guard, Captain of the Port, Los Angeles-Long Beach, California.

[FR Doc. 01–26816 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301182; FRL–6805–8]

RIN 2070–AB78

Vinyl Acetate Polymers; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of vinyl acetate polymers; when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Uniqema submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of vinyl acetate polymers.

DATES: This regulation is effective October 24, 2001. Objections and requests for hearings, identified by docket control number OPP–301182, must be received by EPA on or before December 24, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301182 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8373 and e-mail address: *alston.treva@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/.* To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the'' **Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html,* a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301182. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 20, 2001, (66 FR 33081) (FRL–6785–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP 1E6294) by Uniqema, 900 Uniqema Blvd, New Castle, DE 19720. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c), and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of vinyl acetate polymers.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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....'' and specifies factors EPA is to consider in establishing an exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers that should present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b). The following exclusion criteria for identifying these low risk polymers are described in 40 CFR 723.250(d).

1. These vinyl acetate polymers, are not cationic polymers nor are they reasonably anticipated to become cationic polymers in a natural aquatic environment.
2. These polymers do contain as an integral part of their compostion the atomic elements carbon, hydrogen, and oxygen.
3. These polymers do not contain as an integral part of their composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).
4. These polymers are neither designed nor can they be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. These polymers are manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. These polymers are not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, vinyl acetate polymers, also meet as required the following exemption criteria specified in 40 CFR 723.250(e).

7. The polymer's number average MW of 1,200 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, vinyl acetate polymers meet all the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to theabove criteria, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to vinyl acetate polymers.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that vinyl acetate polymers could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of these vinyl acetate polymers is 1,200 daltons. Generally, polymers of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since vinyl acetate polymers conform to the criteria that identify low risk polymers, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.'' The Agency has not made any conclusions as to whether or not vinyl acetate polymers share a common mechanism of toxicity with any other chemicals. However, vinyl acetate polymers conform to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of vinyl acetate polymers.

VIII. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin safety will be safe for infants and children. Due to the expected low

toxicity of vinyl acetate polymers, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that vinyl acetate polymers are endocrine disruptors.

B. Existing Exemptions from a Tolerance

There are no existing tolerance exemptions for vinyl acetate polymers.

C. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for vinyl acetate polymers nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusion

Accordingly, EPA finds that exempting residues of vinyl acetate polymers from the requirement of a tolerance will be safe.

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301182 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 on or before December 24, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301182, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications '' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This 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: October 3, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. In § 180.1001 the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * * * * *	*	
Vinyl acetate polymer with none and/or one or more of the following monomers: ethylene, propylene, N-methyl acrylamide, acrylamide, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate, maleic anhydride, maleic acid, octyl acrylate, butyl acrylate, ethyl acrylate, methyl acrylate, acrylic acid, octyl methacrylate, butyl methacrylate, ethyl methacrylate, methyl methacrylate, methacrylic acid carboxyethyl acrylate, and diallyl phthalate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine and/or triethanolamine salts; the resulting polymer having a minium number average molecular weight (in amu) 1200.	.....	Components of films, binders, carriers, adhesives, or related adjuvants
* * * * * *	*	

* * * * *

(e) * * *

Inert ingredients	Limits	Uses
* * * * * *	*	
Vinyl acetate polymer with none and/or one or more of the following monomers: ethylene, propylene, N-methyl acrylamide, acrylamide, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate, maleic anhydride, maleic acid, octyl acrylate, butyl acrylate, ethyl acrylate, methyl acrylate, acrylic acid, octyl methacrylate, butyl methacrylate, ethyl methacrylate, methyl methacrylate, methacrylic acid carboxyethyl acrylate, and diallyl phthalate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine and/or triethanolamine salts; the resulting polymer having a minium number average molecular weight (in amu) of 1200.	.....	Components of films, binders, carriers, adhesives, or related adjuvants
* * * * * *	*	

[FR Doc. 01–26532 Filed 10–23–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301183; FRL–6805–6]

RIN 2070–AB78

Modified Acrylic Polymers; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of modified acrylic polymers; when used as inert ingredients in pesticide formulations in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Uniqema submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of modified acrylic polymers.

DATES: This regulation is effective October 24, 2001. Objections and requests for hearings, identified by docket control number OPP–301183, must be received by EPA on or before December 24, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control numberOPP–301183 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva C. Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8373 and e-mail address: alston.treva@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301183. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 20, 2001 (66 FR 33081) (FRL–6785–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 1E6293) by Uniqema, 900

Uniqema Blvd, New Castle, DE 19720. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c), (d), and/or (e) be amended by establishing an exemption from the requirement of a tolerance for residues of a group of modified acrylic polymers.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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. . .'' and specifies factors EPA is to consider in establishing an exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers that should present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b). The following exclusion criteria for identifying these low risk polymers are described in 40 CFR 723.250(d).

1. These modified acrylic polymers, are not cationic polymers nor are they reasonably anticipated to become cationic polymers in a natural aquatic environment.

2. These polymers do contain as an integral part of their compostion the atomic elements carbon, hydrogen, and oxygen.

3. These polymers do not contain as an integral part of their composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. These polymers are neither designed nor can they be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. These polymers are manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. These polymers are not water absorbing polymers with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer's number average MW of 1,200 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Additionally, the modified acrylic polymers, also meet as required the following exemption criteria specified in 40 CFR 723.250(e).

Thus, modified acrylic polymers meet all the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the above criteria, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to modified acrylic polymers.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that modified acrylic polymers could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of modified acrylic polymers is 1,200 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since modified acrylic polymers conform to the criteria that identify a low risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.'' The Agency has not made any conclusions as to whether or not modified acrylic polymers share a common mechanism of toxicity with any other chemicals. However, modified acrylic polymers conform to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of modified acrylic polymers.

VIII. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin safety will be safe for infants and children. Due to the expected low toxicity of modidfied acrylic polymers, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that modified acylic polymers is an endocrine disruptor.

B. Existing Exemptions from a Tolerance

There are no existing tolerance exemptions for modified acrylic polymers.

C. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for modified acrylic polymers nor have any Codex Maximum Residue Levels been established for any food crops at this time.

X. Conclusion

Accordingly, EPA finds that exempting residues of modified acrylic polymers from the requirement of a tolerance will be safe.

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301183 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 on or before December 24, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov,* or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301183, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue

of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This 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: October 3, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. In § 180.1001, the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * *	* * * *	
Acrylic polymers composed of one or more of the following monomers: Acrylic acid, methyl acrylate, ethyl acrylate, butyl acrylate, hydroxyethyl acrylate, hydroxypropyl acrylate, hydroxybutyl acrylate, carboxyethyl acrylate, methacrylic acid, methyl methacrylate, ethyl methacrylate, butyl methacrylate, isobutyl methacrylate, hydroxyethyl methacrylate, hydroxypropyl methacrylate, hydroxybutyl methacrylate, lauryl methacrylate, and stearyl methacrylate; with none and/or one or more of the following monomers: Acrylamide, *N*-methyl acrylamide, *N*-octylacrylamide, maleic anhydride, maleic acid, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine,and/or triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu) 1,200.	.....	Components of films, binders, carriers, adhesives, or related adjuvants
* * * *	* * *	

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(e) * * *

Inert ingredients	Limits	Uses
* * * *	* * *	
Acrylic polymers composed of one or more of the following monomers: Acrylic acid, methyl acrylate, ethyl acrylate, butyl acrylate, hydroxyethyl acrylate, hydroxypropyl acrylate, hydroxybutyl acrylate, carboxyethyl acrylate, methacrylic acid, methyl methacrylate, ethyl methacrylate, butyl methacrylate, isobutyl methacrylate, hydroxyethyl methacrylate, hydroxypropyl methacrylate, hydroxybutyl methacrylate, lauryl methacrylate, and stearyl methacrylate; with none and/or one or more of the following monomers: Acrylamide, *N*-methyl acrylamide, *N*-octylacrylamide, maleic anhydride, maleic acid, monoethyl maleate, dietyl maleate, monooctyl maleate, dioctyl maleate; and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine, and/or triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu) 1,200.	.....	Components of films, binders, carriers, adhesives, or related adjuvants
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[FR Doc. 01–26531 Filed 10–23–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 272

[FRL–7014–9]

Indiana: Incorporation by Reference of Approved State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Under the Resource Conservation and Recovery Act of 1976, as amended (RCRA), the EPA may grant States Final Authorization to operate their hazardous waste management programs in lieu of the Federal program. EPA uses part 272 of Title 40 Code of Federal Regulations (CFR) to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and regulations that are part of the authorized State program. The purpose of this action is to codify Indiana's authorized hazardous waste program in 40 CFR part 272. This rule incorporates by reference provisions of Indiana's hazardous waste statutes and regulations and clarifies which of these provisions are authorized and federally enforceable. Unless adverse written comments are received during the comment period, the EPA's decision to incorporate by reference Indiana's authorized hazardous waste program will take effect as provided.

DATES: This document will become effective December 24, 2001 without further notice, if EPA receives no adverse comment on this rule by November 23, 2001. Should the Agency receive such comments, it will withdraw this rule before its effective date by publishing a withdrawal in the **Federal Register**. The Director of the Federal Register approved the incorporation by reference of the Indiana statutes and regulations contained in this rule as of December 24, 2001.

ADDRESSES: Send written comments to Gary Westefer, Indiana Regulatory Specialist, U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7450.

FOR FURTHER INFORMATION CONTACT: Gary Westefer, Indiana Regulatory Specialist, U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7450.

SUPPLEMENTARY INFORMATION:

A. Background

Section 3006 of RCRA, 42 U.S.C. 6926 *et seq.*, allows the EPA to authorize State hazardous waste programs to operate in the State in lieu of the Federal hazardous waste program. EPA

provides notice of its authorization of State programs in 40 CFR part 272 and incorporates by reference therein the State statutes and regulations that are a part of the authorized State program under RCRA. This effort provides clearer notice to the public of the scope of the authorized programs. The incorporation by reference of State authorized programs in the CFR should substantially enhance the public's ability to discern the current status of the authorized State program and clarify the extent of Federal enforcement authority.

Effective August 23, 1989 (54 FR 34988), EPA incorporated by reference Indiana's then authorized hazardous waste program. The purpose of today's **Federal Register** document is to incorporate by reference EPA's authorization of Indiana's subsequent nine revisions to that program. This rule incorporates by reference provisions of State hazardous waste statutes and regulations and clarifies which of these provisions are included in the authorized and Federally enforceable program.

B. Indiana Authorized Hazardous Waste Program

Indiana received Final Authorization for its RCRA hazardous waste base program on January 31, 1986, effective January 31, 1986 (51 FR 3955). EPA incorporated by reference the then authorized hazardous waste program in subpart P of 40 CFR part 272. The State statutes and regulations are incorporated by reference at 40 CFR 272.751, and the Memorandum of Agreement, the Attorney General's Statement and the Program Description are referenced at Sec. 272.751(b)(5),(b)(6), and (b)(7), respectively.

Since the initial codification, Indiana has received authorization for revisions to its program on July 13, 1989, effective September 11, 1989 (54 FR 29557); July 23, 1991, effective September 23, 1991 (56 FR 33717); July 24, 1991, effective September 23, 1991 (56 FR 33866) (this was a renumbering of Indiana's regulations from 320 IAC 4.1 to 329 IAC 3); July 29, 1991, effective September 27, 1991 (56 FR 35831); July 30, 1991, effective September 30, 1991 (56 FR 36010); August 20, 1996, effective October 21, 1996 (61 FR 43008) (this was a renumbering of Indiana's regulations from 329 IAC 3 to 329 IAC 3.1); August 20 1996, effective October 21, 1996 (61 FR 43018); September 1, 1999, effective November 30, 1999 (64 FR 47692); and on January 4, 2001, effective January 4, 2001 (66 FR 733). In this document EPA is revising the incorporation by reference of Indiana's authorized hazardous waste program in subpart P of 40 CFR part 272, to include these revisions.

The Agency retains the authority under sections 3007, 3008, 3013 and 7003 of RCRA to undertake enforcement actions in authorized States. With respect to such an enforcement action, the Agency will rely on Federal sanctions, Federal inspection authorities, and the Federal Administrative Procedure Act rather than the authorized State analogues to these requirements. Therefore, the Agency does not intend to incorporate by reference for purposes of enforcement such particular, authorized Indiana enforcement authorities. Section 272.751(b)(2) of 40 CFR lists those enforcement authorities that are part of the authorized program but are not incorporated by reference.

The public also needs to be aware that some provisions of a State's hazardous waste management program are not part of the Federally authorized State program. These nonauthorized provisions include:

(1) Provisions that are not part of the RCRA subtitle C program because they are ''broader in scope'' than RCRA subtitle C (see 40 CFR 271.1(i));

(2) Federal provisions which the State incorporated into its regulations when the State adopted Federal regulations by reference, but for which the State is not authorized;

At this time, Indiana has adopted but is not authorized for the Corrective Action for Injection Wells portion of HSWA Codification Rule 2 published in the FR on December 1, 1987 (52 FR 45788); and the Federal rules published in the FR on February 21, 1991 (56 FR 7134); July 17, 1991 (56 FR 32688); August 27, 1991 (56 FR 42504); September 5, 1991 (56 FR 43754); February 18, 1992 (57 FR 5859); August 25, 1992 (57 FR 38558); September 30, 1992 (57 FR 44999); July 20, 1993 (58 FR 38816); November 9, 1993 (58 FR 59598); May 12, 1997 (61 FR 25998); June 13, 1997 (62 FR 32452); June 17, 1997 (62 FR 32974); July 14, 1997 (62 FR 37694) August 28, 1997 (62 FR 45568); December 8, 1997 (62 FR 64636); April 15, 1998 (63 FR 18504); May 6, 1998 (63 FR 24963); May 26, 1998 (63 FR 28556); June 8, 1998 (63 FR 31266); June 19, 1998 (63 FR 33782); July 14, 1998 (63 FR 37780); August 6, 1998 (63 FR 42110); August 31, 1998 (63 FR 46332); September 4, 1998 (63 FR 47409); September 9, 1998 (63 FR 48124); September 24, 1998 (63 FR 51254); October 9, 1998 (63 FR 54356); October 22, 1998 (63 FR 56710); November 30, 1998 (63 FR 65874); December 24, 1998 (63 FR 71225); January 21, 1999 (64 FR 3381) and February 11, 1999 (64 FR 6806). Therefore these Federal amendments included in Indiana's adoption by reference at 329 IAC 3.1 are not part of the State's authorized program and are not part of the incorporation by reference addressed by today's FR document.

Since EPA cannot enforce a State's requirements which have not been reviewed and authorized in accordance with RCRA section 3006 and 40 CFR part 271, it is important to clarify any limitations on the scope of a State's authorized hazardous waste program. Thus, in those instances where a State's method of adopting Federal law by reference has the effect of including unauthorized requirements, or where a State has made unauthorized amendments to previously authorized sections of State code, EPA will provide this clarification by: (1) Incorporating by reference the relevant State legal authorities according to the requirements of the Office of Federal Register; and (2) subsequently identifying in 40 CFR 272.751(b)(4), any requirements which while adopted and incorporated by reference, are not authorized by EPA, and therefore are not Federally enforceable. Thus, notwithstanding the language in the Indiana hazardous waste regulations incorporated by reference at 40 CFR 272.751(b)(1), EPA will only enforce the State provisions that are actually authorized by EPA. For the convenience of the regulated community, the actual State regulatory text authorized by EPA for the citations listed at 40 CFR 272.751(b)(1) is compiled as a separate document, *Addendum to the EPA-Approved Indiana Regulatory and Statutory Requirements Applicable to the Hazardous Waste Management Program, March 2001.* This document is available from U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, attention Gary Westefer. With respect to HSWA requirements for which the State has not yet been authorized, EPA will continue to enforce the Federal HSWA standards until the State receives specific HSWA authorization from EPA.

C. HSWA Provisions

The Agency is not amending 40 CFR part 272 to include HSWA requirements and prohibitions that are implemented by EPA. Section 3006(g) of RCRA provides that any HSWA requirement or prohibition (including implementing regulations) take effect in authorized and not authorized States at the same time. A HSWA requirement or

prohibition supersedes any less stringent or inconsistent State provision which may have been previously authorized by EPA (50 FR 28702, July 15, 1985). EPA has the authority to implement HSWA requirements in all States, including authorized States, until the States become authorized for such requirement or prohibition. Authorized States are required to revise their programs to adopt the HSWA requirements and prohibitions, and then to seek authorization for those revisions pursuant to 40 CFR part 271.

Instead of amending the 40 CFR part 272 every time a new HSWA provision takes effect under the authority of RCRA section 3006(g), EPA will wait until the State receives authorization for its analog to the new HSWA provision before amending the State's 40 CFR part 272 incorporation by reference. Until then, persons wanting to know whether a HSWA requirement or prohibition is in effect should refer to 40 CFR 271.1(j), as amended, which lists each such provision.

Some existing State requirements may be similar to the HSWA requirements implemented by EPA. However, until EPA authorizes those State requirements, EPA can only enforce the HSWA requirements and not the State analogs. EPA will not codify those State requirements until the State receives authorization for those requirements.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The section 202 and 205 requirements do not apply to today's action because it is not a ''Federal mandate'' and because it does not impose annual costs of $100 million or more for State, local and/or tribal governments in the aggregate, or the private sector. Today's action contains no Federal mandates for State, local or tribal governments or the private sector because it does not impose new or additional enforceable duties on any State, local or tribal governments or the private sector. This rule merely incorporates by reference existing requirements with which regulated entities must already comply under State and Federal law. For this same reason, this action will not result in annual expenditures of $100 million or more for State, local, and/or tribal governments in the aggregate, or the private sector because it incorporates by reference an existing State program that EPA previously authorized. Cost to the State, local and/or tribal governments, and to regulated entities already exist under the authorized program. Further, as it applies to the State, this action does not impose a Federal intergovernmental mandate because UMRA does not include duties arising from participation in a voluntary Federal program.

The requirements of section 203 of UMRA also do not apply to today's action because it contains no regulatory requirements that might significantly or uniquely affect small governments. Although small governments may be hazardous waste generators, transporters, or own and/or operate treatment, storage, and disposal facilities, this codification incorporates into the CFR Indiana's requirements which EPA already authorized under 40 CFR part 271. Small governments are not subject to any additional significant or unique requirements by virtue of this action.

Certification Under the Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act 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). This analysis is unnecessary, however, if the agency's administrator certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's action on small entities, small entity is defined as: (1) A small business as specified in the Small Business Administration regulations; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this codification on small entities, I certify pursuant to the provision at 5 U.S.C. 605(b), that this codification will not have a significant economic impact on a substantial number of small entities. This action does not impose any new requirements on small entities because small entities that are hazardous waste generators, transporters, or that own and/or operate TSDFs are already subject to the regulatory requirements under the State laws authorized by EPA under 40 CFR part 271. This codification incorporates Indiana's requirements which have been authorized by EPA under 40 CFR part 271 into the CFR. The EPA's codification does not impose any additional burdens on these small

entities. This rule, therefore, does not require a regulatory flexibility analysis.

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. The 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 today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Executive Order 12866.

Compliance With Executive Order 12898: Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations' as well as through EPA's April 1995, ''Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report,'' and National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income, bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities. Today's rule is not expected to negatively impact any community, and therefore is not expected to cause any disproportionately high and adverse impacts to minority or low-income communities versus non-minority or affluent communities.

Compliance With Executive Order 13045

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' applies to any rule that: (1) The Office of Management and Budget determines is ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions based on environmental health or safety risks.

Compliance With Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''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 section 6 of 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 authorization does not have federalism implications. It will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because this rule affects only one State. This action simply approves Indiana's proposal to be authorized for updated requirements of the hazardous waste program that the State has voluntarily chosen to operate. Further, as a result of this action, newly authorized provisions of the State's program now apply in Indiana in lieu of the equivalent Federal program provisions implemented by EPA under HSWA. Affected parties are subject only to those authorized State program provisions, as opposed to being subject to both Federal and State regulatory requirements. Thus, the requirements of section 6 of the Executive Order do not apply.

Compliance With Executive Order 13175

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 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.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This final rule does not have tribal implications. 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, as specified in Executive Order 13175.

This rule is not subject to Executive Order 13175 because it does not significantly or uniquely affect the communities of Indian tribal governments. Indiana is not authorized to implement the RCRA hazardous waste program in Indian country. This action has no effect on the hazardous waste program that EPA may implement in the Indian country within the State.

Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, Federal agencies must consider the paperwork burden imposed by any information request contained in a proposed rule or a final rule. This rule will not impose any information requirements upon the regulated community.

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 272

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Incorporation by reference, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This rule is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: July 3, 2001.

David A. Ullrich,

Acting Regional Administrator, Region 5.

For the reasons set forth in the preamble, 40 CFR part 272 is amended as follows:

PART 272—APPROVED STATE HAZARDOUS WASTE MANAGEMENT PROGRAMS

1. The authority citation for part 272 continues to read as follows:

Authority: Sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Subpart P—[Amended]

2. Section 272.750 is removed and reserved.

3. Section 272.751 is revised to read as follows:

§ 272.751 Indiana state-administered program: Final authorization.

(a) Pursuant to section 3006(b) of RCRA, 42 U.S.C. 6926(b), Indiana has final authorization for the following elements as submitted to EPA in Indiana's base program application for final authorization which was approved by EPA effective on January 31, 1986. Subsequent program revision applications were approved effective on December 31, 1986, January 19, 1988, September 11, 1989, September 23, 1991 (two separate revisions), September 27, 1991, September 30, 1991, October 21, 1996, November 30, 1999, and January 4, 2001.

(b) *State statutes and regulations.* (1) The Indiana statutes and regulations cited in this paragraph are incorporated by reference as part of the hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.* This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a). Copies of the Indiana regulations that are incorporated by reference in this paragraph are available from the Indiana Legislative Services Agency, Administrative Code and Register Division, 302 State House, Indianapolis, Indiana 46204.

(i) The EPA approved Authorized Indiana Statutory Requirements Applicable to the Hazardous Waste Management Program, dated March 2001.

(ii) The EPA approved Indiana Regulatory Requirements Applicable to the Hazardous Waste Management Program, dated March 2001.

(2) The following statutes and regulations concerning State procedures and enforcement, although not incorporated by reference, are part of the authorized State program:

(i) Annotated Indiana Code, 1998 edition, Title 13, Article 4–21.5, 5–14–3–2, 13–11–2, 13–14–2–2, 13–14–9, 13–14–10, 13–15–2, 13–19–1, 13–19–2, 13–20, 13–22–1, 13–22–3, 13–22–5 through 13–22–14, 13–23, 13–30, and 23–1–16.

(ii) Indiana Administrative Code, as amended, 1996 edition, certified October 24, 1995, 2000 cumulative supplement, certified November 30, 1999, sections 329 IAC 3.1–1–1 through 3.1–1–6; 3.1–1–8 through 3.1–1–14; 3.1–2–1 through 3.1–2–16; 3.1–3–1 through 3.1–3–9; 3.1–4–2 through 3.1–4–26; 3.1–13–5; 3.1–13–8 through 3.1–13–17; 3.1–14–2; 3.1–14–3; and 13–1–3 through 13–1–6.

(3) The following statutory and regulatory provisions are broader in scope than the Federal program, are not part of the authorized program, and are not incorporated by reference: Indiana Administrative Code as amended, 1996 edition, certified October 24, 1995, 2000 cumulative supplement, certified November 30, 1999, sections 329 IAC 3.1–6–3; and 3.1–8–4.

(4) *Unauthorized State provisions:* Although the Federal rules listed in the following table have been adopted by the State and have been included in the materials incorporated by reference in paragraph (b)(1) of this section, EPA has not authorized the State for these rules at this time. While they may be enforceable under State law, they are not enforceable under RCRA:

Federal requirement	**Federal Register** reference	Publication date
1. Hazardous Waste Management System; Testing and Monitoring Activities (Checklist 158).	62 FR 32452	June 13, 1997.
2. Kraft Mill Stream Stripper Condensate Exclusion (Checklist 164)	63 FR 18504	April 15, 1998.
3. Recycled Used Oil Management Standards; Technical Correction and Clarification (Checklist 166) as amended (Checklist 166.1).	63 FR 24963	May 6, 1998.
4. Bevill Exclusion Revisions and Clarification (Checklist 167E)	63 FR 37780	July 14, 1998.
5. Exclusion of Recycled Wood Preserving Wastewaters (Checklist 167F)	63 FR 28556	May 26, 1998.
6. Hazardous Waste Combustors Revised Standards (Checklist 168)	63 FR 33782	June 19, 1998.
7. Universal Waste Rule; Technical Amendment (Checklist 176)	63 FR 71225	December 24, 1998.

(i) Additionally Indiana has adopted but is not authorized to implement the HSWA rules that are listed the following table. EPA will continue to implement the Federal HSWA requirements for which Indiana is not authorized until the State receives specific authorization for those requirements:

Federal requirement	**Federal Register** reference	Publication date
1. HSWA Codification Rule 2; Corrective Action for Injection Wells (Checklist 44C)	52 FR 45788	December 1, 1987.
2. Burning of Hazardous Waste in Boilers and Industrial Furnaces (Checklist 85)	56 FR 7134	February 21, 1991.
3. Burning of Hazardous Waste in Boilers and Industrial Furnaces; Corrections and Technical Amendments (Checklist 94).	56 FR 32688	July 17, 1991.
4. Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendments II (Checklist 96).	56 FR 42504	August 27, 1991.
5. Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment III (Checklist 111).	57 FR 38558	August 25, 1992.
6. Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment IV (Checklist 114).	57 FR 44999	September 30, 1992.
7. Requirements for Preparation, Adoption, and Submittal of Implementation Plans (Checklist 125).	58 FR 38816	July 20, 1993.
8. Burning of Hazardous Waste in Boilers and Industrial Furnaces (Checklist 127)	58 FR 59598	November 9, 1993.
9. Land Disposal Restrictions-Phase IV: Treatment Standards for Wood Preserving Wastes, Paperwork Reduction and Streamlining, Exemptions from RCRA for Certain Processed Materials; and Miscellaneous Hazardous Waste Provisions (Checklist 157).	62 FR 25998	May 12, 1997.
10. Hazardous Waste Management System; Carbamate Production, Identification and Listing of Hazardous Waste; Land Disposal Restrictions (Checklist 159).	62 FR 32974	June 17, 1997.
11. Land Disposal Restrictions-Phase III—Emergency Extension of the K088 National Capacity Variance (Checklist 160).	62 FR 37694	July 14, 1997.
12. Second Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Wastes from Carbamate Production (Checklist 161).	62 FR 45568	August 28, 1997.
13. Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers; Clarification and Technical Amendment (Checklist 163).	62 FR 64636	December 8, 1997.
14. Land Disposal Restrictions-Phase IV: Treatment Standards for Metal Wastes and Mineral Processing Wastes (Checklist 167A), Hazardous Soils Treatment Standards and Exclusions (Checklist 167B), and Corrections (Checklist 167C) as amended (Checklist 167C.1).	63 FR 28556 63 FR 31266	May 26, 1998. June 8, 1998.
15. Petroleum Refining Process (Checklist 169) as amended (Checklist 169.1)	63 FR 42110 63 FR 54356	August 6, 1998. October 9, 1998.
16. Land Disposal Restrictions-Phase IV (Checklist 170)	63 FR 46332	August 31, 1998.
17. Emergency Revisions of the Land Disposal Restrictions Treatment Standards (Checklist 171).	63 FR 47409	September 4, 1998.
18. Emergency Revision of the Land Disposal Restrictions Treatment Standards (Checklist 172).	63 FR 48124	September 9, 1998.
19. Land Disposal Restrictions Treatment Standards (Spent Potliners) (Checklist 173)	63 FR 51254	September 24, 1998.

(ii) Some regulations listed in the table in paragraph (b)(4)(i) of this section are predominantly HSWA authority but contain provisions that are not HSWA authority. EPA will not enforce these non-HSWA provisions. The affected rules are as follows:

(A) Burning of Hazardous Waste in Boilers and Industrial Furnaces (BIF), including BIF (February 21, 1991);

(B) Corrections and Technical Amendments I (July 17, 1991);

(C) Technical Amendments II (August 27, 1991);

(D) Technical Amendments III (August 25, 1992);

(E) Amendment IV (September 30, 1992);

(F) Requirements for Preparation, Adoption, and Submittal of Implementation Plans (July 20, 1993); and

(G) BIF (November 9, 1993).

(iii) EPA will not enforce BIF rules for Sludge Dryers, Infrared Incinerators, Plasma Arc Incinerators, and Carbon Regeneration Units, until Indiana is authorized for these rules. Petroleum Refining Process (August 6, 1998, as amended October 9, 1998) 40 CFR 261.3, 261.4, and 261.6 are non-HSWA provisions. Standards Applicable to Owners and Operators of Closed/Closing Facilities (October 22, 1998) 40 CFR 264.90(e), 265.110(c), 265.118(c)(4), 265.121 (except § 265.121(a)(2)), 270.1, 270.14(a), and 270.28 are non-HSWA provisions. Hazardous Remediation Waste Management Requirements (HWIR Media) (November 30, 1998) 40 CFR 261.4(g), 264.1(j)(1–13), 264.73(b)(17), 270.2, 270.11(d), 270.68, 270.73(a), and 270.79 through 270.230 (40 CFR part 270, subpart H) except § 270.230(e)(1) are non-HSWA provisions. Until Indiana becomes authorized for these rules, EPA will not enforce the non-HSWA provisions.

(5) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region 5 and the Indiana Department of Environmental Management, signed by the Commissioner of the IDEM on February 14, 1996 and acknowledged by the EPA Regional Administrator in the **Federal Register** noticed signed on July 29, 1996, August 2, 1999, and December 14, 2000, is referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(6) *Statement of legal authority.* ''Attorney General's Statement for Final Authorization'', signed by the Attorney General of Indiana on June 28, 1985 and revisions, supplements and addenda to that Statement dated August 26, 1986, June 1, 1987, December 15, 1987, March 25, 1988, July 22, 1988, December 15, 1989, May 29, 1996, March 24, 1997, and January 31, 2000 are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(7) *Program description.* The Program Description and any other materials submitted as part of the original application or as supplements thereto are referenced as part of the authorized hazardous waste management program

under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

3. Appendix A to part 272, State Requirements, is amended by adding in alphabetical order the listing for ''Indiana'' to read as follows:

Appendix A to Part 272—State Requirements

* * * * *

Indiana

The statutory provisions include:

Annotated Indiana Code, 1998 edition, Title 13, Sections 13–14–1, 13–14–7, 13–14–8, 13–19–3, 13–22–2, and 13–22–4.

Copies of the Indiana statutes that are incorporated by reference are available from West Publishing Company, 610 Opperman Drive, P.O. Box 64526, St. Paul, Minnesota 55164–0526.

The regulatory provisions include:

Indiana Administrative Code, 1996 edition, 2000 cumulative supplement, Title 329, Article 3.1, Sections 3.1–1–7, 3.1–4–1, 3.1–5–1, 3.1–5–2, 3.1–5–3, 3.1–5–4, 3.1–5–5, 3.1–5–6, 3.1–6–1, 3.1–6–2, 3.1–7–1, 3.1–7–2, 3.1–7–3, 3.1–7–4, 3.1–7–5, 3.1–7–6, 3.1–7–7, 3.1–7–8, 3.1–7–9, 3.1–7–10, 3.1–7–11, 3.1–7–12, 3.1–7–13, 3.1–7–14, 3.1–7–15, 3.1–7–16, 3.1–8–1, 3.1–9–1, 3.1–9–2, 3.1–9–3, 3.1–10–1, 3.1–10–2(1 through 3), 3.1–10–2(5 through 22), 3.1–11–1, 3.1–11–2, 3.1–12–1, 3.1–13–1, 3.1–13–2(1 through 3), 3.1–13–2(5 through 15), 3.1–13–3, 3.1–13–4, 3.1–13–5, 3.1–13–6, 3.1–13–7, 3.1–13–8, 3.1–13–9, 3.1–13–10, 3.1–13–11, 3.1–13–12, 3.1–13–13, 3.1–13–14, 3.1–13–15, 3.1–13–16, 3.1–13–17, 3.1–14–1, 3.1–14–2, 3.1–14–3, 3.1–14–4, 3.1–14–5, 3.1–14–6, 3.1–14–7, 3.1–14–8, 3.1–14–9, 3.1–14–10, 3.1–14–11, 3.1–14–12, 3.1–14–13, 3.1–14–14, 3.1–14–15, 3.1–14–16, 3.1–14–17, 3.1–14–18, 3.1–14–19, 3.1–14–20, 3.1–14–21, 3.1–14–22, 3.1–14–23, 3.1–14–24, 3.1–14–25, 3.1–14–26, 3.1–14–27, 3.1–14–28, 3.1–14–29, 3.1–14–30, 3.1–14–31, 3.1–14–32, 3.1–14–33, 3.1–14–34, 3.1–14–35, 3.1–14–36, 3.1–14–37, 3.1–14–38, 3.1–14–39, 3.1–14–40, 3.1–15–1, 3.1–15–2, 3.1–15–3, 3.1–15–4, 3.1–15–5, 3.1–15–6, 3.1–15–7, 3.1–15–8, 3.1–15–9, 3.1–15–10, 3.1–16–1, 13–1–1, 13–1–2, 13–2–1, 13–2–2, 13–2–3, 13–2–4, 13–2–5, 13–2–6, 13–2–7, 13–2–8, 13–2–9, 13–2–10, 13–2–11, 13–2–12, 13–2–13, 13–2–14, 13–2–15, 13–2–16, 13–2–17, 13–2–18, 13–2–19, 13–2–20, 13–2–21, 13–2–22, 13–2–23, 13–2–24, 13–2–25, 13–2–26, 13–2–27, 13–3–1, 13–3–2, 13–3–3, 13–4–1, 13–4–2, 13–4–3, 13–4–4, 13–4–5, 13–5–1, 13–5–2, 13–5–3, 13–6–1, 13–6–2, 13–6–3, 13–6–4, 13–6–5, 13–6–6, 13–6–7, 13–6–8, 13–7–1, 13–7–2, 13–7–3, 13–7–4, 13–7–5, 13–7–6, 13–7–7, 13–7–8, 13–7–9, 13–7–10, 13–8–1, 13–8–2, 13–8–3, 13–8–4, 13–8–5, 13–8–6, 13–8–7, 13–8–8, 13–9–1, 13–9–2, 13–9–3, 13–9–4, 13–9–5, 13–9–6, 13–10–1, 13–10–2, 13–10–3.

Copies of the Indiana regulations that are incorporated by reference are available from Indiana Legislative Services Agency, Administrative Code and Register Division, Legislative Information Center, 302 State House, Indianapolis, Indiana 46204.

* * * * *

[FR Doc. 01–26682 Filed 10–23–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2386, MM Docket No. 01–160, RM–10159]

Digital Television Broadcast Service; Albuquerque, NM

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of ACME Television Licenses of New Mexico, LLC, substitutes DTV channel 45 for DTV channel 51c at Albuquerque, New Mexico. *See* 66 FR 40174, August 2, 2001. DTV channel 45 can be allotted to Albuquerque, New Mexico, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (35–12–48 N. and 106–27–00 W.) with a power of 245, HAAT of 1287 meters and with a DTV service population of 759 thousand. With this action, this proceeding is terminated.

DATES: Effective December 3, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 01–160 , adopted October 12, 2001, and released October 18, 2001. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

List of Subjects in 47 CFR Part 73

Television, Digital television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

2. Section 73.622(b), the Table of Digital Television Allotments under New Mexico, is amended by removing DTV channel 51c and adding DTV channel 45 at Albuquerque.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 01–26752 Filed 10–24–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2378; MM Docket No. 00–226; RM–10001]

Radio Broadcasting Services; Fair Bluff, NC, Litchfield Beach, Johnsonville and Olanta, SC

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission denies request of joint petitioners Atlantic Broadcasting Co., Inc., permittee of Station WSIM(FM), Channel 287C3, Fair Bluff, North Carolina, and The Waccamaw Neck Broadcasting Company, licensee of Station WPDT(FM), Channel 286A, Johnsonville, South Carolina. The Report and Order denies the request for the reallotment of Channel 286A from Johnsonville, South Carolina, to Olanta, South Carolina, as the community's first local aural transmission service, because it would remove the community's sole local transmission service without countervailing public interest benefits. It denies as moot the reallotment of Channel 287C3 from Fair Bluff, North Carolina, to Litchfield Beach, South Carolina, as the community's first local aural transmission service.

FOR FURTHER INFORMATION CONTACT: Victoria McCauley, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 00–226, adopted October 3, 2001, and released October 12, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualtex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–26750 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2249; MM Docket No. 01–93; RM–10076]

Radio Broadcasting Services; McCall, ID and Pinesdale, MT

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a proposal filed by Idaho Broadcasting Consortium, Inc., we will substitute Channel 294C1 for Channel 294C2 at McCall, Idaho, reallot Channel 294C1 to Pinesdale, Montana, and modify the authorization for Channel 294C2 to specify operation on Channel 294C1 at Pinesdale, Montana.[1] *See* 66 FR 27059, May 16, 2001. The coordinates for Channel 294C1 at Pinesdale are 46–10–07 and 114–17–06. 112–59–42. Although Canadian concurrence has been requested for the allotment of Channel 294C1 at Pinesdale, notification has not yet been received. Therefore, operation with the facilities specified for Pinesdale herein is subject to modification, suspension, or termination without right to a hearing, if found by the Commission to be necessary in order to conform to the 1991 Canada-USA FM Broadcast Agreement or if specifically objected to by Canada. With this action, this proceeding is terminated.

DATES: Effective November 12, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 01–93, adopted September 19, 2001, and released September 28, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Information Reference Center, Portals II, 445 12th Street, SW, Room Cy-A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY-B402, Washington, DC. 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Idaho, is amended by removing Channel 294A at McCall.

3. Section 73.202(b), the Table of FM Allotments under Montana, is amended by adding Pinesdale, Channel 294C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–26748 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

[1] Channel 294A was allotted to McCall, Idaho, in MM Docket No. 86–350, 52 FR 42438, November 5, 1987. Idaho Broadcasting Consortium, Inc. filed a first-come/first-serve application for the allotment at McCall as a C2 allotment in lieu of a Class A allotment. Idaho Broadcasting Consortium, Inc. was granted a construction permit for Channel 294C2 at McCall on December 8, 1999 (BPH–19971023MD). The Table of FM Allotments will be amended to reflect the substitution of Channel 294C2 for Channel 294A at McCall pursuant to the one-step application.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 544

[Docket No. NHTSA–2001–001; Notice 02]

RIN 2127–AI07

Insurer Reporting Requirements; List of Insurers Required To File Reports

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

ACTION: Final rule.

SUMMARY: This final rule updates Appendices A, B, and C of 49 CFR part 544, insurer reporting requirements. The appendices list those passenger motor vehicle insurers that are required to file reports on their motor vehicle theft loss experiences. An insurer included in any of these appendices must file three copies of its report for the 1998 calendar year before October 25, 2001.

DATES: The final rule on this subject is effective October 24, 2001. Insurers listed in the appendices are required to submit reports on or before October 25, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Henrietta L. Spinner, Office of Planning and Consumer Programs, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Ms. Spinner's telephone number is (202) 366–4802. Her fax number is (202) 493–2290.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 49 U.S.C. 33112, Insurer reports and information, NHTSA requires certain passenger motor vehicle insurers to file an annual report with the agency. Each insurer's report includes information about thefts and recoveries of motor vehicles, the rating rules used by the insurer to establish premiums for comprehensive coverage, the actions taken by the insurer to reduce such premiums, and the actions taken by the insurer to reduce or deter theft. Under the agency's regulation, 49 CFR part 544, the following insurers are subject to the reporting requirements: (1) Those issuers of motor vehicle insurance policies whose total premiums account for 1 percent or more of the total premiums of motor vehicle insurance issued within the United States; (2) those issuers of motor vehicle insurance policies whose premiums account for 10 percent or more of total premiums written within any one state; and (3) rental and leasing companies with a fleet of 20 or more vehicles not covered

by theft insurance policies issued by insurers of motor vehicles, other than any governmental entity.

Pursuant to its statutory exemption authority, the agency exempted certain passenger motor vehicle insurers from the reporting requirements.

A. Small Insurers of Passenger Motor Vehicles

Section 33112(f)(2) provides that the agency shall exempt small insurers of passenger motor vehicles if NHTSA finds that such exemptions will not significantly affect the validity or usefulness of the information in the reports, either nationally or on a state-by-state basis. The term ''small insurer'' is defined, in Section 33112(f)(1)(A) and (B), as an insurer whose premiums for motor vehicle insurance issued directly or through an affiliate, including pooling arrangements established under state law or regulation for the issuance of motor vehicle insurance, account for less than 1 percent of the total premiums for all forms of motor vehicle insurance issued by insurers within the United States. However, that section also stipulates that if an insurance company satisfies this definition of a ''small insurer,'' but accounts for 10 percent or more of the total premiums for all motor vehicle insurance issued in a particular state, the insurer must report about its operations in that state.

In the final rule establishing the insurer reports requirement (52 FR 59; January 2, 1987), 49 CFR part 544, NHTSA exercised its exemption authority by listing in Appendix A each insurer that must report because it had at least 1 percent of the motor vehicle insurance premiums nationally. Listing the insurers subject to reporting, instead of each insurer exempted from reporting because it had less than 1 percent of the premiums nationally, is administratively simpler since the former group is much smaller than the latter. In Appendix B, NHTSA lists those insurers required to report for particular states because each insurer had a 10 percent or greater market share of motor vehicle premiums in those states. In the January 1987 final rule, the agency stated that it would update Appendices A and B annually. NHTSA updates the appendices based on data voluntarily provided by insurance companies to A.M. Best, which A.M. Best publishes in its State/Line Report each spring. The agency uses the data to determine the insurers' market shares nationally and in each state.

B. Self-Insured Rental and Leasing Companies

In addition, upon making certain determinations, NHTSA grants exemptions to self-insurers, i.e., any person who has a fleet of 20 or more motor vehicles (other than any governmental entity) used for rental or lease whose vehicles are not covered by theft insurance policies issued by insurers of passenger motor vehicles, 49 U.S.C. 33112(b)(1) and (f). NHTSA may exempt a self-insurer from reporting, if the agency determines:

(1) The cost of preparing and furnishing such reports is excessive in relation to the size of the business of the insurer; and

(2) The insurer's report will not significantly contribute to carrying out the purposes of Chapter 331.

In a final rule published June 22, 1990 (55 FR 25606), the agency granted a class exemption to all companies that rent or lease fewer than 50,000 vehicles, because it believed that the largest companies' reports sufficiently represent the theft experience of rental and leasing companies. NHTSA concluded that smaller rental and leasing companies' reports do not significantly contribute to carrying out NHTSA's statutory obligations and that exempting such companies will relieve an unnecessary burden on them. As a result of the June 1990 final rule, the agency added Appendix C, consisting of an annually updated list of the self-insurers subject to part 544. Following the same approach as in Appendix A, NHTSA included, in Appendix C, each of the self-insurers subject to reporting instead of the self-insurers which are exempted. NHTSA updates Appendix C based primarily on information from Automotive Fleet Magazine and Business Travel News.

C. When a Listed Insurer Must File a Report

Under Part 544, as long as an insurer is listed, it must file reports on or before October 25 of each year. Thus, any insurer listed in the appendices must file a report by October 25, and by each succeeding October 25, absent an amendment removing the insurer's name from the appendices.

Notice of Proposed Rulemaking

1. Insurers of Passenger Motor Vehicles

On August 7, 2001, NHTSA published a notice of proposed rulemaking (NPRM) to update the list of insurers in Appendices A, B, and C required to file reports (66 FR 41190). Appendix A lists insurers that must report because each had 1 percent of the motor vehicle insurance premiums on a national basis. The list was last amended in a final rule published on August 14, 2000 (65 FR 49505). Based on the 1998 calendar year data market shares from A.M. Best, we proposed to remove Prudential of America Group and Zurich Insurance Group-U.S. from Appendix A and to add CGU Group, SAFECO Insurance Companies, and St. Paul Companies to Appendix A.

Each of the 19 insurers listed in Appendix A is required to file a report before October 25, 2001, setting forth the information required by Part 544 for each State in which it did business in the 1998 calendar year. As long as these 19 insurers remain listed, they would be required to submit reports by each subsequent October 25 for the calendar year ending slightly less than 3 years before.

Appendix B lists insurers required to report for particular States for calendar year 1998, because each insurer had a 10 percent or greater market share of motor vehicle premiums in those States. Based on the 1998 calendar year data for market shares from A.M. Best, we proposed to remove Allmerica P & C Companies, Commercial Union Insurance Companies, and Nodak Mutual Insurance Company from Appendix B and to add New Jersey Manufacturers Group to Appendix B.

The nine insurers listed in Appendix B are required to report on their calendar year 1998 activities in every State where they had a 10 percent or greater market share. These reports must be filed by October 25, 2001, and set forth the information required by part 544. As long as these nine insurers remain listed, they would be required to submit reports on or before each subsequent October 25 for the calendar year ending slightly less than 3 years before.

2. Rental and Leasing Companies

Appendix C lists rental and leasing companies required to file reports. Based on information in Automotive Fleet Magazine and Business Travel News for 1998, NHTSA proposed to remove Ford Rent-A-Car-System, Ryder System, Inc., and USL Capital Fleet Services from Appendix C and to add Consolidated Service Corporation to Appendix C. Each of the 17 companies (including franchisees and licensees) listed in Appendix C would be required to file reports for calendar year 1998 no later than October 25, 2001, and set forth the information required by Part 544. As long as those 17 companies remain listed, they would be required to submit reports before each subsequent

October 25 for the calendar year ending slightly less than 3 years before.

Public Comments on Final Determination

Insurers of Passenger Motor Vehicles

In response to the NPRM, the agency received no comments. Accordingly, this final rule adopts the proposed changes to Appendices A, B, and C.

Regulatory Impacts

1. Costs and Other Impacts

This notice has not been reviewed under Executive Order 12866. NHTSA has considered the impact of this proposed rule and has determined that the action is not ''significant'' within the meaning of the Department of Transportation's regulatory policies and procedures. This rule implements the agency's policy of ensuring that all insurance companies that are statutorily eligible for exemption from the insurer reporting requirements are in fact exempted from those requirements. Only those companies that are not statutorily eligible for an exemption are required to file reports.

NHTSA does not believe that this rule, reflecting current data, affects the impacts described in the final regulatory evaluation prepared for the final rule establishing part 544 (52 FR 59; January 2, 1987). Accordingly, a separate regulatory evaluation has not been prepared for this rulemaking action. Using the Bureau of Labor Statistics Consumer Price Index for 2000, the cost estimates in the 1987 final regulatory evaluation were adjusted for inflation. The agency estimates that the cost of compliance is $86,100 for any insurer added to Appendix A, $34,440 for any insurer added to Appendix B, and $9,936 for any insurer added to Appendix C. In this final rule, for Appendix A, the agency removed two companies and added three companies; for Appendix B, the agency removed three companies and added one company; and for Appendix C, the agency removed two companies and added one company. The agency estimates that the net effect of this final rule, would be $7,284 to insurers as a group.

Interested persons may wish to examine the 1987 final regulatory evaluation. Copies of that evaluation were placed in Docket No. T86–01; Notice 2. Any interested person may obtain a copy of this evaluation by writing to NHTSA, Docket Section, Room 5109, 400 Seventh Street, SW, Washington, DC 20590, or by calling (202) 366–4949.

2. Paperwork Reduction Act

The information collection requirements in this final rule were submitted and approved by the Office of Management and Budget (OMB) pursuant to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This collection of information is assigned OMB Control Number 2127–0547 (''Insurer Reporting Requirements'') and approved for use through August 31, 2003, and the agency will seek to extend the approval afterwards.

3. Regulatory Flexibility Act

The agency also considered the effects of this rulemaking under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). I certify that this final rule will not have a significant economic impact on a substantial number of small entities. The rationale for the certification is that none of the companies proposed for Appendices A, B, or C are construed to be a small entity within the definition of the RFA. ''Small insurer'' is defined, in part under 49 U.S.C. 33112, as any insurer whose premiums for all forms of motor vehicle insurance account for less than 1 percent of the total premiums for all forms of motor vehicle insurance issued by insurers within the United States, or any insurer whose premiums within any State, account for less than 10 percent of the total premiums for all forms of motor vehicle insurance issued by insurers within the State. This notice would exempt all insurers meeting those criteria. Any insurer too large to meet those criteria is not a small entity. In addition, in this rulemaking, the agency proposes to exempt all ''self insured rental and leasing companies'' that have fleets of fewer than 50,000 vehicles. Any self insured rental and leasing company too large to meet that criterion is not a small entity.

4. Federalism

This action has been analyzed according to the principles and criteria contained in Executive Order 12612, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

5. Environmental Impacts

In accordance with the National Environmental Policy Act, NHTSA has considered the environmental impacts of this final rule and determined that it would not have a significant impact on the quality of the human environment.

6. Civil Justice Reform

This final rule does not have any retroactive effect, and it does not preempt any State law. 49 U.S.C. 33117 provides that judicial review of this rule may be obtained pursuant to 49 U.S.C. 32909, and section 32909 does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

List of Subjects in 49 CFR Part 544

Crime insurance, Insurance, Insurance companies, Motor Vehicles, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR part 544 is amended as follows:

PART 544—[AMENDED]

1. The authority citation for part 544 continues to read as follows:

Authority: 49 U.S.C. 33112; delegation of authority at 49 CFR 1.50.

2. Paragraph (a) of § 544.5 is revised to read as follows:

§ 544.5 General requirements for reports.

(a) Each insurer to which this part applies shall submit a report annually before October 25, beginning on October 25, 1986. This report shall contain the information required by § 544.6 of this part for the calendar year 3 years previous to the year in which the report is filed (e.g., the report due by October 25, 2001 will contain the required information for the 1998 calendar year).

* * * * *

3. Appendix A to Part 544 is revised to read as follows:

Appendix A—Insurers of Motor Vehicle Insurance Policies Subject to the Reporting Requirements in Each State in Which They Do Business

Allstate Insurance Group
American Family Insurance Group
American Financial Group
American International Group
California State Auto Association
CGU Group [1]
CNA Insurance Companies
Erie Insurance Group
Farmers Insurance Group
Berkshire Hathaway/GEICO Corporation Group
Hartford Insurance Group
Liberty Mutual Insurance Companies
Nationwide Group
Progressive Group
SAFECO Insurance Companies[1]
St. Paul Companies[1]
State Farm Group
Travelers PC Group
USAA Group

4. Appendix B to Part 544 is revised to read as follows:

[1] Indicates a newly listed company which must file a report beginning with the report due October 25, 2001.

Appendix B—Issuers of Motor Vehicle Insurance Policies Subject to the Reporting Requirements Only in Designated States

Alfa Insurance Group (Alabama)
Arbella Mutual Insurance (Massachusetts)
Auto Club of Michigan Group (Michigan)
Commerce Group, Inc. (Massachusetts)
Concord Group Insurance Companies (Vermont)
Kentucky Farm Bureau Group (Kentucky)
New Jersey Manufacturers Group (New Jersey)[1]
Southern Farm Bureau Group (Arkansas, Mississippi)
Tennessee Farmers Companies (Tennessee)

5. Appendix C to Part 544 is revised to read as follows:

Appendix C—Motor Vehicle Rental and Leasing Companies (Including Licensees and Franchisees) Subject to the Reporting Requirements of Part 544

Alamo Rent-A-Car, Inc.
ARI (Automotive Rentals, Inc.)
Associates Leasing Inc.
A T & T Automotive Services, Inc.
Avis, Rent-A-Car, Inc.
Budget Rent-A-Car Corporation
Consolidated Service Corporation [1]
Dollar Rent-A-Car Systems, Inc.
Donlen Corporation
Enterprise Rent-A-Car
GE Capital Fleet Services
Hertz Rent-A-Car Division (subsidiary of The Hertz Corporation)
Lease Plan USA, Inc.
National Car Rental System, Inc.
PHH Vehicle Management Services
U-Haul International, Inc. (Subsidiary of AMERCO)
Wheels Inc.

Issued on: October 18, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–26812 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–59–P

[1] Indicates a newly listed company which must file a report beginning with the report due October 25, 2001.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1244

[STB Ex Parte No. 385 (Sub–No. 5)]

Modification of the Carload Waybill Sample Reporting Procedures

AGENCY: Surface Transportation Board, DOT.

ACTION: Final rule.

SUMMARY: The Board modifies its regulations to require all railroads operating in the United States to include in the Carload Waybill Sample (Waybill Sample) export traffic moving from or through the United States. To comply with this regulation, railroads may report data on either the U.S. portion of movements or on entire international movements. Railroads reporting information on only the U.S. portion of movements may use a mileage proration to estimate the revenues attributable to the U.S. leg of the movement. When actual revenue divisions are reported, carriers may encrypt (mask) the revenue information if such information is commercially sensitive. This modification of the reporting requirements is designed to improve the accuracy of the Waybill Sample.

EFFECTIVE DATE: January 1, 2002.

FOR FURTHER INFORMATION CONTACT: James Nash, (202) 565–1542 or H. Jeff Warren, (202) 565–1533. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: We require railroads that annually terminate 4,500 or more carloads (or 5 percent of the carloads in any state) to report data, including revenues, on individual movements drawn from a random sampling of their traffic. 49 CFR 1244.2. This Waybill Sample is used for a variety of purposes by the Board, parties appearing before the Board, other Federal and state agencies, and the public in general. Because of the increased volume of rail traffic moving between the United States and Canada or Mexico, or between Canada and Mexico through the United States, we proposed (in a Notice of Proposed Rulemaking served September 8, 2000 (65 FR 54471)) to require railroads to include in the sampling process export traffic moving on the U.S. rail system.

Comments were filed by the United States Department of Transportation (DOT), the Western Coal Traffic League (WCTL), and the Association of American Railroads (AAR). DOT and WCTL support the proposal but ask for clarification.

DOT asks whether, when using data on the U.S. portion of international movements, we will modify our revenue and costing algorithms to account for the fact that the traffic does not actually terminate at the U.S. border. We recognize that, when waybill information is used to develop costs associated with specific rail service or assign revenues to segments of a movement, we must account for the fact that export traffic does not terminate at the border. Accordingly, when estimating segment costs and revenues for cross-border traffic, we will not assign the extra costs or revenues generally associated with actual terminations to points where international traffic simply crosses the border on the way to its final destination.

WCTL suggests that, to the extent possible, railroads should specify the foreign destination and revenues associated with the export traffic. As discussed below, railroads will be permitted to report such information but will not be required to do so. We do not have the authority to require foreign carriers that terminate export traffic to report information on traffic moving outside the United States. 49 U.S.C. 10501(a)(2). WCTL further asks whether export traffic will be sampled and tracked as a specific category, or whether it will be sampled on the same basis as, and subsumed within, other traffic generally. While our regulations will require the specific identification of export traffic in the Waybill Sample, we do not intend that such traffic be treated as a separate category of traffic but rather be sampled and tracked like other railroad traffic.

AAR, while acknowledging the need for an accurate Waybill Sample, expresses concern that the proposal may be burdensome for some railroads to implement because it could require expensive data processing changes in order to develop revenue data on only the U.S. portion of international movements. We note that the Canadian National Railroad Company and the Canadian Pacific Railroad Company, which are currently voluntarily reporting the information that the proposed regulations would require, have not complained of an undue burden. Nevertheless, should other carriers find it impractical to allocate revenues between the U.S. and foreign legs of movements, we will allow the reporting of information on entire international movements. With this modification, we believe that any expense associated with implementing the new regulations should be limited.

Because actual U.S. revenues are only available for traffic that is interchanged at or near the border, AAR notes that for much of the international traffic a mileage proration formula or other estimation process must be used to allocate revenues. AAR suggests that if such a revenue allocation procedure is adopted, it may be easier for carriers to rely on the mileage proration formula now used by ALK Associates (ALK).

We recognize that an allocation of revenues may be necessary. Indeed, we currently use a mileage formula to allocate revenues between U.S. carriers on multi-carrier domestic movements.

Furthermore, as with other reporting requirements, carriers are free to use an outside contractor to develop their reports. We are familiar with the ALK revenue allocation procedure and do not object to its use for this purpose.

Finally, AAR expresses concern that the proposal may result in the disclosure of commercially sensitive revenue-division information. We share AAR's concern. Therefore, as with contract revenue information, we will allow carriers to encrypt (mask) actual revenue divisions on traffic interchanged at or near the U.S. border.[1]

In sum, we are adopting regulations that will require carriers to include export traffic in the Waybill Sample. Railroads may report information on either the entire international movement or treat the U.S. portion of the movement as terminating at or near the border[2] for purposes of developing the data required by the Waybill Sample.

This action will not significantly affect either the quality of the human environment or energy conservation.

Pursuant to 5 U.S.C. 605(b), we conclude that our action will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

List of Subjects in 49 CFR Part 1244

Freight, Railroads, Reporting and recordkeeping requirements.

Decided: October 17, 2001.

By the Board, Chairman Morgan, Vice Chairman Clyburn, and Commissioner Burkes.

Vernon A. Williams,

Secretary.

For the reasons set forth in the preamble, title 49, part 1244 of the Code of Federal Regulations will be amended as follows:

PART 1244—WAYBILL ANALYSIS OF TRANSPORTATION OF PROPERTY—RAILROADS

1. The authority citation for title 49, part 1244 continues to read as follows:

Authority: 49 U.S.C. 721, 10707, 11144, 11145.

2. Section 1244.3 is amended by revising the section heading and adding paragraphs (c) through (f) to read as follows:

§ 1244.3 Reporting contract shipment waybills and Canadian and Mexican international waybills.

* * * * *

(c) Railroads moving traffic on the U.S. rail system to the Canadian or Mexican border shall include a representative sample of such international export traffic in the Waybill Sample.

(d) Railroads shall identify (flag) such movements as international traffic in the waybill records.

(e) Railroads may report information on the complete rail routing or report only information related to the U.S. portion of the movement.

(f) Railroads may mask revenue divisions associated with cross-border traffic following the masking procedures set forth in paragraphs (a) and (b) of this section.

[FR Doc. 01–26773 Filed 10–23–01; 8:45 am]

BILLING CODE 4915–00–P

[1] Carriers that mask cross-border waybill revenues must follow the procedures set forth in 49 CFR 1244.3(a) and (b) and use the same masking factors they use to mask contract revenues. Masked contract revenues should have the waybill flag set to one (1) and non-contract cross-border waybill revenues that are masked should have the flag set to two (2).

[2] Near the border is defined as the first station or interchange point through which the shipment moves in either Canada or Mexico.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 011005243–1243–01; I.D. 091001B]

RIN 0648–AO48

International Fisheries; Pacific Tuna Fisheries; 2001 Quotas and Management Measures for Yellowfin and Juvenile Bigeye Tuna

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

ACTION: Final rule; 2001 quotas and management measures for yellowfin and juvenile bigeye tuna.

SUMMARY: NMFS announces the 2001 quotas and associated purse seine fishery conservation measures for the eastern tropical Pacific Ocean (ETP), consistent with recommendations by the Inter-American Tropical Tuna Commission (IATTC) that have been approved by the Department of State (DOS) under the terms of the Tuna Conventions Act.

DATES: Effective October 24, 2001, through December 31, 2001, or attainment of either or both quotas, which will be announced in the **Federal Register**.

ADDRESSES: Copies of the environmental assessment (EA) and the biological opinion (BO) for the January 3, 2000, interim final rule implementing the International Dolphin Conservation Program Act (IDCPA) and the aggregate data upon which the action is based are available from: Rodney McInnis, Acting Regional Administrator, Southwest Region, NMFS, 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: Svein Fougner, Sustainable Fisheries Division, Southwest Region, NMFS, 562–980–4040.

SUPPLEMENTARY INFORMATION:

Background

The United States is a member of the IATTC, which was established under the Convention for the Establishment of an Inter-American Tropical Tuna Commission signed in 1949. The IATTC was established to ensure the effective international conservation and management of highly migratory species of fish in the Convention Area. The IATTC has maintained a scientific research and fishery monitoring program for many years and annually assesses the status of stocks of tuna and the fisheries to determine appropriate harvest limits or other measures to prevent overexploitation of the stocks and promote viable fisheries. The area covered by the Convention is all waters of the eastern Pacific Ocean (EPO) between 40° N. lat. and 40° S. lat. from North and South America west to 150° W. long. Within the area covered by the Convention, the IATTC has designated a smaller Commission Yellowfin Regulatory Area (CYRA) in which the total catch of yellowfin tuna historically has been limited. The boundaries of the CYRA are found at 50 CFR 300.21.

Under the regulations implementing the Tuna Conventions Act at 50 CFR 300.29, the Southwest Regional Administrator, NMFS (Regional Administrator), directly notifies owners or agents of U.S. tuna vessels of fishery management recommendations made by the IATTC and approved by the DOS. As soon as practicable after such notification, NMFS publishes a notification of the approved IATTC recommendations in the **Federal Register**.

Action by IATTC

At its annual meeting June 19–21, 2001, the IATTC adopted a resolution dealing with yellowfin tuna conservation. This resolution set an initial quota of 250,000 metric tons (mt) for yellowfin tuna taken in calendar year 2001 by purse seine vessels in the CYRA. This quota could be raised by up

to three successive increments of 20,000 mt each if the Director of the IATTC concludes from examination of available data that such increases will pose no substantial danger to the stocks. After the quota is reached and the yellowfin tuna fishery is closed, catches of any vessel may include a maximum of 15 percent yellowfin tuna (relative to its total catch of all species of fish) caught while fishing for other species of tuna.

In a separate resolution adopted in June 2001, the IATTC recommended that action be taken to limit the catch of juvenile bigeye tuna in the purse seine fisheries to the level reached in 1999, which was 5,813 mt. The Director of IATTC will monitor the fisheries and determine the date on which the quota is projected to be reached (if at all). The Director will then inform the member nations that they should prohibit further use of purse seine sets on floating objects within 2 weeks of that date, except that the floating objects fishery will not close sooner than November 1, 2001.

The yellowfin tuna quota and juvenile bigeye tuna quota are both based on 2001 stock assessments of yellowfin and bigeye tuna stocks in the ETP. The stock assessments indicate that both the yellowfin and bigeye tuna stocks are healthy, although there is substantial uncertainty with respect to the bigeye tuna stock assessment. This stock extends throughout the Pacific and has not been assessed throughout its range by any international organization. However, the quotas set for yellowfin tuna and juvenile bigeye tuna are believed to be conservative because of the conservative assumptions used in the stock assessments concerning life history parameters of yellowfin and bigeye tuna.

NMFS Action

After receiving oral approval of this recommendation from the DOS on September 6, 2001, the Regional Administrator provided actual notice of these fishery management recommendations to owners or agents of U.S. tuna vessels on September 12, 2001. The DOS subsequently provided written approval of the IATTC recommendation on September 25, 2001. This notice is the formal announcement to the public of the implementation of the recommendations of the IATTC. As provided in 50 CFR 300.29(b), if any quota is reached, NMFS will announce a closure directly to the owners or agents of U.S. tuna vessels and publish the announcement in the **Federal Register** as soon as practicable after the attainment of the quota.

Classification

This action is authorized by 50 CFR part 300, subpart C.

The Assistant Administrator for Fisheries, NOAA (AA) finds that this action constitutes a foreign affairs function under 5 U.S.C. 553(a)(1), which exempts such functions from that section of the Administrative Procedure Act. This action implements quotas and management measures that have been recommended by the IATTC and approved by DOS, as authorized by the Tuna Conventions Act of 1949 and this part. Therefore, the provisions of 5 U.S.C. 553(b)(3)(B) for providing prior notice and an opportunity for public comment and the provisions of 5 U.S.C. 553(d)(3) for a 30-day delay in effectiveness do not apply to this action.

An EA was prepared for the interim final rule to implement the IDCPA (65 FR 47, January 3, 2000). This document is available from the Acting Regional Administrator (see **ADDRESSES**). The AA concluded that that rule would pose no significant impact on the human environment. The impacts of the fisheries as they will operate under quotas set in this action are within the range of impacts considered in the alternatives of that EA, and do not pose significant threats to the human environment; therefore, this action does not require further environmental analysis.

NMFS prepared a BO assessing the impacts of the fisheries as they would operate under the regulations implementing the IDCPA (65 FR 47, January 3, 2000). This document is available from the Acting Regional Administrator (see **ADDRESSES**). NMFS concluded that the fishing activities conducted under those regulations are not likely to jeopardize the continued existence of any endangered or threatened species under the jurisdiction of NMFS or result in the destruction or adverse modification of critical habitat. This rule will not result in any changes to the fisheries that would cause impacts beyond those considered in the BO.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C., 601 *et seq.*, are inapplicable.

This action is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 951–961 and 971 *et seq.*

Dated: October 18, 2001.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 01–26794 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 010112013–1013–01; I.D. 101901D]

Fisheries of the Economic Exclusive Zone Off Alaska; Trawl Gear in the Gulf of Alaska

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

ACTION: Closure.

SUMMARY: NMFS is closing directed fishing for groundfish by vessels using trawl gear in the Gulf of Alaska (GOA), except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA open to directed fishing for pollock. This action is necessary because the 2001 Pacific halibut prohibited species catch (PSC) limit specified for trawl gear in the GOA has been caught.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), October 21, 2001, until 1200 hrs, A.l.t., December 31, 2001.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and at 50 CFR part 679.

The Pacific halibut PSC limit for vessels using trawl was established as 2,000 metric tons (mt) by the Final 2001 Harvest Specifications and Associated Management Measures for the Groundfish Fisheries Off Alaska (66 FR 7276, January 22, 2001), and adjusted (66 FR 17087, March 29, 2001, and 66 FR 37167, July 17, 2001). The Administrator, Alaska Region, has determined, in accordance with § 679.21(d)(7)(i), that vessels engaged in

directed fishing for groundfish with trawl gear in the GOA have caught the 2001 Pacific halibut PSC limit. Therefore, NMFS is closing the directed fishery for groundfish by vessels using trawl gear in the GOA, except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA that remain open to directed fishing for pollock.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20 (e) and (f).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds that the need to immediately implement this action to prevent exceeding the 2001 Pacific halibut bycatch allowance specified for trawl gear in the GOA constitutes good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553 (b)(3)(B) and 50 CFR 679.20 (b)(3)(iii)(A), as such procedures would be unnecessary and contrary to the public interest. Similarly, the need to implement these measures in a timely fashion to prevent exceeding the 2001 Pacific halibut bycatch allowance specified for trawl gear in the GOA constitutes good cause to find that the effective date of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553 (d), a delay in the effective date is hereby waived.

This action is required by 50 CFR 679.21 and is exempt from review under Executive Order 12866.

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

Dated: October 19, 2001.

Bruce C. Morehead,

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

[FR Doc. 01–26798 Filed 10–19–01; 2:59 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 66, No. 206
Wednesday, October 24, 2001

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–CE–33–AD]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC–7, PC–12, and PC–12/45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all Pilatus Aircraft Ltd. Models PC–7, PC–12, and PC–12/45 airplanes that incorporate a certain engine-driven pump. This proposed AD would require you to: inspect the joints between the engine-driven pump housing, relief valve housing, and the relief-valve cover for signs of fuel leakage or extruding gasket material; replace any engine-driven pump with signs of fuel leakage or extruding gasket material; and inspect to ensure that the relief valve attachment screws are adequately torqued and re-torque as necessary. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by this proposed AD are intended to detect and correct gasket material extruding from the engine-driven pump housing and detect and correct relief valve attachment screws with inadequate torque. Such conditions could lead to fuel leakage and result in a fire in the engine compartment.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before November 30, 2001.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–CE–33–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

You may get information that applies to the proposed AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465–9099; facsimile: (303) 465–6040. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are there any specific portions of this proposed AD I should pay attention to? The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How can I be sure FAA receives my comment? If you want FAA to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2001–CE–33–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What events have caused this proposed AD? The Federal Office for Civil Aviation (FOCA), which is the airworthiness authority for Switzerland, recently notified FAA of an unsafe condition that may exist on Pilatus Models PC–7, PC–12, and PC–12/45 airplanes. The FOCA reports instances of fuel leaking from the engine-driven pump on the referenced airplanes. The compression set of the gasket and diaphragm after thermal cycling could cause the gasket of the engine-driven pump to extrude between the relief valve housing and the engine-driven pump housing. This in turn relieves the torque of the relief-valve cover screws of the engine-driven pump, which could result in fuel leakage.

Information on the affected pumps follows:

—The affected engine-driven pumps are Lear Romec part number RG9570R1 (Pilatus part number 968.84.51.106) as installed on Models PC–12 and PC–12/45 airplanes or Lear Romec part number RG9570M1 (Pilatus part number 968.84.51.105) as installed on Model PC–7 airplanes;

—Pilatus installed these engine-driven pumps on manufacturer serial number (MSN) 101 through MSN 400 of the Models PC–12 and PC–12/45 airplanes and MSN 101 through MSN 618 of the Model PC–7 airplanes; and

—These engine-driven pumps could be installed through field approval on any MSN of the Models PC–7, PC–12, and PC–12/45 airplanes.

What are the consequences if the condition is not corrected? Gasket material extruding from the engine-driven pump housing and relief valve attachment screws with inadequate torque, if not detected and corrected, could lead to fuel leakage and result in a fire in the engine compartment.

Is there service information that applies to this subject? Pilatus has issued the following:

—Service Bulletin No. 28–006, dated August 10, 2001, which applies to the Model PC–7 airplanes; and

—Service Bulletin No. 28–009, dated August 10, 2001, which applies to the Models PC–12 and PC–12/45 airplanes.

What are the provisions of this service information? These service bulletins include procedures for:

—Inspecting the joints between the engine-driven pump housing, relief valve housing, and the relief-valve cover for signs of fuel leakage or extruding gasket material;

—Replacing any engine-driven pump with signs of fuel leakage or extruding gasket material; and

—Inspecting to ensure that the relief valve attachment screws are adequately torqued and re-torque as necessary.

What action did the FOCA take? The FOCA classified this service bulletin as mandatory and issued Swiss AD HB 2001–500 (PC–12 and PC–12/45) and Swiss AD HB–505 (PC–7), both dated August 24, 2001, in order to ensure the continued airworthiness of these airplanes in Switzerland.

Was this in accordance with the bilateral airworthiness agreement? These airplane models are manufactured in Switzerland 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, the FOCA has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of This Proposed AD

What has FAA decided? The FAA has examined the findings of the FOCA; reviewed all available information, including the service information referenced above; and determined that:

—The unsafe condition referenced in this document exists or could develop on other Pilatus Models PC–7, PC–12, and PC–12/45 airplanes of the same type design that are on the U.S. registry;

—The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and

—AD action should be taken in order to correct this unsafe condition.

What would this proposed AD require? This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

Cost Impact

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects 278 airplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the proposed inspections and re-torque:

Labor cost	Parts cost	Total cost Per airplane	Total cost on U.S. operators
2 workhours at $60 an hour = $120	Not applicable	$120	$33,360

We estimate the following costs to accomplish 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 such replacement:

Labor cost	Parts cost	Total cost per airplane.
1 workhour at $60 an hour = $60	$3,900 per new pump	$3,960 per airplane.

Compliance Time of This Proposed AD

What would be the compliance time of this proposed AD? The compliance time of the inspections that would be required by the proposed AD is ''within 20 hours time-in-service (TIS) after the effective date of this AD or within the next 30 days after the effective date to this AD, whichever occurs first.''

Why is the compliance time of this proposed AD presented in both hours TIS and calendar time? The deterioration and potential extrusion of the gasket occurs over time and is not a condition of repetitive airplane operation. However, the relief valve attachment screws becoming inadequately torqued occurs as a result of airplane usage if the compression set of the gasket and diaphragm after thermal cycling causes the gasket of the engine-driven pump to extrude between the relief valve housing and the engine-driven pump housing.

Therefore, to ensure that the unsafe condition defined in this document is detected and corrected in a timely manner, we are proposing the compliance in both calendar time and hours TIS.

Regulatory Impact

Would this proposed AD impact various entities? The regulations proposed herein 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. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed action (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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

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 Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Pilatus Aircraft LTD.: Docket No. 2001–CE–33–AD.

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers that are certificated in any category:

Model	Serial No.
PC–7	All manufacturer serial numbers (MSN) with a Lear Romec part number RG9570M1 (Pilatus part number 968.84.51.105) engine-driven pump.
PC–12 and PC–12/45.	All MSN with a Lear Romec part number RG9570R1 (Pilatus part number 968.84.51.106) engine-driven pump.

Note 1: Pilatus installed these engine-driven pumps on manufacturer serial number (MSN) 101 through MSN 400 of the Models PC–12 and PC–12/45 airplanes and MSN 101 through MSN 618 of the Model PC–7 airplanes. These engine-driven pumps could be installed through field approval on any MSN of the Models PC–7, PC–12, and PC–12/45 airplanes;

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct gasket material extruding from the engine-driven pump housing and detect and correct relief valve attachment screws with inadequate torque. Such conditions could lead to fuel leakage and result in a fire in the engine compartment.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) For all affected airplanes: inspect the joints between the engine-driven pump housing, relief valve housing, and the relief-valve cover for signs of fuel leakage or extruding gasket material.	Initially inspect within the next 20 hours time-in-service (TIS) after the effective date of this AD or within the next 30 days after the effective date of this AD, whichever occurs first.	In accordance with the Accomplishment Instructions section of either Pilatus Service Bulletin No. 28–006 or Pilatus Service Bulletin No. 28–009, both dated August 10, 2001, as applicable.
(2) For the Model PC–7 airplanes: if you find signs of fuel leakage or extruding gasket material during the inspection required by paragraph (d)(1) of this AD, replace the engine-driven pump with a Lear Romec part number RG9570M1/M engine-driven pump.	Replace prior to further flight after the inspection required by paragraph (d)(1) of this AD.	In accordance with the Accomplishment Instructions section of Pilatus Service Bulletin No. 28–006, dated August 10, 2001; and the appropriate maintenance manual.
(3) For the Models PC–12 and PC–12/45 airplanes: if you find signs of fuel leakage or extruding gasket material during the inspection required by paragraph (d)(1) of this AD, replace the engine-driven pump with one of the following and accomplish any specified follow-on action:. (i) a Lear Romec part number RG95701R1/M (Pilatus part number 968.84.51.106/M) engine-driven pump; or. (ii) a Lear Romec part number RG9570R1 (Pilatus part number 968.84.51.106) engine-driven pump. Installation of this part requires you to accomplish the inspection specified in paragraph (d)(1) of this AD. This inspection is to ensure that the compression set of the gasket and diaphragm after thermal cycling does not cause the gasket of the engine-driven pump to extrude between the relief valve housing and the pump housing.	Replace prior to further flight after the inspection required by paragraph (d)(1) of this AD. Accomplish the inspection at least 20 hours TIS after the installation, but not to exceed 30 hours TIS after the installation.	In accordance with the Accomplishment Instructions section of Pilatus Service Bulletin No. 28–009, dated August 10, 2001; and the appropriate maintenance manual.
(4) For all affected airplanes: inspect to ensure that the relief valve attachment screws are adequately torqued and retorque as necessary.	Prior to further flight after the inspection required by paragraph (d)(1) of this AD.	In accordance with the Accomplishment Instructions section of either Pilatus Service Bulletin No. 28–006 or Pilatus Service Bulletin No. 28–009, both dated August 10, 2001, as applicable.
(5) Do not install, on any affected Model PC–7 airplane, a replacement Lear Romec part number RG9570M1 (Pilatus part number 968.84.51.105) engine-driven pump	As of the effective date of this AD	Not Applicable.

Actions	Compliance	Procedures
(6) If you install, on any Model PC–12 or Model PC–12/45 airplane, a part number RG9570R1 (Pilatus part number 968.84.51.106) engine-driven pump, you must accomplish the inspection specified in paragraph (d)(1) of this AD. This inspection is to ensure that the compression set of the gasket and diaphragm after thermal cycling does not cause the gasket of the engine-driven pump to extrude between the relief valve housing and the pump housing.	Accomplish the inspection at least 20 hours TIS after the installation, but not to exceed 30 hours TIS after the installation.	In accordance with the Accomplishment Instructions section of Pilatus Service Bulletin No. 28–009, dated August 10, 2001.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the documents referenced in this AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021. You may examine these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in Swiss AD HB 2001–500 (PC–12 and PC–12/45) and Swiss AD HB–505 (PC–7), both dated August 24, 2001.

Issued in Kansas City, Missouri, on October 16, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–26587 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–86–AD]

RIN 2120–AA64

Airworthiness Directives; Aerostar Aircraft Corporation Models PA–60–601 (Aerostar 601), PA–60–601P (Aerostar 601P), PA–60–602P (Aerostar 602P), and PA–60–700P (Aerostar 700P) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Aerostar Aircraft Corporation (Aerostar) Models 601, 601P, 602P, and 700P airplanes. The proposed AD would require you to replace Roto-Master and Rajay scavenge pumps with Aerostar scavenge pumps. The proposed action is the result of failures of the existing Roto-Master and Rajay scavenge pump found during regular maintenance inspections. The actions specified by this proposed AD are intended to prevent failure of the oil scavenge pumps, which could result in loss of engine oil and possible loss of engine power.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before January 2, 2002.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-CE–86-AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may look at comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

You may get service information that applies to this proposed AD from Aerostar Aircraft Corporation, 10555 Airport Drive, Coeur d'Alene Airport, Hayden Lake, Idaho 83835–8742; Telephone: (208) 762–0338; facsimile: (208) 762–8349. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Richard Simonson, Aerospace Engineer, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055; telephone: (425) 227–2597; facsimile: (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on This Proposed AD?

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are There Any Specific Portions of This Proposed AD I Should Pay Attention to?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that

summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How Can I Be Sure FAA Receives My Comment?

If you want FAA to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments Docket No. 99–CE–86–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What Events Have Caused This Proposed AD?

The FAA has received several reports of excessive internal pump wear found during normal maintenance inspections on Aerostar Models 601, 601P, 602P, and 700P airplanes. Analysis of these incidents reveals that inadequate retention of the existing oil scavenge pump rotor allows the rotor to machine its way through the end plate.

What Are the Consequences if the Condition Is Not Corrected?

This condition, if not corrected, could result in loss of engine oil and possible loss of engine power.

Is There Service Information That Applies to This Subject?

Aerostar has issued Mandatory Service Bulletin SB SB600-131A, dated January 10, 1998.

What Are the Provisions of This Service Bulletin?

The service bulletin describes procedures for replacing the Roto-Master scavenge pumps, part numbers 101633–01 or –02; and Rajay scavenge pumps, part numbers RJ1025–1 or –2; with Aerostar scavenge pumps, part number 300110–001 or –002.

The FAA's Determination and an Explanation of the Provisions of the Proposed AD

What Has FAA Decided?

After examining the circumstances and reviewing all available information related to the incidents, we have determined that:

—The unsafe condition referenced in this document exists or could develop on other Aerostar Models 601, 601P, 602P, and 700P airplanes of the same type design;

—These airplanes should have the actions specified in the above service bulletin incorporated; and

—The FAA should take AD action to correct this unsafe condition.

What Would This Proposed AD Require?

This proposed AD would require you to replace the Roto-Master or Rajay scavenge pumps with Aerostar scavenge pumps, if not already performed.

What Are the Differences Between the Service Bulletin and the Proposed AD?

Aerostar specifies in the service information that you replace the scavenge pumps within the next 50 hours time-in-service (TIS) or at the next annual inspection, whichever comes first. We propose a requirement that you replace the scavenge pumps within the next 50 hours TIS after the effective date of the proposed AD. We cannot enforce a compliance time of ''at the next annual inspection.'' We believe that 50 hours TIS will give the owners/operators of the affected airplanes enough time to have the proposed actions done without compromising the safety of the airplanes. This will allow the owners/operators to work this proposed replacement into regularly scheduled maintenance.

Cost Impact

How Many Airplanes Would This Proposed AD Impact?

We estimate the proposed AD would affect 650 airplanes in the U.S. registry.

What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?

We estimate that it would take about 8 workhours to do the proposed installation of both left and right engine scavenge pumps, at an average labor rate of $60 an hour. We estimate parts costs for each airplane at $4,750. Based on the cost factors presented above, we estimate the total cost impact of the proposed installation on U.S. operators is $3,399,500, or $5,230 for each airplane.

Regulatory Flexibility Determination and Analysis

What Are the Requirements of the Regulatory Flexibility Act?

The Regulatory Flexibility Act of 1980 was enacted by Congress to assure that small entities are not unnecessarily or disproportionately burdened by government regulations. This Act establishes ''as principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that the rule will, the Agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

What Is FAA's Determination?

The FAA has determined that this proposed AD could have a significant economic impact on a substantial number of small entities. However, we have determined that we should continue with this proposed action in order to address the unsafe condition and ensure aviation safety.

You may obtain a copy of the complete Regulatory Flexibility Analysis (entitled ''Initial Regulatory Flexibility Analysis'') that was prepared for this proposed AD from the Docket file at the location listed under the **ADDRESSES** section of this document.

Regulatory Impact

Would This Proposed AD Impact Relations Between Federal and State Governments?

The proposed regulations would 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. We have determined that this proposed rule would not have federalism implications under Executive Order 13132.

Would This Proposed AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this proposed action (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) if

promulgated, could have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. You may obtain a copy of the complete Regulatory Flexibility Analysis (entitled ''Initial Regulatory Flexibility Analysis'') that was prepared for this proposed AD from the Docket file at the location listed under the **ADDRESSES** section of this document.

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 Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. FAA amends Section 39.13 by adding a new airworthiness directive (AD) to read as follows:

Aerostar Aircraft Corporation: Docket No. 99–CE–86–AD.

(a) *What airplanes are affected by this AD?* This AD affects the following airplanes, all serial numbers, certificated in any category: Models PA–60–601 (Aerostar 601), PA–60–601P (Aerostar 601P), PA–60–602P (Aerostar 602P), and PA–60–700P (Aerostar 700P) airplanes.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes on the U.S. Register must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to replace faulty oil scavenge pumps with pumps of improved design. The faulty oil scavenge pumps have rotors that machine through the end plate, resulting in loss of engine oil and possible loss of engine power.

(d) *What must I do to address this problem?* To address this problem, you must do the following actions:

Actions	Compliance times	Procedures
(1) Replace the Roto-Master scavenge pumps, part numbers 101633–01 or –02; and Rajay scavenge umps, part numbers RJ1025–1 or –2; with Aerostar part number 300110–001 or –002.	Within the next 50 hours time-in-service after the effective date of this AD, unless already performed.	Do this replacement following the INSTRUCTIONS paragraph of Aerostar Mandatory Service Bulletin SB600–131A, January 10, 1998, and the Aerostar Maintenance Manual.
(2) Do not install, on any affected airplane, Roto-Master scavenge pumps, part numbers 101633–01 or –02; and Rajay scavenge pumps, part numbers RJ1025–1 or –2	As of the effective date of this AD	Not applicable.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Seattle Aircraft Certification Office (ACO), approves your alternative. Send your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98055.

Note: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. You should include in the request an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Richard Simonson, Aerospace Engineer, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4065; telephone: (425) 227–2597; facsimile: (425) 227–1181.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can do the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get the service information referenced in the AD from Aerostar Aircraft Corporation, 10555 Airport Drive, Coeur d'Alene Airport, Hayden Lake, Idaho 83835–8742; Telephone: (208) 762–0338; facsimile: (208) 762–8349. You may read this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 16, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–26714 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–414–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 757 series airplanes. This proposal would require installation of an extender bracket for the compensator of the Simmonds fuel quantity indication system (FQIS) in the main fuel tanks. This action is necessary to prevent contact between the compensator for the Simmonds FQIS system and a flapper check valve on a baffle rib in the main fuel tanks, which—in conjunction with another wiring failure outside the fuel tank—could result in an electrical arc and a consequent potential source of ignition in the fuel tank. This action is intended

to address the identified unsafe condition.

DATES: Comments must be received by December 10, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–414–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–414–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: John Vann, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1024; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–414–AD.'' The postcard will be date-stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–414–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that contact between the compensator for the Simmonds fuel quantity indication system (FQIS) and a flapper check valve on a baffle rib in a main fuel tank was found on certain Boeing Model 757 series airplanes. Further investigation revealed that such contact is not uncommon. Over time, this contact between the compensator and flapper check valve can wear through the compensator's protective finish and result in electrical contact between the compensator and airplane structure. This condition, in conjunction with another wiring failure outside the fuel tank, if not corrected, could result in an electrical arc and a consequent potential source of ignition in the fuel tank.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Special Attention Service Bulletins 757–28–0057 and 757–28–0059, both dated September 14, 2000. These service bulletins describe procedures for installation of extender brackets for the compensators of the Simmonds FQIS in the left and right main fuel tanks. The procedures include ensuring minimum clearance between the compensators, wiring, and components, and the fuel tank structure, and testing the electrical bond in the fuel tank. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

There are approximately 938 airplanes of the affected design in the worldwide fleet. The FAA estimates that 607 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 5 work hours per airplane to accomplish the proposed installation (not including time for gaining access and closing up), and that the average labor rate is $60 per work hour. Required parts would cost approximately $404 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $427,328, or $704 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2000–NM–414–AD.

Applicability: Model 757 series airplanes listed in Boeing Special Attention Service Bulletin 757–28–0057 or 757–28–0059, both dated September 14, 2000, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent contact between the compensator for the Simmonds fuel quantity indication system (FQIS) and a flapper check valve on a baffle rib in the main fuel tanks, which—in conjunction with another wiring failure outside the fuel tank—could result in an electrical arc and a consequent potential source of ignition in the fuel tank, accomplish the following:

Installation of Brackets

(a) Within 24 months after the effective date of this AD, install an extender bracket for the compensator of the Simmonds FQIS in the left and right main fuel tanks (including ensuring minimum clearance between the compensators, wiring, and components, and the fuel tank structure, and testing the electrical bond in the fuel tank), according to Boeing Special Attention Service Bulletin 757–28–0057 or 757–28–0059, both dated September 14, 2000, as applicable.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on October 17, 2001.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–26713 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1205–AB24

Labor Certification and Petition Process for Temporary Agricultural Employment of Nonimmigrant Workers in the United States (H–2A Workers); Modification of Fee Structure; Extension of Comment Period

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends the period for filing comments on the proposed rule that would require employers to submit fees for labor certification and the associated H–2A petition with a consolidated application form at the time of filing. The proposed rule also would modify the fee structure for H–2A labor certification applications. This action is once again being taken to permit additional comment from interested persons.

DATES: Interested persons are invited to submit written comments on or before December 17, 2001.

ADDRESSES: Submit written comments to the Assistant Secretary for Employment and Training, U.S. Department of Labor, 200 Constitution Avenue, NW., Room C–4318, Washington, DC 20210, Attention: Dale Ziegler, Chief, Division of Foreign Labor Certifications.

FOR FURTHER INFORMATION CONTACT: Charlene Giles; telephone 202–693-2950 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 13, 2000, (65 FR 43545) we published a notice requesting comments on a proposed rule to require employers to submit the fees for temporary foreign agricultural (H–2A) labor certification and the associated non-immigrant H–2A petition with a consolidated application form at the time of filing. The proposal also would modify the fee structure for H–2A labor certification applications. On August 17, 2000, the comment period was reopened and extended to September 18, 2000. 65 FR 50170. On September 27, 2001, the comment period was again reopened through October 29, 2001. 66 FR 49328. Because of comments received during the comment period and continuing interest in the proposal, it is desirable to extend the comment period for all interested persons. Therefore, the comment period for the proposed rule revising 20 CFR part 655, subpart B (Labor Certification Process for Temporary Agricultural Employment in the United States (H–2A Workers) is extended until December 17, 2001.

Signed at Washington, DC, this 19th day of October, 2001.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. 01–26867 Filed 10–23–01; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1205–AB24

Labor Certification and Petition Process for Temporary Agricultural Employment of Nonimmigrant Workers in the United States (H–2A Workers); Modification of Fee Structure; Informal Briefing

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule; notice of informal briefing; reopening and extension of deadline for notices of intention to appear.

SUMMARY: The Division of Foreign Labor Certification, Employment and Training Administration (ETA), Department of Labor (Department), is reopening and extending the deadline for notices of intention to appear at two informal briefings to allow agricultural workers and employers and other interested parties to communicate directly with the Department regarding proposed rule changes which would require employers to submit fees for temporary foreign agricultural labor certification and the associated H–2A petition with a consolidated application form at the time of filing. See proposed rule to amend 20 CFR part 655, published elsewhere in today's issue of the **Federal Register**. The proposed rule also would modify the fee structure for H–2A labor certification applications. These briefings are being held to allow the Department to solicit individual responses and experiences from interested persons and other entities. This notice extends the deadline for filing by the public of their intention to appear.

DATES: The briefing dates are:

Thursday, November 8, 2001, 9:30 a.m. to 4 p.m., Washington, DC.

Friday, November 16, 2001, 9:30 a.m. to 4 p.m., Monterey, CA.

Notices of intention to appear at the briefing must be postmarked no later than October 31, 2001.

ADDRESSES: The briefing locations are:

U.S. Department of Labor, Francis Perkins Building, 200 Constitution Avenue, NW., Plaza Level Auditorium, Washington, DC 20010.

Hilton Monterey, 1000 Oguajito Road, Monterey, CA 93940.

Send notices of intention to appear to: Charlene Giles, U.S. Department of Labor, 200 Constitution Avenue, NW, Room C–4318, Washington, DC 20210. Notices also may be faxed to Charlene Giles at 202–693–2760 (this is not a toll-free number), or submitted by e-mail at *dflc@uis.doleta.gov.*

FOR FURTHER INFORMATION CONTACT: Charlene Giles; telephone 202–693–2950. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The informal public briefings will be chaired by a senior official of the Employment and Training Administration. Persons appearing at the briefings will be allowed to present their views and pose questions to Department staff and other parties presenting their views.

Signed at Washington, DC, this 19th day of October, 2001.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. 01–26866 Filed 10–23–01; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA–203P]

RIN 1117–AA52

Establishment of a Threshold for Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: DEA is proposing a zero kilogram threshold for domestic, export, and import transactions of gamma-butyrolactone (GBL), a List I chemical and the precursor to gamma-hydroxybutyric acid (GHB), a Schedule I controlled substance. DEA is concerned that GBL packaged in individual containers is convenient to traffickers and at risk of diversion. Therefore, DEA is proposing to regulate containers that can be easily transported, stored, and generally dealt with in clandestine settings.

However, most GBL produced is used in captive markets or transported in large quantities in single containers. This material is less likely to be diverted. Therefore, this NPRM proposes to exempt from the definition of a ''regulated transaction'' all transactions of 16,000 kilograms (net weight) or more in a single container.

Pub. L. 106–172, the ''Hillory J. Farias and Samantha Reid Date-Rape Prohibition Act of 1999,'' made GBL a List I chemical. Accordingly, DEA published a Final Rule, on April 24, 2000, (65 FR 21645) conforming its regulations to this Act and making GBL a List I chemical. Because that Final Rule did not establish a threshold, all transactions in GBL are regulated transactions as described by 21 CFR 1300.02(b)(28). The removal from the definition of a ''regulated transaction'' that DEA proposes in this NPRM for large (i.e., over 16,000 kilograms) transactions of GBL will help minimize the potential impact of this rule on legitimate industry while preventing diversion.

DATES: Written comments must be received on or before December 24, 2001.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Division Control, Drug Enforcement Administration, Washington, DC 20537.

SUPPLEMENTARY INFORMATION:

What Is GBL and Why Is It Being Regulated Under the Controlled Substances Act (CSA)?

GBL is gamma-butyrolactone, the precursor used in the clandestine production of the Schedule I controlled substance gamma-hydroxybutyric acid (GHB). Since 1990, DEA has documented over 15,600 overdoses and law enforcement encounters in 46 states with GHB. DEA has documented 71 GHB-related deaths. The GHB obtained in the vast majority of these encounters is by conversion of GBL.

GBL was placed in the CSA as a List I chemical effective February 18, 2000, by enactment of Pub. L. 106–172, the ''Hillory J. Farias and Samantha Reid Date-Rape Prohibition Act of 1999'' (65 FR 21645, April 24, 2000). That law, however, did not establish a threshold. As a result of the law not establishing a threshold, all transactions in GBL are regulated transactions as described in 21 CFR 1300.02(b)(28).

DEA has identified the source for illicit GHB as being clandestinely synthesized from GBL. Law enforcement agencies have encountered GHB on at least 1,700 occasions, including more than 180 clandestine laboratories and more than 750 seized and analyzed laboratory exhibits. GHB has only recently been scheduled in the CSA as

a controlled substance and GBL regulated as a List I chemical.

The Final Rule titled, ''Placement of gamma-Butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))'' was published in the **Federal Register** on April 24, 2000, (65 FR 21645). It amended 21 CFR 1310.02(a) (List I chemicals) to reflect the status of GBL as a List I chemical. For regulatory purposes, DEA had no discretion in taking this action. Therefore, 21 CFR 1310.02(a) was amended as a final rule. Since it was published as a Final Rule, a threshold could not be established at that time because that would circumvent the notice and comment process. Therefore, DEA is proposing to establish a threshold for GBL in this NPRM to allow opportunity for public comment.

Law enforcement authorities have identified GBL in many GHB clandestine laboratories and documented its use as a GHB precursor. GBL is a necessary chemical precursor in the clandestine synthesis of GHB because, to date, no other chemical has been substituted for GBL in this process. Congress recognized this, and controlled GBL as a List I chemical upon enactment of Pub. L. 106–172 on February 18, 2000.

GBL is a unique chemical precursor. It can be converted to GHB by a simple chemical reaction or it can be ingested directly, without running a chemical reaction. That is, the body efficiently converts GBL to GHB when ingested. Because GBL is converted to GHB by the body's own action, GBL is routinely substituted for GHB to obtain the same type of intoxication. Congress recognized this and adopted in Pub. L. 106–172 a new subparagraph to 21 U.S.C. 802(32), which is the section of the CSA that defines a ''controlled substance analogue.'' The subparagraph maintains that the placement of GBL, or any other chemical, as a listed chemical does not preclude a finding that the chemical is a controlled substance analogue. DEA recognizes this concern of Congress that GBL is being used as a direct substitute for a Schedule I controlled substance. Although GBL is a chemical commodity when used by legitimate industry, diversion of GBL can be tantamount to diversion of a Schedule I controlled substance when it is intended for human consumption.

What Amounts of GBL Are Diverted for Conversion to GHB?

DEA is aware that GBL is diverted in a variety of sizes to produce GHB. Unscrupulous suppliers, including those operating through the internet, supply different size containers to the public. GBL diverted from well-known and well-established reputable companies has also been identified. At least fifteen companies operated internet sites that sold GBL and potassium hydroxide or sodium hydroxide. The latter two chemicals are used to convert GBL to GHB in a simple one-step chemical reaction. These sites sold GBL either separately or in ''GHB kits.'' A kit contains premeasured amounts of GBL and potassium hydroxide or sodium hydroxide, as needed to produce GHB. GBL has been made available to anyone who desires it in quantities ranging from 75, 150, and 450 grams, to 55-gallon drums. Most DEA documented diversion or attempted diversion of GBL is in 500-gram, three-kilogram, one-gallon, three-gallon, five-gallon, and 55-gallon sizes. Usually, multiple containers are found at GHB manufacturing sites. However, because GBL has only recently been made a listed chemical and GHB a scheduled substance, law enforcement has only recently been involved with diversion of GBL and mostly concerned with large-scale diversion.

What Transactions of GBL Are of Concern?

GBL is an industrial chemical. Most GBL produced is consumed by the producer or transported in large quantities. DEA is concerned that GBL packaged in smaller individual containers is convenient to traffickers and higher risk of diversion. DEA is proposing to regulate containers that can be easily transported, stored, and generally dealt with in clandestine settings.

The largest size container identified by DEA, short of a tank-truck, is a 55-gallon (500-pound) drum. This size, as well as smaller sizes (see above), have been marketed to the public, used for conversion to GHB, and encountered in clandestine GHB laboratories. Therefore, to address diversion of GBL in 55-gallon and smaller containers, DEA is proposing that no threshold be established. However, because DEA is concerned with these smaller size containers and because large-scale industrial distributions of GBL by tank-truck and rail car containers have not, and are not, likely to be diverted this proposal includes an exemption for large container industrial distributions.

This notice proposes that large, single-container distributions of GBL are exempt from the definition of a regulated transaction. DEA identified approximately 16,330 kilograms as the smallest bulk size distribution in a single container. A tank-truck is used to transport that amount. Therefore, DEA is proposing that distributions of GBL in single container shipments of 16,000 kilograms (35,200 pounds) (net weight) or more be excluded from the definition of a regulated transaction for domestic, import and export distributions. According to this proposal, transactions involving multiple containers each holding less than 16,000 kilograms are regulated, even if the aggregate weight is over 16,000 kilograms.

Why Is DEA Proposing This Rulemaking?

The purpose of this notice is to propose a zero threshold for distribution of GBL, to propose a regulatory exemption for large bulk transactions, and obtain comments on this approach. DEA is soliciting further information on the type and extent of transactions in GBL. This information is required to help minimize the potential impact on industry while maintaining necessary regulatory controls.

What Is a Threshold and Why Are Thresholds Used?

Transactions involving listed chemicals that are not exempt by statute (e.g. certain transactions in chemical mixtures) may be removed from the definition of ''regulated transaction'' (21 U.S.C. 802(39)) if regulation of such transactions is determined to be unnecessary for purposes of law enforcement. Two options for doing so include a categorical exemption under 21 U.S.C. 802(39)(A)(iii) or the establishment of a quality threshold under 21 U.S.C. 802(39)(A).

The CSA provides that the Attorney General may establish a threshold amount for each listed chemical. A threshold amount is established to determine whether a receipt, sale, importation or exportation within a calendar month or cumulative transactions by an individual within a calendar month are considered regulated transactions. If the transaction is considered a regulated transaction, recordkeeping and reporting requirements as specified in 21 CFR part 1310 apply.

Why Is DEA Proposing This Threshold?

Because GBL is easily converted to GHB, GBL is desired by persons not experienced in chemistry and finds its way into both household and traditional clandestine laboratory settings. That is, GBL is converted to GHB for ''individual use'' and by traffickers for wider distribution. Therefore, the control of GBL is necessary for relatively small quantities of GBL used to make ''individual use'' amounts of GHB.

DEA is proposing a zero threshold for domestic, import, and export transactions to capture all quantities of GBL that can be easily used in a clandestine laboratory. In addition, this chemical is efficiently converted to GHB when ingested. Therefore, the zero threshold is proposed to regulate distribution of a chemical that can be, and is, directly converted into and substituted for a Schedule I controlled substance.

DEA identified GBL in quantities as small as 75 grams being sold unconcernedly to the public by unscrupulous persons. If a threshold above zero is established for GBL, DEA believes that individuals will obtain GBL at a quantity below the established threshold, not only from legitimate distributors, but also from businesses that will cater to this market.

The DEA is aware that most businesses that manufacture and/or distribute GBL have recognized its abuse and attempted to prevent its diversion, even before the chemical became a regulated chemical. The GBL that is sold irresponsibly to the general public is not manufactured clandestinely. All GBL is produced by legitimate manufacturers. GBL diverted from legitimate and responsible companies has been identified at clandestine GHB laboratories and at sites where GBL is knowingly diverted. Chemical companies that are concerned about public safety still find it difficult to prevent diversion of their products. However, if records are kept for all transactions, and the buyer understands that the sale is reportable to DEA, persons who intend to use the chemical illegitimately will be discouraged from ordering.

What Is an Exemption and Why Are Exemptions Used?

In addition to setting quantity-based thresholds, DEA is authorized to remove certain categories of transactions from the definition of ''regulated transactions.'' Under 21 U.S.C. 802(39)(A)(ii) the agency may, by regulation, exempt ''any category of transaction of any category of transactions for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter.''

What Exemptions Is DEA Proposing and Why?

DEA is proposing to exempt large single container distributions of GBL based on industry's response to an earlier solicitation of information. DEA published a request for information entitled ''Industrial Uses and Handling of Gamma-butyrolactone; Solicitation of Information'' in the **Federal Register** on October 23, 1998 (63 FR 56941) in anticipation that GBL may become a regulated chemical. Interested persons supplied DEA with pertinent information. Of the eight respondents, three were manufacturers, one a European business association, and four were end-users. There was no response from distributors of GBL, except that the three manufacturers also distribute.

Domestic manufacturers informed DEA that tens of thousands of tons are produced annually. Most GBL is consumed by the manufacturer or transported in net weight of tens of thousands of pounds. The smallest tank-truck size identified by DEA, from the response to the Federal Register request for information, is 16,330 kilograms (net weight). GBL shipped by tank-truck needs to be transferred to a holding container. This equipment implies shipment is made to an established industrial location having facilities able to handle large quantities of industrial chemicals. It is likely that the added difficulty, cost, equipment, and complexity in handling this type of large bulk shipment would deter diversion. Therefore, DEA is proposing to exempt shipments of 16,000 kilograms (35,200 pounds) (net weight) or more in a single container from the definition of a regulated transaction, pursuant to 21 U.S.C. 802(39)(A)(iii).

What Alternatives Has DEA Considered, and Why Were They Not Chosen?

As an alternative to the above exemption, DEA considered proposing a threshold of multiple quantity 55-gallon drums. However, DEA determined that while clandestine operations would have difficulty handling tank-truck shipments they will be able to divert smaller, self-contained receptacles of GBL, *i.e.,* containers of 55-gallons or less. Accordingly, DEA declined to propose a threshold of multiple quantity 55-gallon drums.

DEA also considered exempting smaller quantities of GBL, such as those below 75 grams. However, because these smaller quantities would be desirable to those who would manufacture ''individual use'' quantities of GHB, or consume the GBL without chemical conversion to GHB, DEA decided not to propose this exemption. Further, most legitimate GBL is distributed in larger quantities. Quantities of 75 grams and less is restricted mostly to chemical clearinghouses that supply researchers. The amount of GBL distributed in these quantities is relatively small. The minimal regulatory relief from exemption of small quantity distributions in GBL, weighed against its diversion without fear of reprisal, convinced DEA not to propose small quantity exemptions.

Regulatory Certifications

Regulatory Flexibility, and Small Business Concerns

This NPRM will not have a significant economic impact on small business. Pub. L. 106–172 amended the CSA to make GBL a List I chemical effective February 18, 2000. Regulatory impact due to registration requirements were addressed in the Final Rule ''Placement of gamma-butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))'' (65 FR 21645). In that final rule, DEA concluded that making GBL a List I chemical would not have a significant economic impact. That conclusion was based on an estimated number of new registrants and that all distributions in GBL are regulated. This NPRM does not add new regulatory controls. In fact, it proposes to eliminate some large-scale industrial transactions from the definition of ''regulated transaction,'' thus granting additional relief to industry. DEA identified approximately 16,330 kilograms as the minimum amount available by tank-truck. DEA determined that clandestine operations will have difficulty handling tank-truck shipments but will be able to divert self-contained shipments of GBL, *i.e.,* containers of 55-gallons or less. Therefore, DEA is proposing to exempt tank-truck sized shipments (16,000 kilograms or more, net weight) from the requirements of this regulation.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Deputy Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. DEA has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and

3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

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

Paperwork Reduction Act

This rulemaking imposes no recordkeeping or reporting requirements on registrants. No information collection request is necessary.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

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

Plain Language Instructions

The DEA makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7297.

List of Subjects in 21 CFR Part 1310

Drug traffic control, List I and List II chemicals, reporting requirements.

For the reasons set out above, 21 CFR part 1310 is proposed to be amended to read as follows:

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.04(g)(1) is proposed to be amended by adding a new paragraph to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(ii) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

* * * * *

3. Section 1310.08 is proposed to be amended by adding a new paragraph (j) to read as follows:

§ 1310.08 Excluded transactions.

* * * * *

(j) Domestic, import, and export distributions of gamma-butyrolactone weighing 16,000 kilograms (net weight) or more in a single container.

Dated: October 16, 2001.

Asa Hutchinson,

Administrator.

[FR Doc. 01–26741 Filed 10–23–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV–093–FOR]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the West Virginia surface mining regulatory program (the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The program amendment consists of changes to the Code of West Virginia (W. Va. Code) as contained in Enrolled Senate Bill 5003. The amendment provides for the creation of a special reclamation fund advisory council, and additional revenues for the West Virginia special reclamation fund by increasing the special reclamation tax. The amendment is intended to improve the effectiveness of the West Virginia program and to revise the program to be consistent with SMCRA and the Federal regulations.

This document gives the times and locations that the West Virginia program and proposed amendment 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 until 4:30 p.m. (local time), on November 23, 2001. If requested, we will hold a public hearing or meeting on the amendment on November 19, 2001. We will accept requests to speak at the hearing until 4:30 p.m. (local time), on November 8, 2001.

ADDRESSES: You may mail or hand-deliver written comments and requests to speak at the hearing to Mr. Roger W. Calhoun, Director, Charleston Field Office at the address listed below.

You may review copies of the West Virginia program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Charleston Field Office.

Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301, Telephone: (304) 347–7158. E-mail: *chfo@osmre.gov.*

West Virginia Department of Environmental Protection, 10 McJunkin Road, Nitro, West Virginia 25143, Telephone: (304) 759–0510. The proposed amendment will be posted at the Department's Internet page: *http://www.dep.state.wv.us.*

In addition, you may review copies of the amendment during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Morgantown Area Office, 75 High Street, Room 229, P.O. Box 886, Morgantown, West Virginia 26507, Telephone: (304) 291–4004. (By Appointment Only)

Office of Surface Mining Reclamation and Enforcement, Beckley Area Office, 323 Harper Park Drive, Suite 3, Beckley, West Virginia 25801, Telephone: (304) 255–5265.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston

Field Office; Telephone: (304) 347–7158.

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program
II. Description of the Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the West Virginia 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 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 the Act * * * and rules and regulations consistent with regulations issued by the Secretary pursuant to the 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 West Virginia program on January 21, 1981. You can find background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915–5956). You can also find later actions concerning West Virginia's program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Description of the Proposed Amendment

By letter dated September 17, 2001 (Administrative Record Number WV–1237), the West Virginia Department of Environmental Protection (WVDEP) notified OSM of proposed legislation that was approved during a special session of the West Virginia Legislature. By letter dated September 24, 2001 (Administrative Record Number WV–1238), the WVDEP sent us a proposed amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment was submitted in response to OSM's 30 CFR part 733 notification of June 29, 2001 (Administrative Record Number WV–1218). It is also intended to improve the effectiveness of the West Virginia program and to address required program amendments at 30 CFR 948.16(jjj), (kkk), and (lll).

While the proposed program amendment consists of Enrolled Senate Bill 5003, which was signed by the Governor on October 4, 2001, we are making available for public review and comment Engrossed Senate Bill 5003. Engrossed Senate Bill 5003 is identical to Enrolled Senate Bill 5003 except that the former clearly shows, via underline and strikethrough, all the statutory language that has been added or deleted from the W.Va. Code as a result of Senate Bill 5003.

The program amendment adds new W. Va. Code section 22–1–17 concerning the establishment of the special reclamation fund advisory council. The amendment also revises the provisions of W. Va. Code sections 22–3–11 concerning the special reclamation tax, and section 22–3–12 concerning site-specific bonding. You will find the full amended language of West Virginia's program amendment quoted below.

1. W. Va. Code 22–1–17 Special Reclamation Fund Advisory Council

This provision is new, and provides for the creation of a special reclamation fund advisory council. The new language is quoted below.

Article 1. Division of Environmental Protection

22–1–17. Special reclamation fund advisory council.

(a) There is hereby created within the department of environmental protection a special reclamation fund advisory council. The council's purpose is to ensure the effective, efficient and financially stable operation of the special reclamation fund. The special reclamation advisory council shall consist of eight members, including the secretary of the department of environmental protection, or his or her designee, the treasurer of the state of West Virginia, or his or her designee, the director of the national mine land reclamation center at West Virginia university and five members to be appointed by the governor with the advice and consent of the Senate.

(b) Each appointed member of the council shall be selected based on his or her ability to serve on the council and effectuate its purposes. The governor shall appoint, from a list of three names submitted by the major trade association representing the coal industry regulated under article three of this chapter, a member to represent the interests of the industry. The governor shall appoint, from a list of three names submitted by organizations advocating environmental protection, one member to represent the interest of environmental protection organizations. The governor shall appoint, from a list of four names submitted by the coal mining industry and the organizations advocating environmental protection, one member who, by training and profession, is an actuary or an economist. The governor shall appoint, from a list of three names submitted by the united mine workers of America, one member to represent the interest of coal miners. The governor shall appoint a member to represent the interests of the general public.

(c) The terms of all members shall begin on the first day of July, two thousand two. The secretary shall be an ex officio, nonvoting member and serve as chairperson of the council. The terms of the governor's appointees shall be for six years. Appointees may be reappointed to serve on the council. The terms of the appointed members first taking office are to be expired as designated by the governor at the time of the nomination, two at the end of the second year, two at the end of the forth year and one at the end of the sixth year. As the original appointments expire, each subsequent appointment will be for a full six-year term. Any appointed member whose term has expired shall serve until a successor has been duly appointed and qualified. Any person appointed to fill a vacancy is to serve only for the unexpired term.

(d) Appointed members of the council shall be paid the same compensation and expense reimbursement as is provided for members of the Legislature pursuant to sections six and eight, article two-a, chapter four of this code. Council members who are state employees or officials shall be reimbursed for expenses in accordance with the applicable agency's policy.

(e) The council shall meet at the call of the chairperson or his or her designee, but not less than once every six months. The secretary shall provide funds for necessary administrative and technical services for the council from the special reclamation fund.

(f) The council shall, at a minimum:

(1) Study the effectiveness, efficiency and financial stability of the special reclamation fund with an emphasis on development of a financial process that ensures long-term stability of the special reclamation program;

(2) Identify and define problems associated with the special reclamation fund, including, but not limited to, the enforcement of federal and state law, regulation and rules pertaining to contemporaneous reclamation;

(3) Evaluate bond forfeiture collection, reclamation efforts at bond forfeiture sites and compliance with approved reclamation plans as well as any modifications;

(4) Provide a forum for a full and fair discussion of issues relating to the special reclamation fund;

(5) Contract with a qualified actuary who shall make a determination as to the special reclamation fund's fiscal soundness. This determination shall be completed on the thirty-first day of December, two thousand four, and every four years thereafter. The review is to include an evaluation of the present and prospective assets and liabilities of the special reclamation fund; and

(6) Study and recommend to the Legislature alternative approaches to the current funding scheme of the special reclamation fund, considering revisions which will assure future proper reclamation of all mine sites and continued financial viability of the state's coal industry.

(g) On or before the first day of January, two thousand three, and every year thereafter, the council shall submit to the Legislature and the governor a report on the adequacy of the special reclamation tax and the fiscal condition of the special reclamation fund. The report shall, at a minimum, contain:

(1) A recommendation as to whether or not any adjustments to the special reclamation

tax should be made considering the cost, timeliness and adequacy of bond forfeiture reclamation, including water treatment;

(2) A discussion of the council's required study issues as set forth in subsection (f) of this section; and

(3) The availability of federal abandoned mine lands funds for West Virginia reclamation projects.

2. W. Va. Code 22–3–11 Bonds

Subsection 22–3–11(a) is amended to provide that the penal amount of the bond shall be not less than one thousand dollars nor more than five thousand dollars for each acre or fraction thereof. The existing requirement that the minimum amount of bond furnished for any type of reclamation bonding is ten thousand dollars is relocated within this subsection.

Subsection 22–3–11(g) is amended by adding a reference to section 22–1–17. As amended, the moneys accrued in the special reclamation fund are reserved only for the purposes set forth in sections 22–3–11 and 22–1–17. Language is added which provides that moneys in the special reclamation fund may be spent to reclaim abandoned lands where the amount of bond posted and forfeited is less less than the actual cost of reclamation, ''and where the land is not eligible for abandoned mine land reclamation funds under article two of this chapter.'' Language is deleted that limits expenditures from the special reclamation fund for the purpose of designing, constructing and maintaining water treatment systems when they are required for a complete reclamation of the affected lands to 25 percent of the fees collected. This revision is intended to satisfy the required amendment at 30 CFR 948.16(jjj). As amended, the provision provides that the secretary may use the special reclamation fund for the purpose of designing, constructing and maintaining water treatment systems where they are required for a complete reclamation of the affected lands. Also, the words ''articles two and four of this chapter'' are deleted from the sentence which identifies the administrative provisions for which up to 10 percent of the special reclamation funds may be spent.

Subsection 22–3–11(h) is amended by adding language that provides for a new per-ton special reclamation tax on surface coal mining operations .

Subsections 22–3–11(i) and (j) are amended by adding references to the special reclamation tax.

Subsection 22–3–11(k) is amended by adding a reference to the special ''reclamation'' tax and by deleting the last sentence which provided that the special reclamation tax ''shall be collected whenever the liabilities of the state established in this subsection exceed the accrued amount in the fund.'' This revision is intended to satisfy the required amendment at 30 CFR 948.16 (kkk).

New subsection 22–3–11(n) is added to provide that the amendments to section 22–3–11 will become effective upon the approval by OSM.

The amended section 22–3–11 is quoted below.

Article 3. Surface Coal Mining and Reclamation Act

22–3–11. Bonds; amount and method of bonding; bonding requirements; special reclamation tax and fund; prohibited acts; period of bond liability.

(a) After a surface mining permit application has been approved pursuant to this article, but before a permit has been issued, each operator shall furnish a penal bond, on a form to be prescribed and furnished by the secretary, payable to the state of West Virginia and conditioned upon the operator faithfully performing all of the requirements of this article and of the permit. The penal amount of the bond shall be not less than one thousand dollars nor more than five thousand dollars for each acre or fraction thereof: Provided, That the minimum amount of bond furnished for any type of reclamation bonding shall be ten thousand dollars. The bond shall cover: (1) The entire permit area; or (2) that increment of land within the permit area upon which the operator will initiate and conduct surface mining and reclamation operations within the initial term of the permit. If the operator chooses to use incremental bonding, as succeeding increments of surface mining and reclamation operations are to be initiated and conducted within the permit area, the operator shall file with the secretary an additional bond or bonds to cover the increments in accordance with this section: Provided, however, That once the operator has chosen to proceed with bonding either the entire permit area or with incremental bonding, the operator shall continue bonding in that manner for the term of the permit.

(b) The period of liability for bond coverage begins with issuance of a permit and continues for the full term of the permit plus any additional period necessary to achieve compliance with the requirements in the reclamation plan of the permit.

(c) (1) The form of the bond shall be approved by the secretary and may include, at the option of the operator, surety bonding, collateral bonding (including cash and securities), establishment of an escrow account, self-bonding or a combination of these methods. If collateral bonding is used, the operator may elect to deposit cash or collateral securities or certificates as follows: Bonds of the United States or its possessions, of the federal land bank or of the homeowners' loan corporation; full faith and credit general obligation bonds of the state of West Virginia, or other states, and of any county, district or municipality of the state of West Virginia or other states; or certificates of deposit in a bank in this state, which certificates shall be in favor of the department. The cash deposit or market value of such securities or certificates shall be equal to or greater than the penal sum of the bond. The secretary shall, upon receipt of any deposit of cash, securities or certificates, promptly place the same with the treasurer of the state of West Virginia whose duty it is to receive and hold the same in the name of the state in trust for the purpose for which the deposit is made when the permit is issued. The operator making the deposit is entitled, from time to time, to receive from the state treasurer, upon the written approval of the secretary, the whole or any portion of any cash, securities or certificates so deposited, upon depositing with him or her in lieu thereof, cash or other securities or certificates of the classes herein specified having value equal to or greater than the sum of the bond.

(2) The secretary may approve an alternative bonding system if it will: (1) Reasonably assure that sufficient funds will be available to complete the reclamation, restoration and abatement provisions for all permit areas which may be in default at any time; and (2) provide a substantial economic incentive for the permittee to comply with all reclamation provisions.

(d) The secretary may accept the bond of the applicant itself without separate surety when the applicant demonstrates to the satisfaction of the secretary the existence of a suitable agent to receive service of process and a history of financial solvency and continuous operation sufficient for authorization to self-insure.

(e) It is unlawful for the owner of surface or mineral rights to interfere with the present operator in the discharge of the operator's obligations to the state for the reclamation of lands disturbed by the operator.

(f) All bond releases shall be accomplished in accordance with the provisions of section twenty-three of this article.

(g) The special reclamation fund previously created is continued. The moneys accrued in the fund, including interest, are reserved solely and exclusively for the purposes set forth in this section and section seventeen, article one of this chapter. The fund shall be administered by the secretary who is authorized to expend the moneys in the fund for the reclamation and rehabilitation of lands which were subjected to permitted surface mining operations and abandoned after the third day of August, one thousand nine hundred seventy-seven, where the amount of the bond posted and forfeited on the land is less than the actual cost of reclamation, and where the land is not eligible for abandoned mine land reclamation funds under article two of this chapter. The secretary shall develop a long-range planning process for selection and prioritization of sites to be reclaimed so as to avoid inordinate short-term obligations of the assets in the fund of such magnitude that the solvency of the fund is jeopardized. The secretary may use the special reclamation fund for the purpose of designing, constructing and maintaining water treatment systems when they are required for a complete reclamation

of the affected lands described in this subsection. The secretary may also expend an amount not to exceed ten percent of the total annual assets in the fund to implement and administer the provisions of this article and, as they apply to the surface mine board, articles one and four, chapter twenty-two-b of this code.

(h) Prior to the first day of January, two thousand two, every person conducting coal surface mining operations shall contribute into the fund a sum equal to three cents per ton of clean coal mined. For tax periods commencing on and after the first day of January, two thousand two, every person conducting coal surface mining shall contribute into the fund as follows: (1) For a period not to exceed thirty-nine months, seven cents per ton of clean coal mined; and (2) an additional seven cents per ton of clean coal mined. The tax shall be levied upon each ton of clean coal severed or clean coal obtained from refuse pile and slurry pond recovery or clean coal from other mining methods extracting a combination of coal and waste material as part of a fuel supply on or after the first day of January, two thousand two. The additional seven-cent tax shall be reviewed and, if necessary, adjusted annually by the Legislature upon recommendation of the council pursuant to the provisions of section seventeen, article one of this chapter: Provided, That the tax may not be reduced until the special reclamation fund has sufficient moneys to meet the reclamation responsibilities of the state established in this section.

(i) This special reclamation tax shall be collected by the state tax commissioner in the same manner, at the same time and upon the same tonnage as the minimum severance tax imposed by article twelve-b, chapter eleven of this code is collected: Provided, That under no circumstance shall the special reclamation tax be construed to be an increase in either the minimum severance tax imposed by said article or the severance tax imposed by article thirteen of said chapter.

(j) Every person liable for payment of the special reclamation tax shall pay the amount due without notice or demand for payment.

(k) The tax commissioner shall provide to the secretary a quarterly listing of all persons known to be delinquent in payment of the special reclamation tax. The secretary may take the delinquencies into account in making determinations on the issuance, renewal or revision of any permit.

(l) The tax commissioner shall deposit the fees collected with the treasurer of the state of West Virginia to the credit of the special reclamation fund. The moneys in the fund shall be placed by the treasurer in an interest-bearing account with the interest being returned to the fund on an annual basis.

(m) At the beginning of each quarter, the secretary shall advise the state tax commissioner and the governor of the assets, excluding payments, expenditures and liabilities, in the fund.

(n) To the extent that this section modifies any powers, duties, functions and responsibilities of the department that may require approval of one or more federal agencies or officials in order to avoid disruption of the federal-state relationship involved in the implementation of the federal Surface Mining Control and Reclamation Act, 30 U.S.C. 1270 by the state, the modifications will become effective upon the approval of the modifications by the appropriate federal agency or official.

3. Section 22–3–12 Site-Specific Bonding

Subsection 22–3–12(b) is deleted in its entirety, and the remaining subsections relettered.

Various clarifying word changes have been made to subsections 22–3–12(b) through (d) (formerly (c) through (e)).

Subsection 22–3–12(f) has been deleted in its entirety.

The amended section 22–3–12 is quoted below.

22–3–12. Site-specific bonding; legislative rule; contents of legislative rule; legislative intent.

(a) Notwithstanding the provisions of section eleven of this article, the secretary may establish and implement a site-specific bonding system in accordance with the provisions of this section.

(b) A legislative rule proposed or promulgated pursuant to this section must provide, at a minimum, for the following:

(1) The penal amount of a bond shall be not less than one thousand dollars nor more than five thousand dollars per acre or fraction thereof.

(2) Every bond, subject to the limitations of subdivision (1) of this subsection, shall reflect the relative potential cost of reclamation associated with the activities proposed to be permitted, which would not otherwise be reflected by bonds calculated by merely applying a specific dollar amount per acre for the permit.

(3) Every bond, subject to the provisions of subdivision (1) of this subsection, shall also reflect an analysis under the legislative rule of various factors, as applicable, which affect the cost of reclamation, including, but not limited to: (A) The general category of mining, whether surface or underground; (B) mining techniques and methods proposed to be utilized; (C) support facilities, fixtures, improvements and equipment; (D) topography and geology; and (E) the potential for degrading or improving water quality.

(c) A legislative rule proposed or promulgated pursuant to the provisions of this section may, in addition to the requirements of subsection (b) of this section, provide for a consideration of other factors determined to be relevant by the secretary. For example, the rule may provide for the following:

(1) A consideration as to whether the bond relates to a new permit application, a renewal of an existing permit, an application for an incidental boundary revision or the reactivation of an inactive permit;

(2) A consideration of factors which may result in environmental enhancement, as in a case where remining may improve water quality or reduce or eliminate existing highwalls, or a permitted operation may create or improve wetlands; or

(3) An analysis of various factors related to the specific permit applicant, including, but not limited to: (A) The prior mining experience of the applicant with the activities sought to be permitted; and (B) the history of the applicant as it relates to prior compliance with statutory and regulatory requirements designed to protect, maintain or enhance the environment in this or any other state.

(d) It is the intent of the Legislature that a legislative rule proposed or promulgated pursuant to the provisions of this section shall be constructed so that when the findings of fact by the division [Sic] of environmental protection with respect to the proposed mining activity and the particular permit applicant coincide with the particular factors or criteria to be considered and analyzed under the rule, the rule will direct a conclusion as to the amount of the bond to be required, subject to rebuttal and refutation of the findings by the applicant. To the extent practicable, the rule shall limit subjectivity and discretion by the secretary and the division [Sic] in fixing the amount of the bond.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments, on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the West Virginia program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendation(s). In the final rulemaking, we will not necessarily consider or include in the administrative record any comments received after the time indicated under **DATES** or at locations other than the Charleston Field Office.

Electronic Comments

Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SPATS NO. WV–093–FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Charleston Field office at (304) 347–7158.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during our normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law.

Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comment We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:30 p.m. (local time), on November 8, 2001. 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.

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.

If you are disabled and need special accommodation to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings are open to the public and, if possible, we will post notices of the meetings at the locations listed under **ADDRESSES.** We will make a written summary of each meeting a part of the Administrative Record.

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 regulations.

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, to the extent allowable by law, 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 such 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 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 affect 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

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined 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. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. 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 regulation.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), 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, geographic regions or Federal, State, or local government agencies; and (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 a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 4, 2001.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 01–26770 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 173

[USCG–1999–6094]

RIN 2115–AF87

Raising the Threshold of Property Damage for Reports of Accidents Involving Recreational Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of reopening of comment period.

SUMMARY: The Coast Guard is reopening the period for public comment on a partial suspension of rule with request for comments published on June 26, 2001. The chairman of a subcommittee of the National Association of State Boating Law Administrators (NASBLA) asked that we reopen the comment period so his subcommittee could discuss the rule at their meeting in October 2001 and submit a comment to the docket. We are reopening the period for 30 days so the subcommittee and other interested persons can submit comments.

DATES: Comments must reach the docket on or before November 23, 2001.

ADDRESSES: Identify your comments and related material by the docket number for this rulemaking [USCG–1999–6094]. To make sure they do not enter the docket more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand-delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Internet site for the Docket Management System at *http://dms.dot.gov.*

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, at the address listed above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.* You may obtain a copy of this partial suspension of final rule by calling the Infoline of the U.S. Coast Guard at 1–800–368–5647, or read it on the Internet, at the Web site for the Office of Boating Safety, at *http://www.uscgboating.org* or at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this notice, contact Bruce Schmidt, Project Manager, Office of Boating Safety, U.S. Coast Guard, by telephone at 202–267–0955 or by e-mail at *bschmidt@comdt.uscg.mil.* For questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–5149.

SUPPLEMENTARY INFORMATION:

Regulatory History

The early regulatory history for this rulemaking appears in the preamble of the final rule entitled ''Raising the Threshold of Property Damage for Reports of Accidents Involving Recreational Vessels'' [66 FR 21671 (May 1, 2001)].

Reason for Partial Suspension of Effective Date

After we issued the final rule on May 1, 2001, a State boating-law administrator expressed concern about a provision in the rule requiring reports of all collisions involving two or more vessels resulting exclusively in damage to property, regardless of the amount of such damage.

Currently, few States have statutory authority to require reports of multi-vessel accidents that result neither in personal injury nor in any damage to property. Further, States' legislative calendars precluded compliance by the published effective date, July 2, 2001. We note that States' legislation would be unnecessary if our provision for reporting collisions of two or more vessels included a threshold of $500, since all States do now maintain such a threshold. Because of the concern raised about the impact of our provision on States' legislation, the Coast Guard delayed implementation of that provision, in 33 CFR 173.55(a)(3), requiring a report whenever ''* * * a collision occurs involving two or more vessels, regardless of the amount of damage to property; * * *'', and provided a 90-day comment period on the provision.

Reason for Reopening the Comment Period

In response to the notice of partial suspension of effective date, we received 28 comments, including a request from the Chairman of the Boating Accident Investigation Reporting and Analysis Committee (BAIRAC) of NASBLA to extend the comment period beyond the meeting of BAIRAC in October 2001. We are reopening the comment period until November 23, 2001 to let BAIRAC discuss the suspended provision at that meeting and submit a comment to the docket. We are also reopening it to anyone else who would like to submit a comment, but please do not re-submit comments already in the docket.

Request for Comments

We encourage you to participate in this rulemaking by submitting your comments to the Docket Management Facility as specified in **ADDRESSES.** Please submit comments and materials related only to the provision in 33 CFR 173.55(a)(3), requiring a report whenever ''* * * a collision occurs involving two or more vessels, regardless of the amount of damage to property; * * *''. We will consider comments received during this reopened comment period and may change 33 CFR 173.55(a)(3) in response to the comments.

Dated: October 18, 2001.

Kenneth T. Venuto,

Rear Admiral, U.S. Coast Guard, Acting Assistant Commandant for Operations.

[FR Doc. 01–26814 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 272

[FRL–7014–8]

Indiana: Incorporation by Reference of Approved State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to codify in part 272 of Title 40 of the Code of Federal Regulations (CFR) Indiana's authorized hazardous waste program. EPA will incorporate by reference into the CFR those provisions of the State statutes and regulations that are authorized and federally enforceable. In the ''Rules and Regulations'' section of this **Federal Register**, the EPA is codifying and incorporating by reference the State's hazardous waste program as an immediate final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. The Agency has explained the reasons for this codification and incorporation by reference in the preamble to the immediate final rule. If EPA does not receive adverse written comments, the immediate final rule will become effective and the Agency will not take further action on this proposal. If EPA receives adverse written comments, EPA will withdraw the immediate final rule and it will not take effect. EPA will then address public comments in a later final rule based on this proposal. EPA may not provide further opportunity for comment. Any parties interested in commenting on this action must do so at this time.

DATES: Written comments must be received on or before November 23, 2001.

ADDRESSES: Mail written comments to Gary Westefer, Indiana Regulatory Specialist, U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7450.

FOR FURTHER INFORMATION CONTACT: Gary Westefer at the address listed in **ADDRESSES** and (312) 886–7450.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: July 3, 2001.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 01–26683 Filed 10–23–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2381, MM Docket No. 01–298, RM–10299]

Radio Broadcasting Services; Camden, AL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 280A at Camden, Alabama, providing the community with additional local FM service. The coordinates for Channel 280A at Camden are 32–04–21 and 87–13–52. There is a site restriction 10.7 kilometers (6.6 miles) northeast of the community.

DATES: Comments must be filed on or before December 3, 2001, and reply comments on or before December 18, 2001.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Charles Crawford, 4553 Bordeaux Avenue, Dallas, Texas 75205.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–298, adopted October 3, 2001 and released October 12, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

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* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by adding Channel 280A at Camden.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–26751 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2376; MM Docket No. 01–291; RM–10301; MM Docket No. 01–292; RM–10302; MM Docket No. 01–293; RM–10303; MM Docket No. 01–294; RM–10304; MM Docket No. 01–295; RM–10305]

Radio Broadcasting Services; Cherokee; OK; Ballinger, TX; Crowell, TX; Eldorado, TX; and Jayton, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes new allotments to Cherokee, OK; Ballinger, TX; Crowell, TX; Eldorado, TX and Jayton, TX. The Commission requests comments on a petition filed by Maurice Salsa, proposing the allotment of Channel 237C2 at Cherokee, OK, as that community's first local aural transmission service. Channel 237C2 can be allotted to Cherokee at a restricted site located 23.9 kilometers southwest of the community, utilizing coordinates 36–39–27 NL and 98–35–45 WL. *See* **SUPPLEMENTARY INFORMATION,** *infra.*

DATES: Comments must be filed on or before December 3, 2001, and reply

comments on or before December 18, 2001.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, as follows: Maurice Salsa, 5616 Evergreen Valley Drive, Kingwood, TX 77345 (petitioner for Cherokee, OK); Jeraldine Anderson, 1702 Cypress Drive, Irving, TX 75061 (petitioner for Ballinger, TX; Crowell, TX; and Eldorado, TX); and Linda Crawford, 3500 Maple Ave., #1320, Dallas, TX 75219 (petitioner for Jayton, TX).

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–291; MM Docket No. 01–292; MM Docket No. 01–293; MM Docket No. 01–294; and MM Docket No. 01–295, adopted October 3, 2001, and released October 12, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualtex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893.

In addition to the above, the Commission requests comments on a petition filed by Jeraldine Anderson proposing the allotment of Channel 238A at Ballinger, Texas, as that community's second local commercial FM service. Channel 238A requires a site restriction 12.8 kilometers southeast of the community, utilizing coordinates 31–38–03 NL and 99–53–13 WL. Additionally, as Ballinger, Texas, is located within 320 kilometers of the U.S.-Mexico border, concurrence of the Mexican government will be requested for this allotment.

The Commission further requests comments on a petition filed by Jeraldine Anderson proposing the allotment of Channel 250C3 at Crowell, Texas, as that community's potential second local FM transmission service. Channel 250C3 requires a site restriction 3.1 kilometers southwest of the community, utilizing coordinates 33–57–54 NL and 99–44–59 WL.

The Commission further requests comments on a petition filed by Jeraldine Anderson proposing the allotment of Channel 293A at Eldorado, Texas, as an additional local commercial FM transmission service at that community. Channel 293A requires a site restriction 1.3 kilometers southwest of the community, utilizing coordinates 30–51–14 NL; 100–36–43 WL. Additionally, as Eldorado is located within 320 kilometers of the U.S.-Mexico border, concurrence of the Mexican government will be requested for this allotment.

The Commission further requests comments on a petition filed by Linda Crawford proposing the allotment of Channel 231A at Jayton, Texas, as that community's first local aural transmission service. Channel 231A can be allotted to Jayton at city reference coordinates 33–14–53 NL and 100–34–24 WL.

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

Radio 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by adding Cherokee, Channel 237C2.

3. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 238A at Ballinger; Crowell, Channel 250C3; Channel 293A at Eldorado; and Jayton, Channel 231A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–26749 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AG92

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for Thlaspi californicum (Kneeland Prairie Penny-cress)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for *Thlaspi californicum* (Kneeland Prairie penny-cress). Approximately 30 hectares (74 acres) in Humboldt County, California, are proposed for designation as critical habitat. If this proposal is made final, section 7 of the Act requires Federal agencies to ensure that any actions they fund, authorize, or carry out do not result in the destruction or adverse modification of critical habitat. Section 4 of the Act requires us to consider economic and other relevant impacts when specifying any particular area as critical habitat.

We solicit data and comments from the public on all aspects of this proposal, including data on economic and other impacts of the designation. We may revise this proposal prior to final designation to incorporate or address new information received during the comment period.

DATES: We will accept comments until December 24, 2001. Public hearing requests must be received by December 10, 2001.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Project Leader, Arcata Fish and Wildlife Office, U.S. Fish and Wildlife Service, 1655 Heindon Road, Arcata, California 95521.

2. You may also send comments by electronic mail (e-mail) to *FW1_kneelandpennycress@fws.gov*. See the Public Comments Solicited section below for file format and other information about electronic filing.

3. You may hand-deliver comments to our Arcata Fish and Wildlife Office at the address given above.

Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Bruce Halstead, Project Leader, Arcata Fish and Wildlife Office, U.S. Fish and Wildlife Service, 1655 Heindon Road, Arcata, California 95521 (telephone 707/822–7201; facsimile 707/822–8411).

SUPPLEMENTARY INFORMATION:

Background

Thlaspi californicum (Kneeland Prairie penny-cress) is a perennial member of the mustard family (Brassicaceae). The species grows from 9.5 to 12.5 centimeters (3.7 to 4.9 inches) tall with a basal cluster of green to purplish, sparsely toothed leaves. Leaves borne along the stem are sessile (without a stalk) with entire to toothed margins. The white flowers have strongly ascending flower stalks. *Thlaspi californicum* flowers from April to June. The fruit is a sharply pointed silicle (a short fruit typically no more than two to three times longer than wide), and is elliptic to obovate, without wings, and with an ascending stalk.

Serano Watson (1882) first described *Thlaspi californicum* based on a collection made by Volney Rattan from among rocks at Kneeland Prairie at 760 meters (m) (2,500 feet (ft)) elevation. Jepson (1925) later referred to it as *T. alpestre* var. *californicum*. Munz (1959) referred to the taxon as *T. glaucum* var. *hesperium*; however, he segregated it as *T. californicum* in his supplement (Munz 1968). Holmgren (1971) assigned the name *Thlaspi montanum* var. *californicum*. Finally, the taxon was returned to *T. californicum* in the current Jepson Manual (Hickman 1993; Rollins 1993).

Thlaspi californicum is endemic to serpentine soils in Kneeland Prairie, located in the outer north coast range of Humboldt County, California. Serpentine soils are derived from ultramafic rocks (rocks with unusually large amounts of magnesium and iron). The entire known distribution of *T. californicum* occurs on Ashfield Ridge at elevations ranging from 792 to 841 m (2,600 to 2,760 ft).

Plant communities in Kneeland Prairie include the following: California annual and introduced perennial grasslands; seasonal and perennial wetlands; and mixed oak/Douglas-fir woodlands (SHN 1997). Boulder outcrops in Kneeland Prairie form scattered knobs that protrude out of the grasslands. The majority of these outcrops are volcanic rock types such as greenstone pillow basalt, basalt, tuff, or agglomerates (State of California 1975). Along Ashfield Ridge and nearby side ridges, many of the outcrops are serpentine (State of California 1975). The serpentine outcrops exhibit a distinctive flora compared to the surrounding grassland (SHN 2001). In addition to *Thlaspi californicum*, serpentine outcrops on Ashfield Ridge support the following two special interest plants, both considered as rare by the California Native Plant Society: *Fritillaria purdyi* (Purdy's fritillary) and *Astragalus rattanii* (Rattan's milk-vetch) (SHN 1997).

Little is known about the reproductive biology of *Thlaspi californicum*. Some members of the genus, such as *T. montanum*, are known to be outbreeding, while others, such as *T. alpestre*, are primarily self-pollinating (Holmgren 1971). Due to its very close taxonomic relationship to *T. montanum*, *T. californicum* is almost certainly an outbreeder. The principal pollinators are believed to be generalist bees and/or flies (SHN 2001).

The only known occurrence of *Thlaspi californicum* includes five relatively distinct groups of plants all located within 300 m (980 ft) of each other. The area occupied by the species is divided by the Kneeland Airport and Mountain View Road. We do not know if genetic interchange occurs between plants in these separate groups; therefore, the five areas will be referred to as individual colonies. The location was described as consisting of three colonies in 1990 (Imper 1990; SHN 2001); a fourth colony was discovered in 1999 (SHN 2001), and one additional colony in 2001 (SHN 2001).

In 1997, the largest colony was estimated at 10,840 plants (SHN 1997); this estimate was later corrected to 9,919 plants (SHN 2001). The sizes of the other two colonies known in 1997 were 140 and 40 plants (SHN 1997); therefore, the total revised estimate in 1997 was 10,099 plants. In 2001, the total number of *Thlaspi californicum* plants was estimated at approximately 5,293 (SHN 2001), with 5,142 plants at the largest colony, and 90 plants, 30 plants, 16 plants, and 15 plants at the four smaller colonies. These data suggest the total number of plants has declined by about 48 percent since 1997, even though two new small colonies have been discovered (SHN 2001).

Historically, several land use activities may have altered the distribution and abundance of *Thlaspi californicum* colonies. These activities included construction of the county road in the 1800s (currently Mountain View Road), the Kneeland Airport in 1964, and the California Department of Forestry & Fire Protection (CDFFP) helitack base in 1980. Prior to 1964, suitable habitat for *T. californicum* on Ashfield Ridge consisted of two serpentine patches (1.9 hectares (ha) (4.7 acres (ac)) and 0.6 ha (1.4 ac)) and scattered smaller patches of 0.01 ha (0.02 ac) to 0.2 ha (0.6 ac) in size. The two larger serpentine outcrops formed a semi-continuous ridgetop exposure covering more than 2.4 ha (6 ac), extending in an east-west direction along the top of the ridge in the area now occupied by the airstrip, county road, and helitack base (SHN 2001).

Construction of the county road, airstrip, and helitack base fragmented the two largest patches of suitable habitat into four relatively isolated patches. The construction also reduced the total available habitat by approximately 50 percent. No data are available on the distribution or number of individuals prior to this habitat alteration. However, anecdotal evidence indicates that prior to this habitat loss these colonies occupied more area or formed one large colony. The impacts on population or community processes from this habitat loss and possible population reduction are unknown. In general, smaller serpentine outcrops are known to support fewer native species and more exotic species (Wolf and Harrison 2001). Smaller outcrops may also be more vulnerable to recreational impacts, trampling, and modification of the unique serpentine soil chemistry as a result of enrichment from the surrounding meadow system (SHN 2001). All of these factors, in addition to a reduction and/or fragmentation of the site, increase the likelihood of extinction.

In 2001, all the known colonies occupied an estimated 0.3 ha (0.8 ac), divided among the five colonies as follows: 0.29 ha (0.72 acre); 0.02 ha (0.05 ac); 0.008 ha (0.02 ac); 0.004 ha (0.01 ac); and 0.002 ha (0.005 ac). The five known colonies occur on three separate serpentine outcrops, but currently occupy only about 29 percent of the suitable habitat on these three outcrops (total area 1.1 ha (2.8 ac)). In addition to the three occupied outcrops, fourteen unoccupied serpentine outcrops occur on Ashfield Ridge, ranging in size from 0.01 ha (0.02 ac) to 0.2 ha (0.6 ac) (combined area of 0.9 ha (2.2 ac)). The distances between the outcrops range from 10 m to 85 m (33 ft to 279 ft). All of these patches are located within 400 m (1,312 ft) of the largest *T. californicum* colony. Serpentine soils contiguous with and in the vicinity of the colonies are the most likely to support *T. californicum* in the future.

Historic records for *Thlaspi californicum* refer to Kneeland Prairie and Ashfield Ridge as site locations (Watson 1882; Holmgren 1971). Over 99

percent of the serpentine soils in Kneeland Prairie occur on Ashfield Ridge. Two additional small serpentine outcrops are located on a ridge approximately 4.8 kilometers (km) (3 miles (mi)) southwest of Ashfield Ridge (State of California 1975). We do not have any historic records to show that these two outcrops were once occupied by *T. californicum* or current records to indicate that they are occupied. The next nearest known serpentine outcrops to Kneeland Prairie occur approximately 6.4 km (4 mi) southeast of Ashfield Ridge at Iaqua Buttes. The serpentine at Iaqua Buttes supports the more widespread *T. montanum.* No evidence of *T. californicum* or intergradation between *T. californicum* and *T. montanum* was observed during surveys at the Iaqua Buttes site in 2001 (SHN 2001). *Thlaspi montanum* also occurs on serpentine soils in the vicinity of Horse Mountain approximately 24 km (15 mi) northeast of Ashfield Ridge (SHN 2001). Evidence that the historic range of *T. californicum* ever extended beyond Kneeland Prairie does not currently exist (SHN 2001).

Previous Federal Action

Federal Government actions for *Thlaspi californicum* began when we published an updated notice of review (NOR) for plants on December 15, 1980 (45 FR 82480). This notice included *T. californicum* (referred to as *T. montanum* var. *californicum*) as a category 2 candidate. Category 2 candidates were those taxa for which data in our possession indicated listing might be appropriate, but for which additional biological information was needed to support a proposed rule. On November 28, 1983, we published a supplement to the 1980 NOR (48 FR 53640) as well as the subsequent revision on September 27, 1985 (50 FR 39526) which included *T. m.* var. *californicum* as a category 2 candidate.

We published revised NORs on February 21, 1990 (55 FR 6184) and September 30, 1993 (58 FR 511440). In both notices, we included *Thlaspi montanum* var. *californicum* as a category 1 candidate. Category 1 candidates are those taxa for which we have on file sufficient information on biological vulnerability and threats to support preparation of listing proposals, but issuance of the proposed rules are precluded by other pending listing proposals of higher priority. In our February 28, 1996, **Federal Register** Notice of Review of Plant and Animal Taxa that are Candidates for Listing as Endangered or Threatened Species (CNOR) (61 FR 7595), we discontinued designation of multiple categories of candidates. Only those taxa meeting the definition of former category 1 are now considered candidates for listing. *Thlaspi montanum* var. *californicum* was included as a candidate species in the February 28, 1996, notice. Our September 19, 1997, CNOR (62 FR 49397) included *T. californicum* as a candidate for listing.

On February 12, 1998 (63 FR 7112), we published a proposal to list *Thlaspi californicum* as endangered. Our October 25, 1999, CNOR (64 FR 57533) included *T. californicum* as a taxon proposed for listing as endangered. The final rule listing *T. californicum* as an endangered species was published on February 9, 2000 (65 FR 6332).

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) the species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species; or (2) such designation of critical habitat would not be beneficial to the species. At the time *Thlaspi californicum* was proposed, we determined that designation of critical habitat for *T. californicum* was not prudent because of a concern that publication of precise maps and descriptions of critical habitat in the **Federal Register** could increase the vulnerability of this species to incidents of collection and vandalism. We also indicated that designation of critical habitat was not prudent because we believed it would not provide any additional benefit beyond that provided through listing as endangered.

A series of court decisions for a variety of species overturned our determinations that designation of critical habitat would not be prudent (*e.g., Natural Resources Defense Council* v. *U.S. Department of the Interior* 113 F. 3d 1121 (9th Cri. 1997); *Conservation Council for Hawaii* v. *Babbitt,* 2 F. Supp. 2d 1280 (D. Hawaii 1998)). Based on the standards applied in those judicial opinions, we reexamined the question of whether designation of critical habitat for *Thlaspi californicum* was prudent. At the time *T. californicum* was listed, we found that designation of critical habitat was prudent.

On June 17, 1999, our failure to issue final rules for listing *Thlaspi californicum* and nine other plant species as endangered or threatened, and our failure to make a final critical habitat determination for the 10 species was challenged in *Southwest Center for Biological Diversity and California Native Plant Society* v. *Babbitt* (Case No. C99–2992 (N.D.Cal.)). On May 19, 2000, the U.S. District Court for the Northern District of California issued an order setting the timetable for the promulgation of the critical habitat designations. We agreed to complete the proposed critical habitat designations for the 10 species by September 30, 2001. However, in mid-September 2001, plaintiffs agreed to a brief extension of this due date until October 19, 2001. We will make our final critical habitat determinations no later than May 1, 2002.

Critical Habitat

Critical habitat is defined in section 3(5)(A) of the Act as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. Areas outside the geographic area currently occupied by the species shall be designated as critical habitat only when a designation limited to its present range would be inadequate to ensure the conservation of the species.

Conservation is defined in section 3(3) of the Act as the use of all methods and procedures which are necessary to bring any endangered or threatened species to the point at which listing under the Act is no longer necessary. Regulations under 50 CFR 424.02(j) define special management considerations or protection to mean any methods or procedures useful in protecting the physical and biological features of the environment for the conservation of listed species.

In order to be included in a critical habitat designation, the habitat must first be ''essential to the conservation of the species.'' Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (i.e., areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

When we designate critical habitat at the time of listing, as required under

Section 4 of the Act, or under short court-ordered deadlines, we may not have the information necessary to identify all areas which are essential for the conservation of the species. Nevertheless, we are required to designate those areas we know to be critical habitat, using the best information available to us.

We will designate only currently known essential areas. Essential areas should already have the features and habitat characteristics that are necessary to sustain the species. We will not speculate about what areas might be found to be essential if better information became available, or what areas may become essential over time. If the information available at the time of designation does not show that an area provides essential life cycle needs of the species, then the area should not be included in the critical habitat designation. We will not designate areas that do not now have the primary constituent elements, as defined at 50 CFR 424.12(b), that provide essential life cycle needs of the species.

Our regulations state that, ''The Secretary shall designate as critical habitat areas outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species.'' (50 CFR 424.12(e)). Accordingly, we do not designate critical habitat in areas outside the geographic area occupied by the species unless the best scientific and commercial data demonstrate that the unoccupied areas are essential for the conservation needs of the species.

Our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), provides criteria, establishes procedures, and provides guidance to ensure that our decisions represent the best scientific and commercial data available. It requires our biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, and biological assessments, unpublished materials, and expert opinion or personal knowledge.

Methods

As required by the Act and regulations (section 4(b)(2) and 50 CFR 424.12) we used the best available scientific information in determining which areas are essential for the conservation of *Thlaspi californicum*. This information included data from the following sources: 1993 United States Geological Survey (USGS) 1:24,000 scale 3.75′ infrared color digital orthophotographic quarter quadrangle images; geologic map of the Van Duzen River Basin (State of California 1975); 1962 panchromatic 1:12,000 scale aerial photograph HCN–222–17; ownership parcels from the Humboldt County Planning Department, updated as of August 2000; recent biological surveys and reports; and discussions with botanical experts. We also conducted or contracted for site visits, either cursory or more extensive, at locations on private lands where access had been obtained, on State lands managed by CDFFP, and on public lands managed by Six Rivers National Forest and the Bureau of Land Management, including Iaqua Buttes and Board Camp Mountain.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat, we consider those physical and biological features (primary constituent elements) that are essential to the conservation of the species and that may require special management considerations or protection. These include, but are not limited to: space for individual and population growth, and for normal behavior; food, water, air, light, minerals or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

The long-term probability of survival and recovery of *Thlaspi californicum* is dependent upon a number of factors, including protection of serpentine sites containing existing colonies; protection of all serpentine sites on Ashfield Ridge to allow for recolonization or expansion; preservation of the connectivity between serpentine sites to allow gene flow between the colonies through pollinator activity and seed dispersal mechanisms; and protection and maintenance of proximal areas for the survival of pollinators and seed dispersal agents. In addition, the small, fragmented distribution of this species makes it especially vulnerable to edge effects from adjacent activities, such as the spread of non-native species; nearby uses of herbicides and pesticides; livestock grazing; and erosion due to natural or diverted flow patterns.

Based on our knowledge of this species to date, the primary constituent elements of critical habitat for *Thlaspi californicum* consist of, but are not limited to:

(1) Thin rocky soils that have developed on exposures of serpentine substrates (SHN 2001);

(2) Plant communities that support a relatively sparse assemblage of serpentine indicator or facultative-serpentine indicator species, including various native forbs and grasses but not trees or shrubs, such that competition for space and water (both above and below ground), and light is reduced, compared to the surrounding habitats (SHN 2001). Known associated species include: *Festuca rubra* (red fescue), *Koeleria macrantha* (junegrass), *Elymus glaucus* (blue wildrye), *Eriophyllum lanatum* (woolly sunflower), *Lomatium macrocarpum* (large-fruited lomatium), and *Viola hallii* (Hall's violet) (SHN 2001);

(3) Serpentine substrates that contain 15 percent or greater (by surface area) of exposed gravels, cobbles, or larger rock fragments, which may contribute to alteration of factors of microclimate, including surface drainage and moisture availability, exposure to wind and sun, and temperature (SHN 2001); and

(4) Prairie grasslands and oak woodlands located within 30 m (100 ft) of the serpentine outcrop area on Ashfield Ridge. Protection of these habitats is essential to the conservation of the *Thlaspi californicum* in that it will provide connectivity among the serpentine sites, help to maintain the hydrologic and edaphic integrity of the serpentine sites, and support populations of pollinators and seed dispersal organisms.

Criteria Used To Identify Critical Habitat

In our delineation of the critical habitat unit, we selected areas to provide for the conservation of *Thlaspi californicum* at the only location it is known to occur. Adult individuals of the species are currently only growing on approximately 0.3 ha (0.8 ac) of land on Ashfield Ridge in Kneeland Prairie. However, the area essential for the conservation of the species is not restricted solely to the area where the plant is physically visible. It must include an area large enough to maintain the ecological functions upon

which the species depends (*e.g.,* the hydrologic and edaphic conditions).

We first mapped all the known *T. californicum* occurrences. Due to the historic loss and fragmentation of the largest patches of suitable habitat, we also mapped all suitable habitat in proximity to the known occurrences. Maintaining the number and distribution of serpentine outcrops on Ashfield Ridge will help to ensure the long-term viability of *T. californicum*, as high-quality habitat patches in close proximity to a source population which have the highest likelihood of future occupancy (Murphy *et al.* 1990). Protection of these outcrops will provide a range in habitat conditions, for example, moisture availability, temperature, and wind exposure, which will optimize the opportunities for recolonization or expansion and reduce the likelihood of extinction due to stochastic events. They will also provide protection of undetected *T. californicum* colonies and seed banks.

We also mapped grasslands and oak woodlands surrounding the serpentine outcrops. These areas provide connectivity between all serpentine outcrops; maintain the hydrologic and edaphic integrity of the serpentine sites; and support biological agents of pollination and seed dispersal deemed necessary for the conservation of the species. Inclusion of the grasslands and oak woodlands will also minimize impacts to the serpentine outcrops resulting from external peripheral influences, such as erosion, grazing, or the spread of exotic species.

At this time, we do not propose to designate as critical habitat any serpentine outcrops within Kneeland Prairie, other than the outcrops on Ashfield Ridge. Serpentine outcrops not located on Ashfield Ridge, however, may also be necessary for the conservation of *Thlaspi californicum*. Since *T. californicum* has an extremely restricted range, establishment at new locations may be necessary to provide insurance against stochastic events. A draft recovery plan for this species has not been completed. The recovery plan may provide additional guidance regarding areas essential for the conservation of the species. If necessary, we will reexamine our critical habitat designation after completion of the recovery plan.

We considered ownership status in proposing areas as critical habitat. *Thlaspi californicum* is known only to occur on State, county, and private lands. We could not depend on Federal lands for critical habitat designation because we are not currently aware of any Federal lands occupied by this taxon. We are not aware of any Tribal lands in or near our proposed critical habitat unit for *T. californicum*. However, should we learn of any Tribal lands in the vicinity of the critical habitat designation subsequent to this proposal, we will coordinate with the Tribes before making a final determination as to whether any Tribal lands should be included as critical habitat for *T. californicum*.

We used a geographic information system (GIS) to facilitate the identification of proposed critical habitat. We used information from recent biological surveys and reports; discussions with botanical experts; and locations of serpentine soils to create GIS data layers. The serpentine soil sites were derived from a geologic map, infrared color digital orthophotos, and global positioning system data collected in the field during 2000 and 2001. These data layers were created on a base of 1:24,000 scale USGS 3.75′ infrared color digital orthophotographic quarter quadrangle images. We used the data layers to map the primary constituent elements. We defined the boundaries for the proposed critical habitat unit by overlaying this map with a 100-m Universal Transverse Mercator (UTM) North American Datum of 1927 (NAD27) grid and removing all NAD27 grid cells that did not contain the primary constituent elements.

In selecting areas of proposed critical habitat, we attempted to avoid developed areas and other lands unlikely to contribute to the conservation of *Thlaspi californicum*. However, we did not map the critical habitat unit in sufficient detail to exclude all such areas. Existing features and structures within the critical habitat unit boundary, such as buildings, roads, airports, and other paved areas will not contain one or more of the primary constituent elements. Federal actions limited to these areas, therefore, would not trigger a section 7 consultation, unless they affect the species and/or primary constituent elements in adjacent critical habitat.

Special Management Considerations

As noted in the Critical Habitat section, ''special management considerations or protection'' is a term that originates in the definition of critical habitat. We believe the proposed area may require special management considerations or protection because *Thlaspi californicum* occupies an extremely localized range and the number of individuals may be declining. Potential threats to the habitat of *T. californicum* include: Expansion of Kneeland Airport and CDFFP helitack base; road realignment; fires caused by airplane or vehicular accidents; contaminant spills; erosion; application of herbicides and pesticides; livestock grazing; and introduction and spread of exotic species.

Additional special management is not required if adequate management or protection is already in place. Adequate special management considerations or protection is provided by a legally operative plan/agreement that addresses the maintenance and improvement of the primary constituent elements important to the species and manages for the long-term conservation of the species. Currently, no plans meeting these criteria have been developed for *T. californicum*.

Proposed Critical Habitat Designation

The proposed critical habitat area described below includes all the primary constituent elements discussed above, and constitutes our best assessment at this time of the areas needed for the species' conservation. Critical habitat is being proposed for *Thlaspi californicum* at the only location it is known to occur. We are not proposing any critical habitat units that do not contain the species.

We propose designating one unit of critical habitat, comprising 30 ha (74 ac), surrounding Kneeland Airport and roughly bisected by Mountain View Road. The unit includes all five known colonies and all other serpentine outcrops in close proximity to the colonies. All of the proposed critical habitat for *Thlaspi californicum* is located on Ashfield Ridge in Kneeland Prairie, Humboldt County, California. This ridge separates the Van Duzen and Mad River basins near the community of Kneeland in central Humboldt County.

The unit contains approximately 2 ha (5 ac) of serpentine soils. Approximately 16 percent of the serpentine soils are known to be occupied. However, undetected colonies may exist on the serpentine soils within the unit. The approximate area, by land ownership, of this unit is shown in Table 1. Approximately 5 percent (2 ha (4 ac)) of this area consists of State lands, while County lands comprise approximately 11 percent (3 ha (8 ac)), and private lands comprise approximately 84 percent (25 ha (62 ac)). No Federal lands are within the proposed critical habitat unit. This species is not currently known to occur or to have occurred historically on Federal lands.

TABLE 1.—APPROXIMATE AREAS AND PERCENT OF PROPOSED CRITICAL HABITAT OF *Thlaspi californicum* IN HECTARES (HA) (ACRES (AC)) IN HUMBOLDT COUNTY, CALIFORNIA, BY LAND OWNERSHIP.

[Estimates reflect the total area within critical habitat unit boundaries]

Ownership	Hectares	Acres	Percent
State	2	4	5
Private	25	62	84
County	3	8	11
Federal	0	0	0
Total	30	74	100

Effects of Critical Habitat Designation

Section 7 Consultation

Habitat is often dynamic, and populations may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, all should understand that critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the applicable prohibitions of section 9, as determined on the basis of the best available information at the time of the action. If *Thlaspi californicum* is discovered outside of the designated critical habitat area, it is possible that federally funded or assisted projects affecting plants outside of the designated critical habitat area may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 also requires Federal agencies to confer with the Service on any actions that are likely to result in the destruction or adverse modification of critical habitat. In our regulations at 50 CFR 402.02, we define destruction or adverse modification as ''* * * a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.'' Aside from the added protection that may be provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat. Because consultation under section 7 of the Act does not apply to activities on private or other non-Federal lands that do not involve a Federal nexus, critical habitat designation would not afford any additional protections under the Act against such activities.

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, permit, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for the survival and recovery of the species. Individuals, organizations, States, local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding.

Section 7(a) of the Act requires Federal agencies, including the Service, to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat, if any is designated or proposed. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist Federal agencies in eliminating conflicts that may be caused by their proposed action(s). The conservation measures in a conference report are advisory. If a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to ensure that actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Through this consultation we would ensure that the permitted actions do not jeopardize the species or destroy or adversely modify critical habitat.

When we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. ''Reasonable and prudent alternatives'' are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation or conference with us on actions for which formal consultation

has been completed, if those actions may affect designated critical habitat, or adversely modify or destroy proposed critical habitat.

We may issue a formal conference report if requested by a Federal agency. Formal conference reports on proposed critical habitat contain an opinion that is prepared according to 50 CFR 402.14, as if critical habitat were designated. We may adopt the formal conference report as the biological opinion when the critical habitat is designated, if no substantial new information or changes in the action alter the content of the opinion (see 50 CFR 402.10(d)).

If *Thlaspi californicum* is discovered on Federal lands, those activities on Federal lands that may affect *Thlaspi californicum* or its critical habitat would require a section 7 consultation. Activities on private or State lands requiring a permit from a Federal agency, such as a permit from the Army Corps of Engineers under section 404 of the Clean Water Act, a section 10(a)(1)(B) permit from the Service, or some other Federal action, including funding (e.g., Federal Housing Administration or Federal Emergency Management Agency), will also continue to be subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat and actions on non-Federal and private lands that are not federally funded, authorized, or permitted do not require section 7 consultation.

Section 4(b)(8) of the Act requires us to evaluate briefly and describe within any proposed or final regulation that designates critical habitat those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat are those that appreciably reduce the value of critical habitat for both the survival and recovery of *Thlaspi californicum.* We note that such activities may also jeopardize the continued existence of the species.

To properly portray the effects of critical habitat designation, we must first compare the section 7 requirements for actions that may affect critical habitat with the requirements for actions that may affect a listed species. Section 7 prohibits actions funded, authorized, or carried out by Federal agencies from jeopardizing the continued existence of a listed species or destroying or adversely modifying the listed species' critical habitat. Actions likely to ''jeopardize the continued existence'' of a species are those that would appreciably reduce the likelihood of the species' survival and recovery. Actions likely to ''destroy or adversely modify'' critical habitat are those that would appreciably reduce the value of critical habitat for the survival and recovery of the listed species.

Common to both definitions is an appreciable detrimental effect on both survival and recovery of a listed species. Given the similarity of these definitions, actions likely to destroy or adversely modify critical habitat would almost always result in jeopardy to the species concerned, particularly when the area of the proposed action is occupied by the species concerned. Designation of critical habitat in areas occupied by *Thlaspi californicum* is not likely to result in a regulatory burden above that already in place due to the presence of the listed species. Designation of critical habitat in areas not occupied by *T. californicum* may result in an additional regulatory burden when a Federal nexus exists.

Activities that, when carried out, funded, or authorized by a Federal agency, may directly or indirectly destroy or adversely modify critical habitat include, but are not limited to:

(1) Ground disturbance of serpentine outcrops and grassland and oak woodland areas, including but not limited to, grading, ripping, tilling, and paving;

(2) Alteration of serpentine outcrops, including but not limited to, removal of boulders, mining, and quarrying;

(3) Removing, destroying, or altering vegetation in the critical habitat unit, including but not limited to inappropriately managed livestock grazing, clearing, introducing or encouraging the spread of nonnative species, recreational activities, and maintaining an unnatural fire regime either through fire suppression or prescribed fires that are too frequent or poorly timed;

(4) Hydrologic changes or other activities that alter surface drainage patterns resulting in erosion of serpentine outcrops or adjacent areas, including but not limited to water diversion, groundwater pumping, irrigation, and erosion control;

(5) Construction or maintenance activities that destroy or degrade critical habitat, including but not limited to road building, building construction, airport expansion, drilling, and culvert maintenance or installation;

(6) Application or runoff of pesticides, herbicides, fertilizers, or other chemical or biological agents; and

(7) Emergency response and clean-up of fuel or other contaminant spills.

Designation of critical habitat could affect the following agencies and/or actions: development on private, State, or county lands requiring permits or funding from Federal agencies, such as the U.S. Army Corps of Engineers, the Department of Housing and Urban Development, the Federal Aviation Administration, or the Federal Highway Administration; construction of communication sites licensed by the Federal Communications Commission; and authorization of Federal grants or loans. These actions would be subject to the section 7 process. Where federally listed wildlife species occur on private lands proposed for development, any habitat conservation plans submitted by the applicant to secure a permit to take according to section 10(a)(1)(B) of the Act would be subject to the section 7 consultation process.

If you have questions regarding whether specific activities will likely constitute adverse modification of critical habitat, contact the Project Leader, Arcata Fish and Wildlife Office (see **ADDRESSES** section). Requests for copies of the regulations on listed wildlife, and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Region 1, Division of Endangered Species, 911 NE 11th Avenue, Portland, Oregon 97232–4181 (503/231–6131, facsimile 503/231–6243).

Relationship to Habitat Conservation Plans and Other Planning Efforts

Currently, no habitat conservation plans (HCPs) exist that include *Thlaspi californicum* as a covered species. However, we believe that, in most instances, the benefits of excluding HCPs from critical habitat designations will outweigh the benefits of including them. In the event that future HCPs covering *T. californicum* are developed within the boundaries of the designated critical habitat, we will work with applicants to ensure that the HCPs provide for protection and management of habitat areas essential for the conservation of this species. This will be accomplished by either directing development and habitat modification to nonessential areas, or appropriately modifying activities within essential habitat areas so that such activities will not adversely modify the primary constituent elements. The HCP development process would provide an opportunity for more intensive data collection and analysis regarding the use of particular habitat areas by *T. californicum*. The process would also enable us to conduct detailed evaluations of the importance of such lands to the long-term survival of the species in the context of constructing a biologically configured system of

interlinked habitat blocks. We will also provide technical assistance and work closely with applicants throughout the development of any future HCPs to identify lands essential for the long-term conservation of *T. californicum* and appropriate management for those lands. The take minimization and mitigation measures provided under such HCPs would be expected to protect the essential habitat lands proposed as critical habitat in this rule.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available, and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species concerned. We will conduct an analysis of the economic impacts of designating these areas as critical habitat prior to a final determination. When completed, we will announce the availability of the draft economic analysis with a notice in the **Federal Register**, and we will open a 30-day public comment period on the draft economic analysis and proposed rule at that time.

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefit of designation will outweigh any threats to the species due to designation;

(2) Specific information on the amount and distribution of *Thlaspi californicum* habitat, and what habitat is essential to the conservation of the species and why;

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(4) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families;

(5) Economic and other values associated with designating critical habitat for *T. californicum* such as those derived from non-consumptive uses (e.g., hiking, camping, bird-watching, enhanced watershed protection, improved air quality, increased soil retention, ''existence values'', and reductions in administrative costs); and

(6) Whether our approach to critical habitat designation could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concern and comments.

If you wish to comment on this proposed rule, you may submit your comments and materials by any one of several methods (see **ADDRESSES**). Please submit electronic mail comments as an ASCII file and avoid the use of special characters and any form of encryption. Please also include ''Attn: 1018–AG92'' and your name and return address in your electronic message. Please note that the electronic address *FW1_kneelandpennycress@.fws.gov* will be closed out at the termination of the public comment period. If you do not receive a confirmation from the system that we have received your electronic message, contact us directly by calling our Arcata Fish and Wildlife Office at phone number 707/822–7201.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will solicit the expert opinions of three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed listing and designation of critical habitat.

We will consider all comments and information received during the public comment period on this proposed rule during preparation of a final rulemaking. Accordingly, the final determination may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. Requests for public hearings must be made within 45 days of the date of publication of this proposal within the **Federal Register**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings in the **Federal Register** and local newspapers at least 15 days before the first hearing is held.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations and notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical jargon that interferes with the clarity? (3) Does the format of the proposed rule (grouping and order of the sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Is the description of the notice in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? What else could we do to make this proposed rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to the Field Supervisor, Arcata Fish and Wildlife Office (see **ADDRESSES**).

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant

rule and was reviewed by the Office of Management and Budget (OMB) in accordance with the four criteria discussed below. We are preparing a draft analysis of this proposed action, which will be available for public comment, to determine the economic consequences of designating the specific areas as critical habitat. The availability of the draft economic analysis will be announced in the **Federal Register** so that it is available for public review and comments.

(a) While we will prepare an economic analysis to assist us in considering whether areas would be excluded pursuant to section 4 of the Act, we do not believe this rule will 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 communities. Therefore, we do not believe a cost benefit and economic analysis pursuant to EO 12866 is required.

Thlaspi californicum was listed as endangered on February 9, 2000. As needed, we will conduct, formal and informal section 7 consultations with other Federal agencies to ensure that their actions will not jeopardize the continued existence of *Thlaspi californicum.* Under the Act, critical habitat may not be adversely modified by a Federal agency action; critical habitat does not impose any restrictions on non-Federal persons unless they are conducting activities funded or otherwise sponsored or permitted by a Federal agency. Section 7 of the Act requires Federal agencies to ensure that they do not jeopardize the continued existence of the species. Based on our experience with the species and its needs, we believe that any Federal action or authorized action that could potentially cause an adverse modification of the proposed critical habitat would currently be considered as jeopardy to the species under the Act in areas occupied by the species.

Accordingly, we do not expect the designation of occupied areas as critical habitat to have any incremental impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons that receive Federal authorization or funding. The designation of areas as critical habitat where section 7 consultations would not have occurred but for the critical habitat designation, may have impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons who receive Federal authorization or funding that are not attributable to the species listing. We will evaluate any impact through our economic analysis (under section 4 of the Act: see Economic Analysis section of this rule). Non-federal persons who do not have a Federal sponsorship of their actions are not restricted by the designation of critical habitat.

(b) This rule is not expected to create inconsistencies with other agencies' actions. As discussed above, Federal agencies have been required to ensure that their actions do not jeopardize the continued existence of *Thlaspi californicum* since its listing in 2000. The prohibition against adverse modification of critical habitat is expected to impose few, if any, additional restrictions to those that currently exist in the proposed critical habitat on currently occupied lands. We will evaluate any impact of designating areas where section 7 consultations would not have occurred but for the critical habitat designation through our economic analysis. Because of the potential for impacts on other Federal agency activities, we will continue to review this proposed action for any inconsistencies with other Federal agencies' actions.

(c) This proposed rule, if made final, is not expected to significantly affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Federal agencies are currently required to ensure that their activities do not jeopardize the continued existence of the species, and, as discussed above, we do not anticipate that the adverse modification prohibition resulting from critical habitat designation will have any incremental effects in areas of occupied habitat on any Federal entitlement, grant, or loan programs. This conclusion is based on the small acreage and number of entities affected by this proposal. We will evaluate any impact of designating areas where section 7 consultations would not have occurred but for the critical habitat designation through our economic analysis.

(d) OMB has determined that this rule may raise novel legal or policy issues and, as a result, this rule has undergone OMB review.

TABLE 2.—IMPACTS OF *Thlaspi californicum* LISTING AND CRITICAL HABITAT DESIGNATION

Categories of activities	Activities potentially affected by species listing only	Additional activities potentially affected by critical habitat designation [1]
Federal Activities Potentially Affected [2].	Activities conducted by the Army Corps of Engineers, the Federal Aviation Administration, the Department of Housing and Urban Development, and any other Federal Agencies, including, but not limited to, grading, construction, road building, hydrologic changes or other activities that alter surface drainage patterns, herbicide application, and recreational activities that would destroy habitat for this species or appreciably decrease habitat value or quality through indirect effects (e.g., edge effects, invasion of exotic plants or animals, or fragmentation).	Activities identified in column one by these Federal Agencies in designated areas where section 7 consultations would not have occurred but for the critical habitat designation.
Private or other non-Federal Activities Potentially Affected [3].	Activities that require a Federal action (permit, authorization, or funding) and may remove or destroy habitat for *Thlaspi californicum* by mechanical, chemical, or other means or appreciably decrease habitat value or quality through indirect effects (e.g., edge effects, invasion of exotic plants, fragmentation of habitat).	Funding, authorization, or permitting actions by Federal Agencies in designated areas where section 7 consultations would not have occurred but for the critical habitat designation.

[1] This column represents activities potentially affected by the critical habitat designation in addition to those activities potentially affected by listing the species.

[2] Activities initiated by a Federal agency.

[3] Activities initiated by a private or other non-Federal entity that may need Federal authorization or funding.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement 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 effects of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that rule will not have a significant economic effect on a substantial number of small entities. The following discussion explains our determination.

Designation of critical habitat only affects activities conducted, funded, or permitted by Federal agencies; non-Federal activities are not affected by the designation if they lack any Federal nexus. In areas occupied by *Thlaspi californicum*, Federal agencies funding, permitting, or implementing activities are already required, through consultation with us under section 7 of the Act, to avoid jeopardizing the continued existence of *Thlaspi californicum.* If this critical habitat designation is finalized, Federal agencies also must ensure, also through consultation with us, that their activities do not destroy or adversely modify designated critical habitat. However, for the reasons discussed above, we do not believe this will result in any additional regulatory burden on Federal agencies or their applicants.

In unoccupied areas, or areas of uncertain occupancy, designation of critical habitat could trigger additional review of Federal activities under section 7 of the Act, and may result in additional requirements on Federal activities to avoid destroying or adversely modifying critical habitat. However, outside the existing developed areas, land use on the majority of the proposed critical habitat consists of homesteading, grazing, and unforested lands surrounding timber lands. The likelihood of future development in these areas is low, although the airport may expand in the future. Any development that lacked Federal involvement would not be affected by the critical habitat designation. Should a federally funded, permitted, or implemented project be proposed that may affect designated critical habitat, we will work with the Federal action agency and any applicant, through section 7 consultation, to identify ways to implement the proposed project while minimizing or avoiding any adverse effect to the species or critical habitat. In our experience, the vast majority of such projects can be successfully implemented with at most minor changes that avoid significant economic impacts to project proponents. In addition, the area proposed as critical habitat is small, less than 75 acres, and we have identified fewer than a half-dozen landowners. The scale of the designation ensures that the ''substantial number of small entities'' threshold of the Regulatory Flexibility Act will not be met.

Therefore, we are certifying that the proposed designation of critical habitat for *Thlaspi californicum* is not expected to have a significant adverse impact on a substantial number of small entities. Thus, an initial flexibility analysis is not required.

Executive Order 13211

On May 18, 2001, the President issued an Executive Order (E.O. 13211) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Although this rule is a significant regulatory action under Executive Order 12866, it is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) This rule, as proposed, will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. Small governments will not be affected unless they propose an action requiring Federal funds, permits, or other authorization. Any such activity will require that the Federal agency ensure that the action will not adversely modify or destroy designated critical habitat.

(b) This rule, as proposed, will not produce a Federal mandate on State, local, or tribal governments or the private sector of $100 million or greater in any year; that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments.

Takings

In accordance with Executive Order 12630, this proposed rule does not have significant takings implications, and a takings implication assessment is not required. This rule would not take private property. As discussed above, the designation of critical habitat affects only Federal agency actions; it does not provide additional protection for the species on non-Federal lands or regarding actions that lack any Federal involvement. Furthermore, the Act provides mechanisms, through section 7 consultation, to resolve apparent conflicts between proposed Federal actions, including Federal funding or permitting of actions on private land, and the conservation of the species, including avoiding the destruction or adverse modification of designated critical habitat. While we have not conducted any formal consultations on *Thlaspi californicum* since its listing, and we are not aware of any upcoming or proposed projects that would require consultation, we recognize that such Federal projects that also affect private property may be proposed in the future. We fully expect that, through section 7 consultation, such projects can be implemented consistent with both the conservation of the species; therefore, this rule would not result in a takings.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior policy, we requested information from, and coordinated development of this critical habitat designation with, appropriate State resource agencies in California. The designation of critical habitat in areas currently occupied by *Thlaspi californicum* imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designations may have some benefit to these governments in that the areas essential to the conservation of these species are more clearly defined, and the primary constituent elements of the habitat necessary to the survival of the species are identified. While this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning

(rather than waiting for case-by-case section 7 consultation to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order. We are proposing to designate critical habitat in accordance with the provisions of the Endangered Species Act. The rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of *Thlaspi californicum.*

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act. This rule will not impose record-keeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act

We have determined we do not need to prepare an Environmental Assessment and/or an Environmental Impact Statement as defined by the National Environmental Policy Act of 1969 in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. We published a notice outlining our reason for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment.

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), E.O. 13175, and 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a government-to-government basis. We have determined that there are no Tribal lands essential for the conservation of *Thlaspi californicum* because they do not support the species, nor do they provide essential habitat. Therefore, critical habitat for *Thlaspi californicum* has not been designated on Tribal lands.

References Cited

A complete list of all references cited herein, as well as others, is available upon request from the Arcata Fish and Wildlife Office (*see* **ADDRESSES** section).

Author

The author of this proposed rule is Robin Hamlin (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. In § 17.12(h) revise the entry for *Thlaspi californicum* under ''FLOWERING PLANTS'' to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*	*	
Thlaspi californicum	Kneeland Prairie penny-cress.	U.S.A. (CA)	Brassicaceae—Mustard.	E	684	17.96(b)	NA
*	*	*	*	*	*	*	

3. In § 17.96, as proposed to be amended at 65 FR 66865, November 7, 2000, add critical habitat for the Kneeland Prairie penny-cress (*Thlaspi californicum*) under paragraph (b) by adding an entry for *Thlaspi californicum* in alphabetical order under Brassicaceae to read as follows:

§ 17.96 Critical habitat—plants.

* * * * *

(b) Single-species critical habitat—flowering plants.

Family Brassicaceae: *Thlaspi californicum* (Kneeland Prairie penny-cress)

1. A critical habitat unit is depicted for Humboldt County, California, on the map below.

2. The primary constituent elements of critical habitat for *Thlaspi californicum* are the habitat components that provide:

(i) Thin rocky soils that have developed on exposures of serpentine substrates;

(ii) Plant communities that support a relatively sparse assemblage of serpentine indicator, or facultative-serpentine indicator species, including various native forbs and grasses, but not trees or shrubs, such that competition for space and water (both above and below ground) and light is reduced, compared to the surrounding habitats. Known associated species include the following: *Festuca rubra* (red fescue), *Koeleria macrantha* (junegrass), *Elymus glaucus* (blue wildrye), *Eriophyllum lanatum* (woolly sunflower), *Lomatium macrocarpum* (large-fruited lomatium), and *Viola hallii* (Hall's violet);

(iii) Serpentine substrates that contain 15 percent or greater (by surface area) of exposed gravels, cobbles, or larger rock fragments, which may contribute to alteration of factors of microclimate, including surface drainage and moisture availability, exposure to wind and sun, and temperature; and

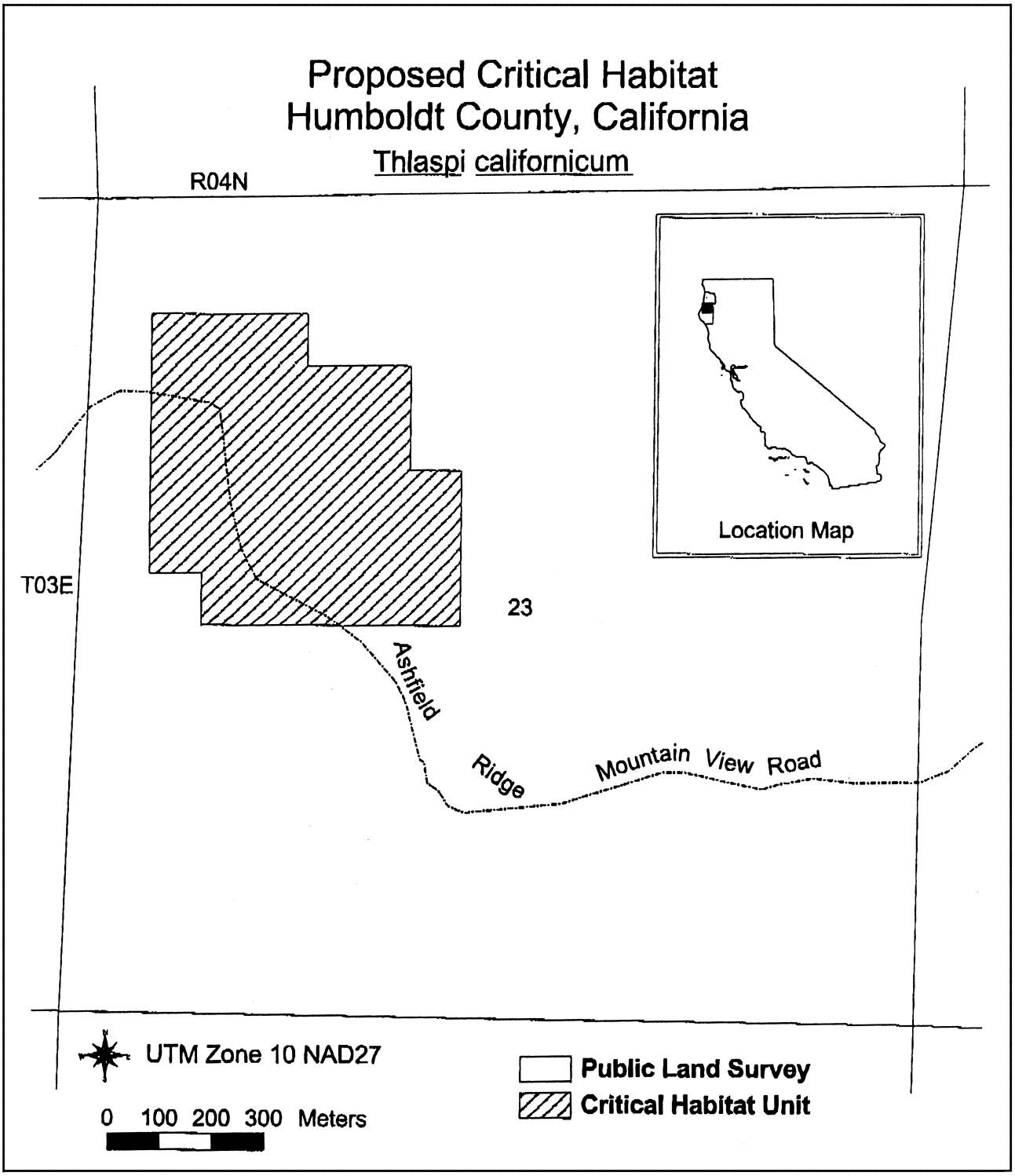
(iv) Prairie grasslands and oak woodlands located within 30 m (100 ft) of the serpentine outcrop area on Ashfield Ridge. Protection of these habitats is essential to the conservation of the *Thlaspi californicum* in that it will provide connectivity among the serpentine sites, help to maintain the hydrologic and edaphic integrity of the serpentine sites, and support populations of pollinators and seed dispersal organisms.

3. Existing features and structures within the boundaries of mapped critical habitat units, such as buildings, roads, airports, and other paved areas will not contain one or more of the primary constituent elements. Federal actions limited to those areas, therefore, would not trigger a section 7 consultation, unless they affect the species and/or primary constituent elements in adjacent critical habitat.

4. Critical habitat unit. Humboldt County, California. From U.S.G.S. 1:24,000 scale Iaqua Buttes quadrangle, land bounded by the following UTM Zone 10 NAD27 coordinate pairs (East, North): 421700,4507300; 422100,4507800; 422100,4507300; 422200,4507600; 421600,4507400; 421700,4507900; 421700,4507800; 421900,4507900

Note: Map follows:

BILLING CODE 4310–55–P



* * * * *

Dated: October 17, 2001.

Joseph E. Doddridge,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–26711 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–55–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 101701A]

New England Fishery Management Council; Public Meeting

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

ACTION: Public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a 3–day Council meeting on November 6 through 8, 2001, to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday, and Thursday, November 6, 7, and 8, 2001. The meeting will begin at 9 a.m. on Tuesday and 8:30 a.m. on Wednesday and Thursday.

ADDRESSES: The meeting will be held at the Tavern on the Harbor, 30 Western Avenue, Gloucester, MA 01930; telephone (978) 283–4200. Requests for special accommodations should be addressed to the New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone (978) 465–0492.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Tuesday, November 6, 2001

Following introductions, the Council staff will present the 2001 Whiting Stock Assessment and Fishery Evaluation (SAFE) Report for small mesh multispecies, including Whiting Monitoring Committee recommendations concerning future management actions. The Scallop Committee will request approval of additional management alternatives to be included in draft Amendment 10 to the Atlantic Sea Scallop Fishery Management Plan (FMP) and analyzed in the Draft Supplemental Environmental Impact Statement (DSEIS). Primary issues include alternatives to manage limited access fishing effort and general category scallop vessels, minimize habitat and bycatch impacts, and address monitoring and data collection issues.

The afternoon session will include consideration and approval of a schedule of management actions for 2002. The Spiny Dogfish Committee will then seek approval of New England Council recommendations for spiny dogfish specifications for the 2002–2003 fishing year. Measures may include a Total Allowable Catch (TAC) quota, trip limits, and/or any other measures specified in the Spiny Dogfish FMP.

Wednesday, November 7, 2001

The meeting will reconvene with reports on recent activities from the Council Chairman and Executive Director, the NMFS Regional Administrator, Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel and representatives of the U.S. Coast Guard, NMFS Enforcement and the Atlantic States Marine Fisheries Commission. A brief period for general comments from the public concerning fisheries management issues will follow. The Multispecies Monitoring Committee (MSMC) will present an update on stock status and management alternatives to meet Northeast Multispecies FMP goals and objectives. During the Groundfish Committee Report, the Council will review scoping comments on the Notice of Intent for Framework Adjustment 36 to the Northeast Multispecies FMP. Measures in this action would be designed to reduce Gulf of Maine cod fishing mortality and discards, extend or change the Western Gulf of Maine closed area, change the area authorized for the northern shrimp fishery, and allow tuna purse seine vessels access to groundfish closed areas. The Council is considering the full range of measures for reducing Gulf of Maine cod fishing mortality, including changes to recreational fishing measures. In addition, because Framework 36 will address the Northeast multispecies annual adjustment process for the 2002 fishing year, the Council will also consider alternatives that may be necessary to meet the goals and objectives of the plan. The Framework 36 discussions will include opportunities for the public to comment. During this discussion, the Council also will review the MSMC-proposed management alternatives for achieving plan goals for possible inclusion in Framework Adjustment 36, as well as identify alternatives for analyses in the accompanying DSEIS.

Thursday, November 8, 2001

On the final day of the meeting, the agenda will include red crab and monkfish issues. During the Red Crab report, the Council intends to approve the Red Crab FMP DEIS (including possible identification of a preferred alternative) and public hearing document. Discussion will include review and approval of the Habitat Committee's recommendations for the designation of red crab Essential Fish Habitat. There will be a presentation of the Monkfish SAFE Report for the 2000–2001 fishing year, including the recommendations of the Monkfish Monitoring Committee concerning management recommendations. The Council also intends to approve initial action on Framework Adjustment 1 to the Monkfish FMP (annual framework adjustment) to implement management measures for the 2002–2003 fishing year (Year 4 of the rebuilding program). Measures under consideration include, but are not limited to, no action, which would allow the Year 4 default measures to take effect; continue the Year 3 measures with adjustments to the gear-based trip limits to account for the recent federal court decision; or adjust Year 3 measures to achieve Year 3 target total allowable catch (TAC) levels. Any outstanding business will be addressed following this report.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

The New England Council will consider public comments at a minimum of two Council meetings before making recommendations to the National Marine Fisheries Service Regional Administrator on any framework adjustment to a fishery management plan. If the Regional Administrator concurs with the adjustment proposed by the Council, the Regional Administrator may publish the action either as proposed or final regulations in the **Federal Register**. Documents pertaining to framework adjustments are available for public review 7 days prior to a final vote by the Council.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul

J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: October 19, 2001.

Bruce C. Morehead,

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

[FR Doc. 01–26781 Filed 10–19–01; 2:40 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 011004242–1242–01; I.D. 092401F]

RIN 0648–AP09

Fisheries of the Northeastern United States; Proposed 2002 Fishing Quotas for Atlantic Surfclams, Ocean Quahogs, and Maine Mahogany Ocean Quahogs

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

ACTION: Proposed 2002 fishing quotas for Atlantic surfclams, ocean quahogs, and Maine mahogany ocean quahogs; request for comments.

SUMMARY: NMFS proposes quotas for the Atlantic surfclam, ocean quahog, and Maine mahogany ocean quahog fisheries for 2002. Regulations governing these fisheries require NMFS to propose for public comment specifications for the 2002 fishing year. The intent of this action is to propose allowable harvest levels of Atlantic surfclams and ocean quahogs from the exclusive economic zone and an allowable harvest level of Maine mahogany ocean quahogs from the waters north of 43°50′ N. lat. in 2002.

DATES: Comments must be received no later than 5 p.m., eastern standard time, on November 23, 2001.

ADDRESSES: Copies of supporting documents, including the Environmental Assessment, Regulatory Impact Review, Initial Regulatory Flexibility Analysis (EA/RIR/IRFA), and the Essential Fish Habitat Assessment, are available from: Daniel Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19904–6790. A copy of the EA/RIR/IRFA is accessible via the Internet at *http:/www.nero.gov/ro/doc/nr.htm.*

Written comments on the proposed specifications should be sent to: Patricia A. Kurkul, Regional Administrator, Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298. Mark on the outside of the envelope, ''Comments--2002 Clam and Quahog Specifications.'' Comments may also be sent via facsimile (fax) to (978) 281–9371. Comments will not be accepted if submitted via e-mail or the Internet.

FOR FURTHER INFORMATION CONTACT: Walter Gardiner, Fishery Management Specialist, 978–281–9326.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for the Atlantic Surfclam and Ocean Quahog Fisheries (FMP) requires NMFS, in consultation with the Mid-Atlantic Fishery Management Council (Council), to specify quotas for surfclams and ocean quahogs on an annual basis from a range that represents the optimum yield (OY) for each fishery. It is the policy of the Council that the levels selected allow sustainable fishing to continue at that level for at least 10 years for surfclams and 30 years for ocean quahogs. While staying within this constraint, the Council must also consider the economic impacts of the quotas. Regulations implementing Amendment 10 to the FMP published on May 19, 1998 (63 FR 27481), added Maine mahogany ocean quahogs to the management unit and provides that a small artisanal fishery for ocean quahogs in the waters north of 43°50′ N. lat. will have an annual quota within a range of 17,000 to 100,000 Maine bushels (bu) (5,991 to 35,240 hectoliters (hL)), with an initial amount of 100,000 Maine bu (35,240 hL). As specified in Amendment 10, the Maine mahogany ocean quahog quota is in addition to the quota specified for the ocean quahog fishery.

The quotas recommended by the Council must be in compliance with overfishing definitions for each species. The overfishing definition for ocean quahogs is based on a control rule, which specifies a biomass target of one half of the virgin biomass, or 2 billion lb (907,200 mt) of meats (200 million bu); a target fishing mortality rate (F) of $F_{0.1}$ = 0.02; a minimum biomass threshold of one half of the biomass target, or 1 billion lb (453,600 mt) of meats (100 million bu); and a maximum fishing mortality threshold of F = 0.042. The current biomass of ocean quahog is estimated to be about 3.3 billion lb (1.6 million mt) of meats (330 million bu), or about 80 percent of the virgin biomass, and currently F is estimated to be 0.02. Thus, the stock is not overfished and overfishing is not occurring. NMFS approved the overfishing definition for ocean quahogs in Amendment 12 to the FMP, but disapproved the proposed overfishing definition for surfclams because it was based only on surfclams from the Northern New Jersey area and did not take into account the entire range of the resource. The December 1999 Stock Assessment Review Committee (SARC) proposed an overfishing definition for surfclams, which the Council reviewed and approved at their March 2000 meeting.

The definition approved by the Council for surfclams has a biomass target of one half of the current biomass as a proxy for F_{MSY} (1.4 billion lb, or 640,000 mt, or 82.4 million bu); a minimum biomass threshold of one-half of the proxy for B_{MSY} (700,000 million lb or 320,000 mt); and a maximum fishing mortality rate threshold of F_{MSY}, where the current best proxy for F_{MSY} is the natural mortality rate of M =(0.15). The fishing mortality target is always to be set less than the F threshold and is to be the F associated with the Council-selected quota (approximately 0.03 for 2002). This new overfishing definition for surfclams will be submitted to the Secretary of Commerce for approval in Amendment 13 to the FMP, which the Council is currently developing. If the Secretary were to approve these standards, the surfclam resource will not be overfished and overfishing will not be occurring.

In proposing the 2002 quotas, the Council considered the available stock assessments, data reported by harvesters and processors, and other relevant information concerning exploitable biomass and spawning biomass, fishing mortality rates, stock recruitment, projected effort and catches, and areas closed to fishing. This information was presented in a written report prepared by the Council staff. The proposed quotas for the 2002 Atlantic surfclam, ocean quahog, and Maine mahogany ocean quahog fisheries are shown in the following table. The Council's recommended quotas for 2002 would maintain the status quo levels of 2001 for both the ocean quahog and Maine mahogany ocean quahog, but the surfclam quota would be increased by 10 percent, from 2.85 million bu to 3.135 million bu (1.518 million hL to 1.669 million hL).

PROPOSED 2002 SURFCLAM/OCEAN QUAHOG QUOTAS

Fishery	2002 final quotas (bu)	2002 final quotas (hL)
[1]Surfclam	3,135,000	1,669,000
[1]Ocean quahog	4,500,000	2,396,000

PROPOSED 2002 SURFCLAM/OCEAN QUAHOG QUOTAS—Continued

Fishery	2002 final quotas (bu)	2002 final quotas (hL)
[2]Maine mahogany quahog	100,000	35,240

[1] 1 bushel = 1.88 cubic ft = 53.24 liters
[2] 1 bushel = 1.2445 cubic ft = 35.24 liters

Surfclams

The Council's recommended 2002 quota of 3.135 million bu (1.669 million hL) for surfclams is the second change in the quota since 1995. The most recent biological assessments (from both the 1997 and 1999 surveys) indicate that the surfclam resource is healthy, composed of many age classes, and can safely sustain increased harvests. Sufficient recruitment is also evident; thus, this level of quota will not harm the long-term sustainability of the resource. The F in 1999 (the last time it was measured at a peer-reviewed SARC) associated with a quota of 2.565 million bu (1.366 million hL) was approximately 0.02 ($F=_{0.2}$); this slight quota increase proposed for 2002 could increase the F in 2002 to, at most, $F=_{0.3}$, which is consistent with the Council-adopted control rule.

Ocean Quahogs

The Council recommended a 2002 quota of 4.5 million bu (2.396 million hL) for ocean quahogs. This quota would be identical to that adopted for the past 3 years, but represents an increase of 13 percent from the 1998 quota level.

The 1999 quota yielded an F (the last time it was measured at a peer-reviewed SARC) of approximately 0.02 ($F=_{0.02}$), compared to the F threshold of 0.04 ($F=_{0.04}$) contained in the overfishing definition. The F associated with the 2002 quota is expected to be close to the F in 1999, because a similar proportion of the biomass remains unexploited compared to 1999.

The Atlantic surfclam and ocean quahog quotas are specified in standard bushels of 53.24 L. per bushel, while the Maine mahogany ocean quahog quota is specified in ''Maine'' bushels of 35.24 L. per bu. Because Maine mahogany ocean quahogs are the same species as ocean quahogs, they are managed under the ocean quahog overfishing definition. When the two quota amounts (ocean quahog and Maine mahogany quahog) are added, the total allowable harvest is still lower than the level that would result in overfishing for the entire stock.

The Council proposed a 2002 ocean quahog quota based on the analysis of abundance for that species found in the 31st Northeast Regional Stock Assessment Workshop (SAW 31), which concluded in August 2000. Although SAW 31 showed that the ocean quahog quota could have been increased beyond the 2001 quota level, the Council did not recommend any change for 2002 because of four major factors: (1) The 2000 quota was not constraining to the industry; (2) nearly all industry members supported the 4.5 million bu (2.396 million hL) harvest level; (3) repeated concern was expressed by industry over the continued lack of apparent ocean quahog recruitment south of Georges Bank; and (4) unless prices or technology change significantly in the near future, it is unlikely that the ocean quahog fishery extractions in the past are sustainable, because those extractions have been dependent on rich unexploited beds.

The Council recommended that the Maine mahogany ocean quahog quota remain unchanged from the 2001 quota level at 100,000 Maine bu (35,240 hL) for 2002. No additional information on the impacts of the mahogany quahog quota is available at this time that would allow a more in-depth analysis of the stock and, therefore, allow the quota to be increased beyond the current maximum level of 100,000 Maine bu (35,240 hL). A scientific survey and assessment of the extent of the resource is currently under way by the State of Maine and will be fully analyzed in the development of Amendment 13 to the FMP, which is expected to be submitted by the Council in 2002. From the information currently available, maintaining the quota at its current level for another year will not seriously constrain the fishery or endanger the resource.

Classification

This action is authorized by 50 CFR part 648 and has been determined to be not significant for purposes of Executive Order 12866.

This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132; therefore, preparation of a Federalism assessment is not necessary.

The Council prepared an IRFA in section 9.0 of the RIR that describes the economic impacts this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, the objectives and the legal basis for this action are contained at the beginning of the **SUPPLEMENTARY INFORMATION** section. This action does not duplicate, overlap, or conflict with any other Federal rules. A summary of the IRFA follows:

Vessels

In 2000, a total of 48 vessels reported harvesting surfclams or ocean quahogs from Federal waters under an Individual Transferable Quota (ITQ) system. Average 2000 gross income from surfclam harvests was $702,317 per vessel, and $470,854 per vessel from ocean quahog harvests. In the small artisanal fishery for ocean quahogs in Maine, 34 vessels reported harvests in the clam logbooks, with an average value of $97,223 per vessel. All of these vessels fall within the definition of a small entity. The Council recommends no change in the 2002 quotas for ocean quahogs or Maine mahogany ocean quahogs from their 2001 quotas, and a 10-percent increase in the surfclam quota. Since 2000 harvest levels of 2.561 and 3.161 million bu (1.364 million hL to 1.683 million hL) for surfclams and ocean quahogs, respectively, were below the 2002 proposed quotas, and the Council assumes no changes in fishing effort or yield-to-effort will take place in 2001, the Council believes that the proposed 2002 quotas will yield a surplus quota available to vessels participating in these fisheries. In the case of a surplus quota, vessels would not be constrained from harvesting additional product, thus, allowing them to increase their revenues.

The Council analyzed four ocean quahog quota alternatives in addition to the preferred 4.500-million bu (2.396-million hL) option, including 4.000, 4.250, 4.750, and 6.000 million bu (2.129, 2.263, 2.529, and 3.195 million hL). The minimum allowable quota specified in the current OY range is 4.000 million bu (2.129 million hL) of ocean quahogs. Adoption of a 4.000 million bu (2.129 million hL) quota would represent a 12-percent decrease from the current 4.500 million bu (2.396 million hL) quota and, assuming the entire quota is harvested, a 27-percent increase in harvest from the 2000 harvest level of 3.161 million bu (1.683 million hL). This alternative would take the most conservative approach to managing the fishery that is currently available to the Council. Adopting the maximum allowable quota of 6.000 million bu (3.195 million hL) for ocean quahogs would represent a 33-percent increase in allowable harvest and a 90-percent increase in landings from 2000, assuming that all of the quota is harvested. However, the industry does not have a market available to absorb such a massive increase in landings and may not have the vessel capacity necessary to harvest a quota this large (two of the most productive ocean quahog vessels sank in January 1999

and have not been replaced). Since all alternatives, including the preferred, would yield increases relative to the actual 2000 landings, increased revenues, would be likely to occur.

The Council identified four surfclam quota alternatives in addition to the preferred alternative of 3.135 million bu (1.669 million hL), including 1.850, 2.850, 3.000, and 3.400 million bu (0.985, 1.517, 1.597, and 1.810 million hL). The minimum allowable quota specified in the current OY range is 1.850 million bu (0.985 million hL) of surfclams. Adoption of a 1.81 million bu (0.985 million hL) quota would represent a 35-percent decrease from the current 2.850-million bu (1.517-million hL) quota, and a 28-percent decrease from the 2000 harvest level of 2.561 million bu (1.364 million hL). A reduction in quota of this magnitude would have a substantially negative impact on overall exvessel revenues. Adoption of the 2.850 million bu (1.517 million hL) quota would most likely have a limited impact on small entities, since it is identical to the 2001 quota. Adopting the maximum allowable quota of 3.400 million bu (1.810 million hL) for surfclams would allow for a 19-percent increase in harvest. The Council considered a 5-percent increase in quota from the 2001 level to 3.000 million bu (1.597 million hL), but industry representatives asked for, and stated that they preferred, a 10-percent increase. The preferred alternative allows for the 10-percent increase of 2.850 million bu (1.517 million hL) to 3.135 million bu (1.669 million hL). The Council determined that the only alternative that would significantly negatively impact revenues to vessels is the 1.850 million bu (0.985 million hL) alternative for surfclams. Both the status quo quota alternative and the 5-percent increase could be constraining on industry. At best, the 5-percent increase would probably increase revenues by a small amount. The resource can support the 10-percent increase in landings and the industry believes it can harvest and process this additional product.

The quota for Maine mahogany ocean quahogs is specified at a maximum 100,000 Maine bu (35,240 hL). The FMP specifies that upward adjustments to the quota would require a scientific survey and stock assessment of the Maine mahogany ocean quahog resource. However, no survey or assessment has been conducted. The Council considered two alternative quotas for the Maine mahogany fishery, in addition to the preferred alternative of 100,000 Maine bu (35,240 hL), including 50,000 Maine bu and 72,466 bu (17,620 and 25,537 hL). Any quota the Council would have recommended below the 1999 landing level of 93,938 Maine bu (33,104 hL) would most likely have resulted in a decrease in revenues to individual vessels.

Processors

Nine to 12 processors currently participate in the surfclam and ocean quahog fisheries. However, five firms are responsible for the vast majority of purchases in the ex-vessel market and sale of processed clam products in wholesale markets. Impacts to surfclams and ocean quahog processors would most likely mirror the impacts of the various quota alternatives to vessels, as discussed above. Revenues earned by processors would be derived from the wholesale market for clam products and, since a large number of substitute products (i.e., other food products) are available, the demand for processed clam products is likely to be price-dependent.

Allocation Holders

In 2001, there were 99 surfclam allocation holders, while 63 firms or individuals held an ocean quahog allocation. If the recommended quotas are accepted, i.e., no change from 2001 quotas on ocean quahogs or Maine mahogany ocean quahogs, and an increase of 10-percent for surfclams, it is likely that impacts to allocation holders or buyers will be minimal. Theoretically, increases in the quota would most likely benefit those who purchase quota (through lower prices (values)) and negatively impact sellers of quota because of reduction in value. Decreases in the quota would most likely have an opposite effect.

Reporting and Recordkeeping Requirements

This proposed rule would not impose any new reporting, recordkeeping, or other compliance requirements. Therefore, the costs of compliance would remain unchanged.

The RIR/IRFA is available from the Council (see **ADDRESSES**).

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

Dated: October 18, 2001.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 01–26791 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 66, No. 206

Wednesday, October 24, 2001

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.

APPALACHIAN STATES LOW-LEVEL RADIOACTIVE WASTE COMMISSION

Annual Meeting

TIME AND DATE: 9:30 a.m.–12 p.m. November 7, 2001.

PLACE: Harrisburg Hilton and Towers, One North Second Street, Harrisburg, PA 17101.

STATUS: Most of the meeting will be open to the public. If there is a need for an executive session (closed to the public), it will be held at about 9:30 a.m.

MATTERS TO BE CONSIDERED:

Portions Open to the Public: The primary purpose of this meeting is to (1) Review the independent auditors' report of Commission's financial statements for fiscal year 2000–2001; (2) Review the information on LLRW generation within the Appalachian Compact; (3) Discuss LLRW generation reporting requirements for the Compact; (4) Consider a proposed budget for fiscal year 2002–2003; (5) Review and discuss the recent developments in South Carolina and Utah related to the Barnwell and Envirocare disposal facilities; (6) Review the EPA's Final Rule on Mixed Low-Level Waste; and (7) Elect the Commission's officers.

Portions Closed to the Public: Executive Session, if deemed necessary, will be held at about 9:30 a.m.

CONTACT PERSON FOR MORE INFORMATION: Richard R. Janati, Pennsylvania Staff member on the Commission, at 717–787–2163.

Richard R. Janati,

Staff Member on the Commission.

[FR Doc. 01–26723 Filed 10–23–01; 8:45 am]

BILLING CODE 0000–00–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Government Employment Forms.

Form Number(s): E–1, E–2, E–3, E–4, E–5, E–6, E–7, E–9.

Agency Approval Number: 0607–0452.

Type of Request: Revision of a currently approved collection.

Burden: 82,520.

Number of Respondents: 96,591.

Avg Hours Per Response: 51 minutes.

Needs and Uses: The Census Bureau requests OMB clearance of the questionnaires needed to conduct the 2002 Census of Governments, Employment Phase, and the 2003 Annual Survey of Government Employment. Title 13, Section 161, of the United States Code requires the Secretary of Commerce to conduct a census of governments every fifth year. Section 182 allows the Secretary to conduct annual surveys in other years. There are eight survey forms used to collect data on government employment, pay, and hours. Since there are many different types and sizes of governments, each form is tailored to the unique characteristics of the type and size of government or government agency to be surveyed. The type of employment and pay data to be collected in the 2002 Census of Governments and the 2003 Annual Survey of Government Employment is identical to data collected in recent annual surveys of government employment.

The 2002 Census of Governments will collect data for all of the governments in our universe by type of government and by government function. By state, the 2003 Employment sample supports estimates of total local government employment and payrolls by type of government and government function.

Statistics compiled from data gathered using these forms are used in several important Federal government programs. Economists at the Bureau of Economic Analysis use the statistics for developing the National Income and Product Accounts. The Department of Housing and Urban Development determines the allocation of operating subsidies to local housing authorities based on these survey data. The Bureau of Labor Statistics uses these data in its benchmarking procedures for state and local government components of its monthly employment and earnings statistics. Other users include state and local government executives and legislators, policy makers, economists, researchers, and the general public.

Affected Public: Federal Government; State, local or Tribal Government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 161 and 182.

OMB Desk Officer: Susan Schechter, (202) 395–5103.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, Department of Commerce, room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *mclayton@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Susan Schechter, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: October 18, 2001.

Madeleine Clayton,

Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–26737 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

[I.D. 101901C]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: National Marine Sanctuary Permits.

Form Number(s): None.

OMB Approval Number: 0648–0141.

Type of Request: Regular submission.

Burden Hours: 1,018.

Number of Respondents: 336.

Average Hours Per Response: 1 hour for a general permit application; 15 minutes for a baitfish permit application; 13 hours for a historical resource permit application; 24 hours for a special use permit application; 1 hour for a notification of other agency permits or requests; 15 minutes for a permit amendment; 30 minutes for a request for certification of a pre-existing lease, license or permit; 15 minutes for an entry to a voluntary registry of activities; and 90 minutes for a appeal of an application rejection.

Needs and Uses: National Marine Sanctuary (NMS) regulations list specific activities that are prohibited in the sanctuaries. These otherwise-prohibited activities are permissible if a permit is issued by the NMS program. Persons wanting permits must submit applications, and persons obtaining permits must submit reports on the activity conducted under the permit. The information is needed by NMS to protect and manage the sanctuaries.

Affected Public: Not-for-profit institutions, individuals or households, business or other for-profit organizations, and State, local, or tribal government.

Frequency: On occasion, annually.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *MClayton@doc.gov).*

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: October 17, 2001.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–26793 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–NK–S

DEPARTMENT OF COMMERCE

[I.D. 101901A]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Northwest Region Gear Identification Requirements.

Form Number(s): None.

OMB Approval Number: 0648–0352.

Type of Request: Regular submission.

Burden Hours: 3,079.

Number of Respondents: 1,046.

Average Hours Per Response: 15 minutes per marking.

Needs and Uses: Regulations implementing the Pacific Coast Groundfish Fisheries Management Plan at 50 CFR 660.322 (c)(3) specify that federally-permitted vessels are required to mark their fixed-gear with an identifying number. This number is used by NOAA, the U.S. Coast Guard, and other agencies for fishery enforcement activities.

Affected Public: Business or other for-profit organizations.

Frequency: Third party disclosure.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *MClayton@doc.gov).*

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: October 17, 2001.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–26795 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Census Bureau

Survey of Income and Program Participation (SIPP) Wave 5 of the 2001 Panel

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before December 24, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *MClayton@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Judith H. Eargle, Census Bureau, FOB 3, Room 3387, Washington, DC 20233–0001, (301) 457–3819.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts the SIPP which is a household-based survey designed as a continuous series of national panels. New panels are introduced every few years with each panel usually having durations of one to four years. Respondents are interviewed at 4-month intervals or ''waves'' over the life of the panel. The survey is molded around a central ''core'' of labor force and income questions that remain fixed throughout the life of the panel. The core is supplemented with questions designed to address specific needs, such as obtaining information on school enrollment, child support agreements, adult and child disabilities and employer provided health benefits. These supplemental questions are included with the core and are referred to as ''topical modules.''

The SIPP represents a source of information for a wide variety of topics and allows information for separate topics to be integrated to form a single,

unified database so that the interaction between tax, transfer, and other government and private policies can be examined. Government domestic-policy formulators depend heavily upon the SIPP information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population. The SIPP has provided these kinds of data on a continuing basis since 1983 permitting levels of economic well-being and changes in these levels to be measured over time.

The 2001 Panel is currently scheduled for three years and will include nine waves of interviewing beginning February 2001. Approximately 50,000 households will be selected for the 2001 Panel, of which 37,500 are expected to be interviewed. We estimate that each household will contain 2.1 people, yielding 78,750 interviews in Wave 1 and subsequent waves. Interviews take 30 minutes on average. Three waves of interviewing will occur in the 2001 SIPP Panel during FY 2002. The total annual burden for the 2001 Panel SIPP interviews would be 118,125 hours in FY 2002.

The topical modules for the 2001 Panel Wave 5 collect information about:

- School Enrollment and Financing.
- Child Support Agreements.
- Support for Non-Household Members.
- Adult Disability.
- Child Disability.
- Employer—Provided Health Benefits.

Wave 5 interviews will be conducted from June 2002 through September 2002.

A 10-minute reinterview of 2,500 people is conducted at each wave to ensure accuracy of responses. Reinterviews would require an additional 1,253 burden hours in FY 2002.

An additional 2,100 burden hours is requested in order to continue the SIPP Methods Panel testing. The test targets SIPP items and sections that require thorough and rigorous testing in order to improve the quality of core data.

II. Method of Collection

The SIPP is designed as a continuing series of national panels of interviewed households that are introduced every few years with each panel having durations of one to four years. All household members 15 years old or over are interviewed using regular proxy-respondent rules. During the 2001 Panel, respondents are interviewed a total of nine times (nine waves) at 4-month intervals making the SIPP a longitudinal survey. Sample people (all household members present at the time of the first interview) who move within the country and reasonably close to a SIPP primary sampling unit will be followed and interviewed at their new address. Individuals 15 years old or over who enter the household after Wave 1 will be interviewed; however, if these individuals move, they are not followed unless they happen to move along with a Wave 1 sample individual.

III. Data

OMB Number: 0607–0875.

Form Number: SIPP/CAPI Automated Instrument.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 78,750 people per wave.

Estimated Time Per Response: 30 minutes per person, on average.

Estimated Total Annual Burden Hours: 121,478.

Estimated Total Annual Cost: The only cost to respondents is their time.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Section 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) 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.

Comments submitted in response to this notice will be summarized or included in the request for the Office of Management and Budget approval of this information collection. They also will become a matter of public record.

Dated: October 18, 2001.

Madeleine Clayton,

Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–26736 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–337–806]

Notice of Postponement of Preliminary Antidumping Duty Determination: IQF Red Raspberries From Chile

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary determination in the antidumping duty investigation on individually quick frozen red raspberries from Chile.

EFFECTIVE DATE: October 24, 2001.

FOR FURTHER INFORMATION CONTACT: Cole Kyle (202) 482–1503 or Annika O'Hara (202) 482–3798; Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to 19 CFR part 351 (April 2001).

Postponement of Preliminary Determinations

On June 6, 2001, the Department published the initiation of the antidumping duty investigation of imports of individually quick frozen (IQF) red raspberries from Chile. The notice of initiation stated that we would make our preliminary determination for these antidumping duty investigation no later than 140 days after the date of issuance of the initiation (*i.e.,* November 7, 2001). *See Notice of Initiation of Antidumping Duty Investigations: IQF Red Raspberries from Chile,* 66 FR 34407 (June 28, 2001).

On October 12, 2001, the petitioners[1] made a timely request pursuant to 19 CFR 351.205(e) for a 35-day postponement of the preliminary determination until December 12, 2001. The petitioners requested a postponement of the preliminary determination because of the need for additional time to submit comments regarding the respondents'

[1] The petitioners are the IQF Red Raspberries Fair Trade Committee and its members.

supplemental questionnaire responses and for the Department to analyze the respondents' data and seek additional data, if necessary, prior to the issuance of the preliminary determination.

For the reasons identified by the petitioners, and because there are no compelling reasons to deny the request, we are postponing the preliminary determination under section 733(c)(1) of the Act. We will make our preliminary determination no later than December 12, 2001.

This notice is published pursuant to sections 733(f) and 777(i) of the Act.

Dated: October 18, 2001.

Faryar Shirzad,

Assistant Secretary for Import Administration.

[FR Doc. 01–26788 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–867]

Notice of Amended Preliminary Antidumping Duty Determination of Sales at Less Than Fair Value: Automotive Replacement Glass Windshields From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amended preliminary antidumping duty determination of sales at less than fair value.

EFFECTIVE DATE: October 24, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Bailey, AD/CVD Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1102.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations for the Tariff Act of 1930, as amended (''the Act''), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations codified at 19 CFR part 351 (2000).

Scope of the Investigation

The products covered by this investigation are automotive replacement glass (''ARG'') windshields, and parts thereof, whether clear or tinted, whether coated or not, and whether or not they include antennas, ceramics, mirror buttons or VIN notches, and whether or not they are encapsulated. ARG windshields are laminated safety glass (*i.e.,* two layers of (typically float) glass with a sheet of clear or tinted plastic in between (usually polyvinyl butyral)), which are produced and sold for use by automotive glass installation shops to replace windshields in automotive vehicles (*i.e.,* passengers cars, light trucks, vans, sport utility vehicles, etc.) that are cracked, broken or otherwise damaged.

ARG windshields subject to this investigation are currently classifiable under subheading 7007.21.10.10 of the Harmonized Tariff Schedules of the United States (HTSUS). Specifically excluded from the scope of this investigation are laminated automotive windshields sold for use in original assembly of vehicles. While HTSUS subheadings are provided for convenience and Customs purposes, our written description of the scope of this investigation is dispositive.

As discussed in our notice of initiation, the scope of this investigation poses unique problems of administration. For the final determination, we continue to invite parties to provide information on physical characteristics which would allow U.S. Customs officials to distinguish between ARG windshields, and windshields for new automobiles. We also invite comments on procedures for administering any order which may result from this investigation on the basis of end use. Finally, information on the record shows that all windshields imported from the PRC during the POI were ARG windshields; consequently, we note that even if the scope of this order were to cover all windshields, the Department would have all the information necessary to make a final determination.

Amendment of Preliminary Determination

On September 10, 2001, the Department of Commerce (''the Department'') preliminary determined that ARG windshields from the People's Republic of China (''PRC'') is being, or is likely to be, sold in the United States at less than fair value (''LTFV''), as provided in section 735(a) of the Tariff Act. *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Automotive Replacement Glass Windshields from the People's Republic of China,* 66 FR 48233 (September 19, 2001).

On September 21, 2001, respondent, Fuyao Glass Industry Group Company, Ltd. (''FYG'') and petitioners timely filed allegations that the Department made ministerial errors in the final determination.

The Department is amending the preliminary determination in the antidumping investigation of ARG windshields from the PRC only for FYG.

Significant Ministerial Error

A significant ministerial error is defined as an error, the correction of which, singly or in combination with other errors, would result in (1) a change of at least five absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin calculated in the original (erroneous) preliminary determination; or (2) a difference between a weighted-average dumping margin of zero or de minimis and a weighted-average dumping margin of greater than de minimis or vice versa. *See* 19 CFR 351.224(g).

FYG's Allegations of Ministerial Errors by the Department

Comment 1: FYG argues that the Department incorrectly calculated constructed export price (''CEP'') profit. FYG argues that the CEP profit ratio, calculated by the Department, should be multiplied by U.S. selling expenses to derive CEP profit. FYG points out that the Department incorrectly multiplied the CEP profit ratio by gross unit price. FYG cites section 772(d)(3) of the Act and *DOC Policy Memo 97/1* in arguing that the CEP profit ratio must be multiplied by U.S. Selling expenses, not gross unit price.

Department's Position: We are with FYG. The Department's practice is to multiply the CEP profit ratio by U.S. selling expenses. The Department will change the calculation for the final determination by multiplying the CEP profit rate by U.S. selling expenses. The correction of this error in combination with the correction of the other errors would result in a margin of 3.04 percent. This is more than five percentage points different from and more than 25 percent of the weighted-average dumping margin calculated in the preliminary determination (9.79%). Accordingly, the error alleged by respondent is a significant ministerial error within the meaning of 19 CFR 351.224(g)(1).

Comment 2: FYG alleges that the Department double counted molding. FYG argues that the Department deducted an amount from U.S. price to

account for molding purchases made in the U.S. and shipped directly to FYG's U.S. customer. FYG argues that the Department should not deduct an amount for molding from U.S. price when molding is sourced from Taiwan. FYG argues that they provided a ratio for control numbers (''CONNUM'') for which molding was purchased and that the Department should use this ratio to allocate molding purchases from U.S. suppliers.

Department's Position: The Department does not agree that this is a ministerial error. FYG reported in its June 25, 2001 response at 8, that it had no way to distinguish between those sales which used molding sourced in the United States (and shipped directly to the U.S. customer), and those sales which used molding purchased from the United States and shipped to China (to be included in the shipment). The Department, therefore, made an adjustment for molding for all U.S. sales. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

Comment 3: FYG alleges that the Department failed to correctly calculate the freight expense for the input of coal. Citing the Factors of Production Memorandum (''FOP Memo'') at 20, FYG maintains that the Department should use the shorter of the distance from the domestic supplier to FYG's factory or the distance from the nearest seaport to FYG's factory (*See Sigma Corp.* v. *United States,* 117 F. 3d 1401 (Fed. Cir. 1997)). FYG argues that the Department calculated distance using the ''Sigma'' freight distance, and should have instead used the actual distance from the supplies to FYG's factory, which is shorter than the distance between the port and FYG's factory.

Department's Position: We agree with FYG and have used the actual distance between the coal supplier and FYG's factory. We have revised the freight input calculation to reflect this correction. The correction of this error in combination with the correction of the other errors would result in a margin of 3.04 percent. This is more than five percentage points different from and more than 25 percent of the weighted-average dumping margin calculated in the preliminary determination (9.79%). Accordingly, the error alleged by respondent is a significant ministerial error within the meaning of 19 CFR 351.244(g)(1).

Comment 4: FYG alleges that the Department made a ministerial error by improperly deducting a molding cost for a CONNUM that in fact included no molding. Citing Exhibit 6 of its August 15, 2001 submission, FYG argues that the data provided in this exhibit contained a CONNUM that should not have been merged into the U.S. and FOP dataset. FYG argues that the seventh digit in the CONNUM denotes that no molding was sold with this particular model and, therefore, sales with this CONNUM should not have a molding deduction.

Department's Position: The Department does not agree that this a ministerial error. The Department relied on FYG's August 15, 2001 submission which shows that for the CONNUM in question, market economy molding purchases occurred. The Department relied on FYG's response in preparing the calculations and it is not evident that the CONNUM in question did not in fact have molding purchases. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

Comment 5: FYG alleges that the Department made a ministerial error by incorrectly failing to add selling, general and administrative (''SG&A'') costs to the cost of manufacture (''COM'') in calculating cost of production (''COP''). Citing FOP Memo at 17, FYG points out that the Department intended to calculate COP by summing materials, energy, labor, overhead, and selling, general and administrative expenses (''SG&A''). FYG argues that the COP figure did not include costs associated with SG&A, only materials, energy, labor and overhead.

Department's Position: The Department agrees that this is a ministerial error. The Department normally adds SG&A to COM to derive COP, which we failed to do in this case. The correction of this error in combination with the correction of the other errors would result in a margin of 3.04 percent for FYG. This is more than five percentage points different from and more than 25 percent of the weighted-average dumping margin calculated in the preliminary determination (9.79%). Accordingly, the error alleged by respondent is a significant ministerial error within the meaning of 19 CFR 351.224(g)(1).

Comment 6: FYG alleges that the Department used an outdated labor rate in calculating inputs. Citing *1998 Yearbook of Labour Statistics* and the Department's regression-based analysis posted on its Web site, FYG argues that the labor rate used in the preliminary determination is outdated, compared with a more contemporaneous labor rate for 1999 now listed on the Department's Web site.

Department's Position: The Department does not agree that this is a ministerial error. The Department used information available at the time of the preliminary determination and at that time listed on its website. Labor rates for 1999 were not available to the Department at the time of the preliminary determination. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

Petitioner's Allegations of Ministerial Errors by the Department

Comment 7: Petitioners allege that the Department made a ministerial error in the value it assigned to the second panel of glass of FYG's solar windshields. Citing FYG's June 25, 2001 submission at 11, petitioners point out that FYG reported it uses one pane of standard float glass and one pane of solar glass when it constructs a solar windshield. Petitioners argue that the Department should treat standard float glass as clear float glass, instead of colored float glass.

Department's Position: The Department does not agree that this is a ministerial error. FYG explained that standard float glass was used along with a solar panel in the construction of solar windshields. The Department does not consider this record information to be sufficient to make a determination that standard glass is clear glass. The Department also notes that FYG uses a small amount of clear glass in producing subject merchandise. The Department plans to examine this information more closely at verification. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

Comment 8: Petitioners allege that the Department made a ministerial error in the values it assigned to Xinyi Automotive Glass (Shenzhen) Company, Ltd.'s (''Xinyi'') PVB. Citing the FOP Memo at 7, petitioners point out that Attachment 4 to the FOP Memo lists the value for clear PVB and shaded PVB differently then those listed on page 7 of the FOP memo. Petitioners argue that the values listed for clear PVB and shaded PVB should be reversed.

Department's Position: The Department agrees that this is a ministerial error. The Department found that the values calculated for clear and shaded PVB in the FOP Memo were reversed. The Department found that after correction of this error, Xinyi's margin remains de minimis. Accordingly, the error alleged by

respondent is not a significant ministerial error within the meaning of 19 CFR 351.224(g)(1) or (2) and we are not issuing an amended preliminary determination. The Department of Commerce will, however, correct this error for the final determination.

Comment 9: Petitioners allege that the Department made a ministerial error by using the incorrect Wholesale Price Index (''WPI'') value for December 2000. Citing *International Financial Statistics* (''IFS''), May 2001, petitioners argue that the Department used a preliminary value listed in this publication, instead of using the final WPI for December 2000 as it is listed in the IFS for July 2001. Petitioners also argue that the WPI listed for December 2000 was in bold to indicate that it is preliminary. Petitioners also maintain that the WPI for other periods used by the Department (April 2000–December 2000, April 1998–March 1999, 1997, and 1996) do not match what is reported in the July 2001 edition of IFS.

Department's Position: The Department does not agree that this is a ministerial error. Contrary to petitioners' argument, the December 2000 WPI was not bolded (denoting a preliminary number) in the May 2001 issue of IFS used by the Department. The Department utilized the most recent information on the record at the time of the preliminary determination. June WPI data were not available. In regard to the other claimed inaccuracies listed above, petitioners derive different WPI's due to rounding differences. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

Comment 10: Petitioners allege that the Department made a ministerial error by using a 1992 WPI base for data collected from the period November 1991 through April 1992 in calculating an average value in Rupees per metric ton value for domestic inland insurance. Citing the Department's Web site (*http://www.ia.ita.doc.gov/factorv/prc/#Source Index*), which shows the average value in Rupees per metric ton, petitioners argue that the period of data used to calculate the average value in Rupees per metric ton should coincide with the period November 1991 through April 1992, and not the 1992 time period, as used by the Department. Petitioners also argue that the Department should have used the adjusted base year figure for 1992.

Department's Position: The Department does not agree that this is a ministerial error. The Department considers the argument by petitioners to be one of methodology and not ministerial. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision. However, the Department will examine both issues mentioned above more closely for the final determination.

Comment 11: Petitioners allege that the Department made a ministerial error by including labor expenses, both direct and indirect, incurred by surrogate company Saint-Gobain Sekurit India Limited (''St. Gobain'') in the Department's calculation of the financial ratio for factory overhead and ultimately in the SG&A ratio. Petitioners argue that inclusion of total labor from St. Gobain in the calculation of factory overhead by the Department is incorrect because doing so would include not only direct, but indirect labor in the total COM.

Department's Position: The Department does not agree that this is a ministerial error. The Department regards its decision to account for labor in the build-up of COM as one of selected methodology. Based on the information available to the Department, there was no way to distinguish between indirect and direct labor in reviewing St. Gobain's financial statement. The Department also took into consideration that a majority of the labor reported in St. Gobain's financial statement, absent information to the contrary, is more likely to be direct labor. Therefore, we are not making the suggested correction because the alleged error is not an unintentional error covered by the ministerial error provision.

We are amending the preliminary results of the antidumping duty investigation of ARG from the PRC to reflect the correction of the above-cited ministerial errors. The revised final weighted-average dumping margins are as follows:

Exporter/ manufacturer	Original weighted average margin percent	Revised weighted average margin percent
FYG	9.79	3.04
All Others Rate	9.79	3.04

Suspension of Liquidation

In accordance with section 635(c)(1)(B) of the Act, we are directing the United States Customs Service (''Customs'') to continue suspending liquidation on all imports of the subject merchandise from the PRC. Customs shall require a cash deposit or the posting of a bond equal to the weighted-average amount by which normal value exceeds the export price as indicated in the chart above. These suspension-of-liquidation instructions will remain in effect until further notice.

ITC Notification

In accordance with section 635(d) of the Act, we have notified the International Trade Commission of our amended final determination.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act.

Dated: October 17, 2001.

Faryar Shirzad,

Assistant Secretary for Import Administration.

[FR Doc. 01–26787 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

ACTION: Notice of application.

SUMMARY: The Office of Export Trading Company Affairs (''OETCA''), International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review. This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Vanessa M. Bachman, Acting Director, Office of Export Trading Company Affairs, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or e-mail at *oetca@ita.doc.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked privileged or confidential business information will be deemed to be nonconfidential. An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, Room 1104H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 01–00005.'' A summary of the application follows.

Summary of the Application

Applicant: Vinex International, Inc., 1407 Foothill Blvd., Suite 105, La Verne, California 91750.

Contact: Vatche Sahakian, President.

Telephone: (909) 596–3556.

Application No.: 01–00005.

Date Deemed Submitted: October 12, 2001.

Members (in addition to applicant): None.

Vinex International, Inc. (''VINEX'') seeks a Certificate to cover the following specific Export Trade, Export Markets, and Export Trade Activities and Methods of Operations.

Export Trade

1. Products

All products.

2. Services

All services.

3. Technology Rights

Technology Rights, including, but not limited to, patents, trademarks, copyrights and trade secrets that relate to Products and Services.

4. Export Trade Facilitation Services (as they Relate to the Export of Products, Services and Technology Rights)

Export Trade Facilitation Services, including, but not limited to, professional services and assistance relating to: government relations; state and federal export programs; foreign trade and business protocol; consulting; market research and analysis; collection of information on trade opportunities; marketing; negotiations; joint ventures; shipping and export management; export licensing; advertising; documentation and services related to compliance with customs requirements; insurance and financing; trade show exhibitions; organizational development; management and labor strategies; transfer of technology; transportation services; and the formation of shippers' associations.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operation

With respect to the sale of Products and Services, licensing of Technology Rights and provisions of Export Trade Facilitation Services, VINEX may:

1. Provide and/or arrange for the provision of Export Trade Facilitation Services;

2. Engage in promotional and marketing activities and collect information on trade opportunities in the Export Market and distribute such information to clients;

3. Enter into exclusive and/or non-exclusive licensing and/or sales agreements with Suppliers for the export of Products, Services, and/or Technology Rights in Export Markets;

4. Enter into exclusive and/or non-exclusive agreements with distributors and/or sales representatives in Export Markets;

5. Allocate export sales or divide Export Markets among Suppliers for the sale and/or licensing of Products, Services, and/or Technology Rights;

6. Allocate export orders among Suppliers;

7. Establish the price of Products, Services, and/or Technology Rights for sale and/or licensing in Export Markets;

8. Negotiate, enter into, and/or manage licensing agreements for the export of Technology Rights;

9. Enter into contracts for shipping; and

10. Exchange information on a one-on-one basis with individual Suppliers regarding inventories and near-term production schedules for the purpose of determining the availability of products for export and coordinating export with distributors.

Definitions

1. ''Supplier'' means a person who produces, provides, or sells a Product and/or Service.

Dated: October 19, 2001.

Vanessa M. Bachman,

Acting Director, Office of Export Trading Company Affairs.

[FR Doc. 01–26775 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Solicitation of Comments on Modification of Worsted Wool Fabric Tariff Rate Quotas

AGENCY: Department of Commerce, International Trade Administration.

ACTION: Notice of solicitation of comments on requests for modification of tariff rate quota limitations on the import of certain worsted wool fabrics.

DATES: To be considered, comments must be received or postmarked by 5 p.m. November 13, 2001.

ADDRESSES: Comments must be submitted to: Deputy Assistant Secretary for Textiles, Apparel and Consumer Goods Industries, Room 3001, United States Department of Commerce. Washington, D.C. 20230. Six copies of comments should be submitted.

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4058.

SUPPLEMENTARY INFORMATION: The Department of Commerce (Department) hereby solicits comments on requests for an increase in the limitations on the quantity of imports of certain worsted wool fabric under the 2002 tariff rate quotas established by the Trade and Development Act of 2000. To be considered, comments must be received or postmarked by 5:00 p.m. November 13, 2001 and must comply with the requirements of 15 CFR 340 (66 FR 6459, published January 22, 2001). Thirty days after the end of the comment period, the Department will determine whether the limitations should be modified.

1. Background

Title V of the Trade and Development Act of 2000 (the Act) creates two tariff rate quotas, providing for temporary reductions in the import duties on two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers. For worsted

wool fabric with average fiber diameters greater than 18.5 microns (Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11), the reduction in duty is limited to 2,500,000 square meters per year. For worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS heading 9902.51.12), the reduction is limited to 1,500,000 square meters per year. Both these limitations may be modified by the President, not to exceed 1,000,000 square meters per year for each tariff rate quota.

The Act requires the annual consideration of requests by U.S. manufacturers of men's or boys' worsted wool suits, suit-type jackets and trousers for modification of the limitations on the quantity of fabric that may be imported under the tariff rate quotas, and grants the President the authority to proclaim modifications to the limitations. In determining whether to modify the limitations, specified U.S. market conditions with respect to worsted wool fabric and worsted wool apparel must be considered. On January 22, 2001, the Department published regulations establishing procedures for considering requests for modification of the limitations. 66 FR 6459, 15 CFR 340.

On September 14, 2001, the Department published a notice in the Federal Register soliciting requests for modification of the 2002 tariff rate quota limitations. The Department received four such requests from the following: Hartmarx Corporation (on its own behalf, on behalf of its wholly-owned subsidiaries including Hickey-Freeman, and on behalf of the Tailored Clothing Association); Hartz & Company, Inc.; Hugo Boss; and Tom James Company. These requests were for the maximum increase (1,000,000 square meters) in each of the two tariff rate quota limitations (HTS 9902.51.11 and HTS 9902.51.12). A summary of these requests is provided below. The full text of the request and exhibits, with the exception of business confidential information, is available for inspection between 9:00 a.m. and 4:30 p.m. in Room 2233, United States Department of Commerce, 1401 Constitution Avenue, Washington D.C. 20230.

Comments may be submitted by any interested person, including U.S. manufacturers of worsted wool fabric, wool yarn, wool top and wool fiber. Comments must comply with the requirements of 15 CFR 340. If the person submitting comments is a domestic producer of worsted wool fabric, comments should include, to the extent available, the following information for each limitation with respect to which comments are being made: 1) A list of domestic manufacturers of worsted wool suits, suit-type jackets, or trousers for whom orders were filled during the period July 1, 2000 to June 30, 2001, the date of such orders, the total quantity ordered and supplied in square meters of domestically produced worsted wool fabric and of imported worsted wool fabric, and the average price received per square meter of domestically produced worsted wool fabric and of imported worsted wool fabric for such orders; 2) A list of all requests to purchase worsted wool fabric during the period July 1, 2000 to June 30, 2001 that were rejected by the person submitting the comments, indicating the dates of the requests, the quantity requested, the price quoted, and the reasons why the request was rejected; 3) Data indicating the increase and/or decrease in production and sales for the period January 1, 2001 to June 30, 2001 and the comparable six month period in the previous year of domestically-produced worsted wool fabrics used in the production of worsted wool suits, suit-type jackets and trousers; 4) Evidence of lost sales due to the temporary duty reductions on certain worsted wool fabric under the tariff rate quotas; and 5) Other evidence of the ability of domestic producers of worsted wool fabric to meet the needs of the manufacturers of worsted wool suits, suit-type jackets and trousers in terms of quantity, variety, and other relevant factors.

Comments must be accompanied by a statement by the person submitting the request (if a natural person), or an employee, officer or agent of the legal entity submitting the request, with personal knowledge of the matters set forth therein, certifying that the information is complete and accurate, signed and sworn before a Notary Public, and acknowledging that false representations to a federal agency may result in criminal penalties under federal law. Any business confidential information provided that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law. To the extent business confidential information is provided, a non-confidential submission should also be provided, in which business confidential information is summarized or, if necessary, deleted.

II. Summary of Request

All four requests, from Hartmarx Corporation (on its own behalf, on behalf of its wholly-owned subsidiaries including Hickey-Freeman, and on behalf of the Tailored Clothing Association), Hartz & Company, Inc., Hugo Boss, and Tom James Company, request the maximum possible increase (1 million square meters) in each of the two tariff rate quotas (HTS 9902.51.11 and HTS 9902.51.12).

The Hartmarx request claims that current government statistics demonstrate only a small percentage of imported worsted wool fabrics is being entered under the tariff rate quotas and that worsted wool fabric import data for the first six months of 2001, when annualized, demonstrate that in neither HTS category is there a large percentage of worsted wool fabric imports subject to duties that are covered by the tariff rate quota. Of the more than four million square meters of the finer worsted wool fabric imports (annualized), only 37 percent is subject to tariff rate quota duty-rates. Of the more than 10.5 million square meters of coarser worsted wool fabric imports (annualized), only 24 percent is subject to tariff rate quota duty-rates.

The Hartmarx request also addresses the six market factors that the Act requires be considered in determining whether to modify the tariff rate quota limitations. The request cites certain findings of the U.S. International Trade Commission in its report titled ''Certain Wool Articles: First Annual Report on U.S. Market Conditions'' (Investigation No. 332-427, USITC Publication 3454, September 2001) to support its claims that 1) there has been a decrease in the sale and production of domestically-produced worsted wool fabrics during 2000, with additional and significant production cutbacks during 2001; 2) there has been no decrease in the consumption of overall tailored worsted wool apparel on a square meter equivalent basis; 3) there is a growing inability of domestic producers of worsted wool fabrics to meet the needs of the domestic apparel manufacturers, and an increased need to rely on imported fabrics; 4) there is no evidence of reduced sales by domestic worsted wool fabric manufacturers because of any factor other than their decisions to reduce production; 5) there is evidence of lost sales by domestic apparel manufacturers because of an inability to access fabrics on a price competitive basis; and 6) the domestic textile industry is not losing sales because of imports of lower priced fabrics.

The Hartmarx request claims the current market conditions for each relevant factor favor granting the maximum increase permitted under the Act and argues that such an increase would not harm the domestic textile industry because it would not displace current domestic fabric orders nor cover

a sizeable percentage of imports. The request claims that U.S. textile mills are not producing sufficient fabrics to satisfy the needs of the U.S. tailored clothing industry, arguing that the domestic textile industry has made business decisions that have eroded its capacity to supply tailored clothing companies. The request states that the tailored clothing industry has experienced significant economic injury as a result of tariff rate quota limitations that are too small, while the textile industry has demonstrated no harm as a result of the tariff rate quotas. The tailored clothing industry claims it has demonstrated that, given current import levels, the increase being sought does not cover a majority of the worsted wool fabrics that the industry has been importing. Therefore, the request states that the U.S. textile industry remains fully protected by existing duty rates on a majority of the fabric that the tailored clothing industry will continue to import, and by the significant duty rates charged on fabric even under the tariff rate quota.

The Hartmarx request states that under the North American Free Trade Agreement (NAFTA), Canada and Mexico can export to the United States more than 6.5 million square meter equivalents of duty-free tailored clothing manufactured with non-NAFTA fabrics. In addition, these 6.5 million square meters of fabric imported into Canada and Mexico are subject to effective duty rates far lower than the reduced rates U.S. tailored clothing companies pay on the four million square meters of tariff rate quota-subject fabric. The request claims that most of these 6.5 million square meter equivalents of tailored clothing represent lost sales for domestic apparel producers. The request claims that the textile industry has experienced significant financial benefit from the Act, specifically unlimited duty-free access to yarns, top, and fiber. In addition, the sheep industry received significant funding from the Act. The request claims that the tailored clothing industry has received little benefit to date.

Hartz & Company, Inc., Hugo Boss, and Tom James Company associate themselves with the reasons and supporting material included in the petition submitted on behalf of the Tailored Clothing Association. In addition, these requesters argue the following reasons why the tariff rate quota limitations should be increased: 1) domestic fabric mills have significantly reduced their commitment to act as suppliers to domestic producers of men's and boys' worsted wool tailored clothing. Domestic producers of worsted wool fabric do not produce the fabric that the tailored clothing industry customers demand with respect to styling, variety, types, quality, and prices; 2) Canadian and Mexican manufacturers export duty-free to the United States more than 6.5 million square meter equivalents of worsted wool apparel items (suits, suit-type jackets, and trousers) containing fabrics imported from outside NAFTA countries. These fabric imports are subject to lower duty rates than those paid by U.S. importers of worsted wool fabric for apparel, even for imports under the tariff rate quotas and the United States government should provide at least as much access to imported fabric as it has allowed to Canadian and Mexican competitors. Even if the full relief is granted, the domestic tailored clothing industry will be able to import only 6 million square meters of such fabric subject to comparable duty rates; and 3) the tariff rate quota allocations for calendar year 2001 when described as a percentage of fabric imports demonstrate the inadequacy of the tariff rate quota limitations.

Dated: October 18, 2001.

Linda M. Conlin,

Assistant Secretary for Trade Development, Department of Commerce.

[FR Doc.01–26780 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 101901B]

Proposed Information Collection; Comment Request; Coastal Impact Assistance Program: Project Review Checklist

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506 (c)(2)(A)).

DATES: Written comments must be submitted on or before December 24, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington DC 20230 (or via the Internet at *MClayton@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to John R. King, N/ORM3, Room 11357, 1305 East-West Highway, Silver Spring, MD 20910– 3282 (phone 301– 713– 3155, ext. 188).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Coastal Impact Assistance Program (CIAP) recognizes that impacts from Outer Continental Shelf oil and gas activities fall disproportionately on coastal states and localities nearest to where the activities occur. The program provides funds to seven states and 147 local governments to conduct a variety of related projects, including construction and land acquisition. NOAA must review the projects in accordance with the CIAP legislation before disbursing funds. To expedite review, NOAA developed the CIAP Project Checklist for the construction and land acquisition projects. The Checklist, whose use is voluntary, asks applicants to provide project information to allow NOAA to determine their eligibility under the CIAP as well as eligibility under other relevant statutes (NEPA, etc.).

II. Method of Collection

Form submitted in paper or electronic format.

III. Data

OMB Number: 0648–0440.
Form Number: None.
Type of Review: Regular submission.
Affected Public: State, local, or tribal government.
Estimated Number of Respondents: 154.
Estimated Time Per Response: 5 hours.
Estimated Total Annual Burden Hours: 1,875.
Estimated Total Annual Cost to Public: $1,875.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) 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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 17, 2001.

Gwellnar Banks

Management Analyst, Office of the Chief Information Officer Information Officer.

[FR Doc. 01–26796 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–08–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Programs and National Estuarine Research Reserves

AGENCY: Office of Ocean and Coastal Resource Management National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), DOC.

ACTION: Notice of availability of final evaluation findings.

SUMMARY: Notice is hereby given of the availability of the final evaluation findings for the Delaware, Maine, Massachusetts and Texas Coastal Management Programs. Sections 312 and 315 of the Coastal Zone Management Act of 1972 (CZMA), as amended, require a continuing review of the performance of coastal states with respect to approval of coastal management programs, and the operation and management of NERRs.

The states of Delaware, Maine, Massachusetts and Texas were found to be implementing and enforcing their federally approved coastal management programs, addressing the national coastal management objectives identified in CZMA Section 303(2)(A)–(K), and adhering to the programmatic terms of their financial assistance awards.

Copies of these final evaluation findings may be obtained upon written request from: Ralph Cantral, Senior Policy Analyst, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway 10th Floor, Silver Spring, Maryland 20910, or *Ralph.Cantral@noaa.gov,* (301) 713–3155 Extension 118.

Dated: October 16, 2001.

Jamison S. Hawkins,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 01–26724 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 101601B]

Bottlenose Dolphin Take Reduction Team Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Take Reduction Team for Western North Atlantic coastal bottlenose dolphins (BDTRT) will hold its first meeting to develop a take reduction plan as described in the Marine Mammal Protection Act (MMPA). Input will be sought from the BDTRT on a peer review process for all data related to stock structure, abundance, and human-caused mortality and serious injury rates. The BDTRT will focus on reducing bycatch in the following fisheries: Mid-Atlantic coastal gillnet, North Carolina inshore gillnet, Southeast Atlantic gillnet, Southeastern U.S. Atlantic shark gillnet, Atlantic blue crab trap/pot, Mid-Atlantic haul/beach seine, North Carolina long haul seine, North Carolina roe mullet stop net, and Virginia pound net.

DATES: The meeting will be held on November 6, 2001, starting at 9 a.m., and continue on November 7 and 8, starting at 8:30 a.m.

ADDRESSES: The BDTRT meeting will be held at the Sheraton Oceanfront Hotel, located oceanfront at 36th Street in Virginia Beach, Virginia. Phone: 757–425–9000.

FOR FURTHER INFORMATION CONTACT: Kathy Wang, Southeast Region, 727–570– 5312, or Emily Hanson, Office of Protected Resources, 301– 713– 2322, x101.

SUPPLEMENTARY INFORMATION: Invitation letters mailed to BDTRT participants on August 27, 2001, and a **Federal Register** otice published on August 31, 2001 (66 FR 45968), announced that the BDTRT would be convened on September 12 and 13, 2001. However, the terrorist events of September 11, 2001, caused NMFS to cancel the September meeting. NMFS has rescheduled the first BDTRT meeting for November 6– 8, 2001, in Virginia Beach, Virginia.

NMFS has asked the following individuals to be members of the BDTRT: Mike Baker, Florida Gillnet Representative; Dave Beresoff, North Carolina Gillnet and Crab Pot Representative; Tina Berger, Atlantic States Marine Fisheries Commission; Paul Biermann, North Carolina Gillnet Representative; Gordon Colvin, New York Department of Environmental Conservation; David Cupka, South Carolina Wildlife and Marine Resources; Joseph DeAlteris, University of Rhode Island, Fisheries Center; Martin Dunson, Florida Crab Pot Representative; Lewis Gillingham, Virginia Marine Resources Commission; Michael Greco, Delaware Division of Fish and Wildlife; Doug Guthrie, North Carolina Stop Net Representative; Bruce Halgren, New Jersey Division of Fish and Wildlife; Emily Hanson, NMFS Office of Protected Resources; Chris Hickman, Long Haul Seine Fishery Representative; Fulton Love, Georgia Shad Gillnet Representative; Richard Luedtke, New Jersey Gillnet Representative; Rick Marks, New Jersey Gillnet and Haul Seine Representative; Dave Martin, Maryland Gillnet Representative; Bill McLellan, University of North Carolina at Wilmington; Ken Moran, South Carolina Shad Gillnet Representative; Fentress Munden, North Carolina Division of Marine Fisheries; Robert Munson, New Jersey Gillnet, Crab Pot and Pound Net Representative; Margaret Murphy, South Atlantic Fishery Management Council; Peter Nixon, Virginia Gillnet, Beach Seine, Crab Pot, and Pound Net Representative; William Outten, Maryland Department of Natural Resources; Mike Peele, North Carolina Beach Seine, Pound Net, and Gillnet Representative; Carl Poppell, Georgia Crab Pot Representative; Tim Ragen, Marine Mammal Commission; Andy Read, Duke University Marine Laboratory; John Reynolds III, Marine Mammal Commission; Sentiel Rommel, Florida Fish and Wildlife Conservation Commission; Jerry Schill, North Carolina commercial fisheries representative; Richard Seagraves, Mid-Atlantic Fishery Management Council; Larry Simns, Maryland Crab Pot Representative; Mark Swingle, Virginia Marine Science Museum; Leonard Voss, Delaware Gillnet and Crab Pot Representative; Chris Walker, Virginia Gillnet Representative; Kathy Wang, NMFS Southeast Regional Office; Rob West, North Carolina Gillnet, Pound Net, and Crab Pot Representative; A.D.

Willis, North Carolina Recreational Crab Pot and Gillnet Representative; David Woolman, South Carolina Crab Pot Representative; Nina Young, The Ocean Conservancy; Sharon Young, The Humane Society of the United States; Chris Zeman, American Oceans Campaign; Barb Zoodsma, Georgia Coastal Resources, Georgia Department of Natural Resources. The BDTRT will be facilitated by Hans Neuhauser and Jim Feldt, Georgia Environmental Policy Institute.

Meetings are open to the public.

Dated: October 18, 2001.

Wanda L. Cain,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–26792 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Establishment of an Import Limit for Certain Man-Made Fiber Textile Products Produced or Manufactured in Belarus

October 19, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit.

EFFECTIVE DATE: January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs Web site at *http://www.customs.ustreas.gov.* For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel Web site at *http://otexa.ita.doc.gov.*

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The Bilateral Textile Memorandum of Understanding dated February 17, 2000 between the Governments of the United States and Belarus establishes a limit for the period January 1, 2002 through December 31, 2002.

This limit may be revised if Belarus becomes a member of the World Trade Organization (WTO) and the United States applies the WTO agreement to Belarus.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish the 2002 limits.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 65 FR 82328, published on December 28, 2000). Information regarding the availability of the 2002 CORRELATION will be published in the **Federal Register** at a later date.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 19, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Pursuant to section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended; you are directed to prohibit, effective on January 1, 2002, entry into the United States for consumption and withdrawal from warehouse for consumption of glass fiber fabric products in Category 622, produced or manufactured in Belarus and exported during the twelve-month period beginning on January 1, 2002 and extending through December 31, 2002, in excess of 12,921,400 square meters of which not more than 1,123,600 square meters shall be in Category 622–L [1].

Products in the above categories exported during 2001 shall be charged to the applicable category limit for that year (see directive dated November 14, 2000) to the extent of any unfilled balance. In the event the limit established for that period has been exhausted by previous entries, such products shall be charged to the limit set forth in this directive.

The limit set forth above is subject to adjustment pursuant to the current bilateral agreement between the Governments of the United States and Belarus.

This limit may be revised if Belarus becomes a member of the World Trade Organization (WTO) and the United States applies the WTO agreement to Belarus.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception of the rulemaking provisions of 5 U.S.C.553(a)(1).

Sincerely,

D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc.01–26779 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–S

[1] Category 622–L: only HTS numbers 7019.51.9010, 7019.52.4010, 7019.52.9010, 7019.59.4010, and 7019.59.9010.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in India

October 18, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: October 25, 2001.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs Web site at *http://www.customs.gov.* For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel Web site at *http://otexa.ita.doc.gov.*

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for swing, special shift and carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 65 FR 82328, published on December 28, 2000). Also

see 65 FR 79344, published on December 19, 2000.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 18, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 13, 2000, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man–made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in India and exported during the twelve-month period which began on January 1, 2001 and extends through December 31, 2001.

Effective on October 25, 2001, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
219	82,592,155 square meters.
313	45,640,563 square meters.
317	29,568,549 square meters.
326	11,413,085 square meters.
334/634	213,683 dozen.
335/635	951,316 dozen.
336/636	1,360,292 dozen.
338/339	5,134,479 dozen.
340/640	2,778,913 dozen.
341	5,768,744 dozen of which not more than 3,335,245 dozen shall be in Category 341–Y [2]
342/642	1,926,418 dozen.
345	288,718 dozen.
347/348	1,093,834 dozen.
351/651	407,207 dozen.
363	63,229,578 numbers.
369–D [3]	1,807,425 kilograms.
369–S [4]	990,292 kilograms.
641	1,897,413 dozen.
647/648	1,123,847 dozen.
Group II	
200, 201, 220–227, 237, 239pt. [5], 300, 301, 331–333, 350, 352, 359pt. [6], 360–362, 600–604, 606 [7], 607, 611–629, 631, 633, 638, 639, 643–646, 649, 650, 652, 659pt. [8], 666, 669pt. [9], 670, 831, 833–838, 840–858 and 859pt. [10], as a group	181,254,409 square meters equivalent.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2000.

[2] Category 341–Y: only HTS numbers 6204.22.3060, 6206.30.3010, 6206.30.3030 and 6211.42.0054.

[3] Category 369–D: only HTS numbers 6302.60.0010, 6302.91.0005 and 6302.91.0045.

[4] Category 369–S: only HTS number 6307.10.2005.

[5] Category 239pt.: only HTS number 6209.20.5040 (diapers).

[6] Category 359pt.: all HTS numbers except 6406.99.1550.

[7] Category 606: all HTS numbers except 5403.31.0040 (for administrative purposes Category 606 is designated as 606(1)).

[8] Category 659pt.: all HTS numbers except 6406.99.1510 and 6406.99.1540.

[9] Category 669pt.: all HTS numbers except 5601.10.2000, 5601.22.0090, 5607.49.3000, 5607.50.4000 and 6406.10.9040.

[10] Category 859pt.: only HTS numbers 6115.19.8040, 6117.10.6020, 6212.10.5030, 6212.10.9040, 6212.20.0030, 6212.30.0030, 6212.90.0090, 6214.10.2000 and 6214.90.0090.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–26778 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Macau

October 18, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: October 25, 2001.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs Web site at *http://www.customs.gov.* For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel Web site at *http://otexa.ita.doc.gov.*

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 65 FR 82328, published on December 28, 2000). Also see 65 FR 69913, published on November 21, 2000.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 18, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 15, 2000, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Macau and exported during the twelve-month period which began on January 1, 2001 and extends through December 31, 2001.

Effective on October 25, 2001, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
333/334/335/833/834/835.	455,414 dozen of which not more than 239,896 dozen shall be in Categories 333/335/833/835.
336/836	103,369 dozen.
338	538,188 dozen.
339	2,349,081 dozen.
340	539,003 dozen.
342	160,500 dozen.
345	90,231 dozen.
347/348/847	1,286,900 dozen.
351/851	120,780 dozen.
359–C/659–C [2]	625,313 kilograms.
359–V [3]	215,888 kilograms.
638/639/838	3,003,100 dozen.
642/842	211,265 dozen.
647/648	934,689 dozen.
Group II	
400–431, 433–438, 440–448, 459pt. [4], 464 and 469pt. [5], as a group.	1,744,810 square meters equivalent.
Sublevel in Group II	
445/446	94,772 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2000.

[2] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[3] Category 359–V: only HTS numbers 6103.19.2030, 6103.19.9030, 6104.12.0040, 6104.19.8040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.9044, 6110.90.9046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.9030, 6204.12.0040, 6204.19.8040, 6211.32.0070 and 6211.42.0070.

[4] Category 459pt.: all HTS numbers except 6405.20.6030, 6405.20.6060, 6405.20.6090, 6406.99.1505 and 6406.99.1560.

[5] Category 469pt.: all HTS numbers except 5601.29.0020, 5603.94.1010 and 6406.10.9020.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–26776 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the Republic of Turkey

October 18, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: October 25, 2001.

FOR FURTHER INFORMATION CONTACT: Roy Unger, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs Web site at *http://www.customs.gov*. For information on embargoes and quota reopenings, refer to the Office of Textiles and Apparel Web site at *http://www.otexa.ita.doc.gov*.

SUPPLEMENTARY INFORMATION:

Authority Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being increased for the recrediting of unused carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (*see* **Federal Register** notice 65 FR 82328, published on December 28, 2000). Also *see* 65 FR 66730, published on November 7, 2000.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 18, 2001.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on October 27, 2000, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in the Republic of Turkey and exported during the twelve-month period which began on January 1, 2001 and extends through December 31, 2001.

Effective on October 25, 2001, you are directed to increase the current limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit [1]
Limits not in a Group	
338/339/638/639	7,466,052 dozen of which not more than 6,495,087 dozen shall be in Categories 338–S/339–S/638–S/639–S [2].
350	775,336 dozen.
369–S [3]	2,366,427 kilograms.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2000.

[2] Category 338–S: only HTS numbers 6103.22.0050, 6105.10.0010, 6105.10.0030, 6105.90.8010, 6109.10.0027, 6110.20.1025, 6110.20.2040, 6110.20.2065, 6110.90.9068, 6112.11.0030 and 6114.20.0005; Category 339–S: only HTS numbers 6104.22.0060, 6104.29.2049, 6106.10.0010, 6106.10.0030, 6106.90.2510, 6106.90.3010, 6109.10.0070, 6110.20.1030, 6110.20.2045, 6110.20.2075, 6110.90.9070, 6112.11.0040, 6114.20.0010 and 6117.90.9020; Category 638–S: all HTS numbers except 6109.90.1007, 6109.90.1009, 6109.90.1013 and 6109.90.1025; Category 639–S: all HTS numbers except 6109.90.1050, 6109.90.1060, 6109.90.1065 and 6109.90.1070.

[3] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–26777 Filed 10–23–01; 8:45 am]

BILLING CODE 3510–DR–S

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Open Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub.L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 31 October 2001 through 01 November 2001.

Time of Meeting: 0800–1700.

Place: Institute for Defense Analyses, 1801 North Beauregard Street, Alexandria, VA.

Agenda: The Army Science Board's (ASB) FY2002 Summer Study ''Methods to Reduce O&S Costs in the Future Army'' leadership group will meet to discuss the upcoming studies and other related issues. This meeting

will be open to the public. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. For further information, please contact MAJ Robert B. Grier, Executive Officer, Army Science Board (703) 604–7478.

Wayne Joyner,

Executive Assistant, Army Science Board.

[FR Doc. 01–26718 Filed 10–23–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent License; Acambis, Inc.

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Acambis, Inc., a revocable, nonassignable, exclusive license to practice worldwide the Government-owned inventions described in U.S. Patent application Serial No. 09/439,311, entitled ''A Recombinant Polypeptide for Use in the Manufacture of Vaccines Against Campylobacter Induced Diarrhea and to Reduce Colonization'' filed November 14, 1998, and its PCT serial number US99/27195 in the field of vaccines against Campylobacter associated disease.

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with the Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave., Silver Spring, MD 20910–7500.

FOR FURTHER INFORMATION CONTACT: Dr. Charles Schlagel, Director, Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave., Silver Spring, MD 20910–7500, telephone (301) 319–7428.

Dated: October 15, 2001.

T.J. Welsh,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 01–26719 Filed 10–23–01; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board; Notice

AGENCY: National Assessment Governing Board; U.S. Department of Education.

ACTION: Recommendations for candidates to fill board vacancies.

SUMMARY: The Secretary of Education, the Honorable Rod Paige, and the National Assessment Governing Board (NAGB), seek your assistance in identifying qualified individuals who can serve as members of the National Assessment Governing Board.

In 1988 Congress passed legislation creating the Board. In 1994 Congress amended and reauthorized the original legislation. The statute provides that ''* * * the Secretary and the Board shall ensure at all times that the membership of the Board reflects regional, racial, gender, and cultural balance and diversity * * *;'' Currently, the Board is comprised of 26 members, each of whom serves a four-year term. The membership of the Board represents a wide and specified diversity of expertise and experience. As vacancies occur, new members of the Board are appointed by the Secretary from among candidates who are nominated by the Board itself, after national consultation with many organizations, associations, and knowledgeable individuals. For each vacancy, the Board must nominate at least six persons who, by reason of experience or training, are qualified in a particular category. Current members of the Board who have not completed two full terms, and who are otherwise eligible, may be re-nominated.

In order for the Board to consider a candidate, it is essential to have a nominating letter, which sets forth your evaluation of the recommended individual's qualifications, as well as a current resume for the individual being suggested. For 2002, the Board must nominate candidates for eight positions in the following eight categories:

1. Elementary School Principal
2. Secondary School Principal
3. Fourth-Grade Teacher
4. Eighth-Grade Teacher
5. Representative of Business or Industry
6. Representative of the General Public, including Parents
7. State Legislator (Democrat)
8. Chief State School Officer.

Please feel free to nominate potential candidates in any of the above categories. Note, however, that in order to receive full consideration, all recommendations must be received by the Board no later than February 22, 2002. Nominations or inquires should be directed to: National Assessment Governing Board, 800 North Capitol Street, NW, Suite 825, Washington, DC 20002–4233, Attention: Dr. Sharif Shakrani.

FOR FURTHER INFORMATION CONTACT: Sharif Shakrani, Deputy Executive Director, National Assessment Governing Board, 800 North Capitol Street, NW, Suite #825, Washington, DC 20002–4233, telephone: (202) 357–6938.

SUPPLEMENTARY INFORMATION: The National Assessment Governing Board is established under section 412 of the National Education Statistics Act of 1994 (Title IV of the Improving America's Schools Act of 1994) (Pub. L. 103–382). The Board is established to formulate policy guidelines for the National Assessment of Educational Progress. The Board is responsible for selecting subject areas to be assessed, developing assessment objectives, identifying appropriate achievement goals for each grade and subject tested, and establishing standards and procedures for interstate and national comparisons. More detailed information about the Governing Board and the National Assessment of Educational Progress program is available on the NAGB Web site: *http//www.nagb.org.*

Dated: October 19, 2001.

Roy Truby,

Executive Director, National Assessment Governing Board.

[FR Doc. 01–26747 Filed 10–23–01; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL02–6–000]

Dynegy Midwest Generation, Inc. and Dynegy Power Marketing, Inc. Complainants v. Commonwealth Edison Company Respondent; Notice of Complaint

October 18, 2001.

Take notice that on October 17, 2001, Dynegy Midwest Generation, Inc. and Dynegy Power Marketing, Inc. (Dynegy) tendered for filing a Complaint against Commonwealth Edison Company, (ComEd).

In its Complaint, Dynegy alleges that ComEd has failed to properly enforce the network resource designation provisions of its Open Access Transmission Tariff (OATT). Dynegy further alleges that ComEd's actions

jeopardize reliability, deprive Dynegy of revenues for capacity sales, and permits the improper prioritization of network transmission service for bumping and curtailment.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before October 26, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Answers to the complaint shall also be due on or before October 26, 2001. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–26715 Filed 10–23–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–2398–002]

Liberty Electric Power, LLC; Notice of Filing

October 18, 2001.

Take notice that on October 16, 2001, Liberty Electric Power, LLC, which will own and operate a natural gas-fired electric generating facility in the Borough of Eddystone, Pennsylvania submitted for filing with the Federal Energy Regulatory Commission (Commission) its initial FERC Electric Tariff Volume No. 1, in compliance with the Commission's August 15, 2001 and October 12, 2001 letter orders, which will enable Liberty Electric to engage in the sale of electric energy and capacity and ancillary services at market-based rates.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before October 26, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–26756 Filed 10–23–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Meeting on Initial Information Package and Project Site Visit for an Alternative Licensing Procedure

October 18, 2001.

a. *Type of Application:* Alternative Licensing Procedure.

b. *Project No.:* 11803–002.

c. *Applicant:* City of Broken Bow, Oklahoma.

d. *Name of Project:* Broken Bow Reregulating Dam Project.

e. *Location:* On the Mountain Fork River near the town of Broken Bow, McCurtain County, Oklahoma utilizing federal lands administered by the U.S. Army Corps of Engineers.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

g. *Applicant Contact:* Stewart Noland, Crist Engineers, Inc., 1405 North Pierce Street, Suite 301, Little Rock, AR 72207, (501) 664–1552.

h. *FERC Contact:* Peter Leitzke at (202) 219–2803; e-mail *peter.leitzke@ferc.fed.us.*

i. The proposed project would utilize the existing U.S. Army Corps of Engineers' Broken Bow Reregulating Dam and would consist of: (1) A new 50-foot-long, 50-foot-wide, 20-foot-high powerhouse containing one or two generating units having a total installed capacity of 5,000 kilowatts; (2) a short transmission line; and (3) appurtenant facilities.

j. Public Meetings and Project Site Visit

The City of Broken Bow is using the Federal Energy Regulatory Commission's (Commission) alternative licensing procedure (ALP). Under the ALP, the City of Broken Bow will prepare an Applicant Prepared Environmental Assessment (APEA) and license application for the Broken Bow Reregulating Dam Hydroelectric Project.

The ALP includes provisions for the distribution of an initial information package (IIP), and for the cooperative scoping of environmental issues and information needs. The City of Broken Bow plans to distribute its IIP for the Broken Bow Project on or about October 15, 2001, to the mailing list for this proceeding.

The City of Broken Bow will hold informational meetings and a project site visit on November 15, and 16, 2001. The purpose of the meetings is to review the information presented in the IIP and to initiate the identification of areas of interest which should be addressed in the licensing and related Applicant Prepared Environmental Assessment (APEA) processes. All interested individuals, organizations, and agency representatives are invited and encouraged to attend any or all the meetings.

The site visit is intended to provide the opportunity for interested individuals to learn more about the proposed project, its operations and the surrounding environment. Planned activities include a facility tour, a visit to public access sites, and a tour of the project reservoir and waterway.

Additional notices seeking comments on the specific project proposal, public scoping, interventions and protests, and recommended terms and conditions will be issued at later dates.

The site visit will begin at 2 p.m. November 15 at the Broken Bow City Hall, 210 North Broadway, Broken Bow, Oklahoma.

The November 15th meeting will be held at the Broken Bow Library Public Meeting Room, 400 North Broadway, Broken Bow, Oklahoma, beginning at 7 p.m.

The November 16th meeting will be held at the Broken Bow City Hall, 210 North Broadway, Broken Bow, Oklahoma, beginning at 8 a.m.

Based on feedback received on the IIP, the meetings, and the project site visit, the City of Broken Bow will prepare a Scoping Document 1 (SD1) which will provide information on the scoping process, APEA schedule, background information, potential environmental issues, and proposed project alternatives. Additional meetings may be held to assist in the development of SD1.

Upon issuance of SD1, the City of Broken Bow and the Commission will issue public notice of its availability and will hold a public scoping meeting(s) pursuant to the National Environmental Policy Act of 1969 (NEPA).

All interested individuals, organizations, and agencies are invited and encouraged to attend the informational meetings on the IIP and project site visit, and to assist in the identification of environmental issues that should be included in SD1.

For further information regarding the informational meetings and project site visit or to be added to the mailing list for the Broken Bow Reregulating Dam Project ALP, please contact Stewart Noland at (501) 664–1552 or Peter Leitzke of the Commission's staff at (202) 219–2803.

David P. Boergers,

Secretary.

[FR Doc. 01–26717 Filed 10–23–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11566–000—Maine Damariscotta Mills Project]

Ridgewood Maine Hydro Partners, L.P.; Notice of Proposed Restricted Service List for a Programmatic Agreement for Managing Properties Included in or Eligible for Inclusion in the National Register of Historic Places

October 18, 2001.

Rule 2010 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure provides that, to eliminate unnecessary expense or improve administrative efficiency, the Secretary may establish a restricted service list for a particular phase or issue in a proceeding.[1] The restricted service list should contain the names of persons on the service list who, in the judgment of the decisional authority establishing the list, are active participants with respect to the phase or issue in the proceeding for which the list is established.

The Commission staff is consulting with the Maine State Historic Preservation Officer (hereinafter, SHPO) and the Advisory Council on Historic Preservation (hereinafter, Advisory Council) pursuant to the Council's regulations, 36 CFR part 800, implementing Section 106 of the National Historic Preservation Act, as amended, (16 U.S.C. Section 470 f), to prepare a Programmatic Agreement for managing properties included in, or eligible for inclusion in, the National Register of Historic Places at Project No. 11566–000.

The Programmatic Agreement, when executed by the Commission, the SHPO, and the Advisory Council, would satisfy the Commission's Section 106 responsibilities for all individual undertakings carried out in accordance with the license until the license expires or is terminated (36 CFR 800.13[e]). The Commission's responsibilities pursuant to Section 106 for the project would be fulfilled through the Programmatic Agreement, which the Commission staff proposes to draft in consultation with certain parties listed below. The executed Programmatic Agreement would be incorporated into any license issued.

Ridgewood Maine Hydro Partners, L.P., as prospective licensee for Project No. 11566–000, is invited to participate in consultations to develop the Programmatic Agreement and to sign as a concurring party to the Programmatic Agreement. For purposes of commenting on the Programmatic Agreement, we propose to restrict the service list for Project No. 11566–000 as follows:

Dr. Laura Henley Dean, Advisory Council on Historic Preservation, The Old Post Office Building, Suite 803, 1100 Pennsylvania Avenue, NW., Washington, DC 20004

Kevin Webb, CHI Energy, Inc., 200 Bulfinch Drive, Andover, MA 01810

Earle G. Shettleworth, Jr., SHPO, ME Historic Preservation Commission, 55 Capitol Street, State House Station 65, Augusta, ME 04330

Dr. Arthur E. Spiess, ME Historic Preservation Commission, 55 Capitol Street, State House Station 65, Augusta, ME 04330

Kevin Mendik, National Park Service, 15 State Street, Boston, MA 02109

Any person on the official service list for the above-captioned proceedings may request inclusion on the restricted service list, or may request that a restricted service list not be established, by filing a motion to that effect within 15 days of this notice date. An original and 8 copies of any such motion must be filed with the Secretary of the Commission (888 First Street, NE., Washington, DC 20426) and must be served on each person whose name appears on the official service list. If no such motions are filed, the restricted service list will be effective at the end of the 15 day period. Otherwise, a further notice will be issued ruling on the motion.

David P. Boergers,

Secretary.

[FR Doc. 01–26716 Filed 10–23–01; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2010.

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–140292; FRL–6807–6]

Access to Confidential Business Information by Syracuse Research Corporation (SRC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized Syracuse Research Corporation (SRC) of Arlington, VA access to information which has been submitted to EPA under sections 4, 5, 6, and 8 of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be confidential business information (CBI).

DATES: Access to the confidential data submitted to EPA under sections 4, 5, 6, and 8 of TSCA occurred as a result of an approved waiver dated September 24, 2001, which requested granting SRC immediate access to sections 4, 5, 6, and 8 of TSCA CBI.

FOR FURTHER INFORMATION CONTACT: Barbara A. Cunningham, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epamail.epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this Notice Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to ''those persons who are or may be required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA).'' Since other entities may also be interested, the Agency has not attempted to describe all

the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

III. What Action is the Agency Taking?

Under contract number 68–W–01–061, SRC of 1215 Jefferson Davis Highway, Suite 405, Arlington, VA, will assist the Office of Pollution Prevention and Toxics (OPPTS) in preparing chemical reviews for the TSCA New Chemicals Review Program. This includes preparing documents to be used for Chemical Review Search Strategy and Structure Activity Team meetings. The contractor requires access to current and past cases to fulfill these duties.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA contract number 68–W–01–061, SRC will require access to CBI submitted to EPA under sections 4, 5, 6, and 8 of TSCA, to perform successfully the duties specified under the contract.

SRC personnel was given access to information submitted to EPA under sections 4, 5, 6, and 8 of TSCA. Some of the information may be claimed or determined to be CBI.

Access to the confidential data submitted to EPA under sections 4, 5, 6, and 8 of TSCA occurred as a result of an approved waiver dated September 24, 2001, which requested granting SRC immediate access to sections 4, 5, 6, and 8 of TSCA CBI. This waiver was necessary to allow SRC to assist EPA in preparing chemical reviews for the TSCA New Chemicals Review Program.

EPA is issuing this notice to inform all submitters of information under sections 4, 5, 6,and 8 of TSCA, that the Agency may provide SRC access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA Headquarters and at the SRC site located at 1215 Jefferson Davis Highway, Suite 405, Arlington, VA.

SRC will be required to adhere to all provisions of EPA's *TSCA Confidential Business Information Security Manual*.

Clearance for access to TSCA CBI under this contract may continue until September 30, 2006.

SRC personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

List of Subjects

Environmental protection, Confidential business information.

Dated: October 12, 2001.

Allan S. Abramson,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 01–26687 Filed 10–23–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–64061; FRL–6805–4]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request for amendment by registrants to delete uses in certain pesticide registrations.

DATES: Unless a request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on April 22, 2002, unless indicated otherwise.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Office location for commercial courier delivery, telephone number and e-mail address: Rm. 266A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5761; e-mail: *hollins.james@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov*. To access this document, on the homepage select ''Laws and Regulations'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listing at *http://www.epa.gov/fedrgstr/*.

2. *In person*. Contact James A. Hollins at 1921 Jefferson Davis Highway, Crystal Mall #2, Rm. 232, Arlington, VA, telephone number (703) 305–5761. Available from 7:30 a.m. to 4:45 p.m., Monday through Friday, excluding legal holidays.

II. What Action is the Agency Taking?

This notice announces receipt by the Agency of applications from registrants to delete uses in 16 pesticide registrations. These registrations are listed in the following Table 1 by registration number, product name, active ingredient and specific uses deleted:

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Registration No.	Product	Chemical Name	Delete From Label
000228–00095	Riverdale 2,4-D L.V. 6 Ester	Acetic acid, 2,4-D 2-ethylhexyl ester	Drainage ditchbanks and aquatic uses
000228–00126	Riverdale Solution Emulsible	Acetic acid, 2,4-D 2-Ethylhexyl ester	Drainage ditchbanks and aquatic uses

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

Registration No.	Product	Chemical Name	Delete From Label
000228–00139	Riverdale 2,4-D L.V. 4 Ester	Acetic acid, 2,4-D 2-Ethylhexyl ester	Aquatic uses and sugarcane
000228–00185	Riverdale Tri-Ester	Acetic Acid, 2,4-D 2-Ethyl Ester; Isooctyl 2-(2,4-D) propionate	Drainage ditchbanks
000264–00324	Sevin Brand 99% Technical Carbaryl Insecticide	Carbaryl	Poultry
000264–00456	Ethoprop Technical	Ethoprop	Peanuts, citrus seedlings, commercial and golf course turf
000264–00457	MOCAP 15% Nematicide-Insecticide	Ethoprop	Peanuts, sweet corn lay-by applications
000264–00458	MOCAP EC Nematicide-Insecticide	Ethoprop	Peanuts, dry/snap beans, sugarcane, field/sweet corn, citrus seedlings
000264–00465	MOCAP 10% Granular Nematicide-Insecticide	Ethoprop	Peanuts, golf course turf, sweet corn lay-by applications
000264–00469	MOCAP (R) 20% Granular Nematicide-Insecticide	Ethoprop	Sweet corn lay-by application
000264–00599	Ethoprop Technical	Ethoprop	Peanuts, citrus seedlings, commercial and golf course turf
000769–00898	Pratt Triple X NA Weed Killer	Acetic acid, (2,4-D)-2-ethylhexyl ester; Prometon	Drainage ditchbanks
009779–00262	MCPA Amine Herbicide	MCPA, dimethylamine salt	Rice
011656–00021	Carbaryl Cutworm Bait	Carbaryl	Alfalfa and grapes
042750–00014	MCPA Amine 4	MCPA, dimethylamine salt	Rice
042750–00024	MCPA Sodium Salt	MCPA, Sodium salt	Rice

Note: Company numbers 000264 and 011656 have wavied the 180–day comment period

Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before April 22, 2002 unless indicated otherwise, to discuss withdrawal of the application for amendment. This 180–day period will also permit interested members of the public to intercede with registrants prior to the Agency's approval of the deletion.

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
000228	Riverdale Chemical Co., 1333 Burr Ridge Parkway, Suite 125A, Burr Ridge, IL 60521.
000264	Aventis Cropscience USA LP, 2 T.W. Alexander Drive, Box 12014, Research Triangle Park, NC 27709.
000769	The Platinum Group, Agent For: Verdant Brands, Inc., 9855 W. 78th Street, Eden Prairie, MN 55344.
009779	Agriliance, LLC, Box 64089, St. Paul, MN 55164.
011656	Western Farm Service, Inc., Attn: Dunya Haproff-Fondse, Box 1168, Fresno, CA 93715.
042750	Pyxis Regulatory Consulting, Agent For: Albaugh Inc., 11324 17th Ave., Ct. NW., Gig Harbor, WA 98332.

III. What is the Agency Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. How and to Whom Do I Submit Withdrawal Requests?

1. *By mail*: Registrants who choose to withdraw a request for use deletion must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked November 23, 2001.

2. *In person or by courier*: Deliver your withdrawal request to: Document Processing Desk (DPD), Information Services Branch, Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 266A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The DPD is open from 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The DPD telephone number is (703) 305–5263.

3. *Electronically*. You may submit your withdrawal request electronically by e-mail to: *hollins.james@epa.gov.* Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format.

V. Provisions for Disposition of Existing Stocks

The Agency has authorized the registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Dated: October 3, 2001.

Richard D. Schmitt,

Associate Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 01–26268 Filed 10–23–01; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1045; FRL–6802–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1045, must be received on or before November 23, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1045 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112	Crop production Animal production
	311 32532	Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations'' ''Regulation and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1045. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1045 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: *opp-docket@epa.gov,* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1045. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version

of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 5, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Industry Task Force

PP 4E3060

EPA has received a pesticide petition (4E3060) from Industry Task Force II on 2,4-D Research Data, McKenna and Cuneo, 1900 K Street, NW., Washington, DC 20006–1108 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by extending for 3 years, until December 31, 2004, the time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) in or on the raw agricultural commodity soybeans at 0.02 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant and animal metabolism*. The nature of the residue in plants is adequately understood. Acceptable wheat, lemon, and potato metabolism studies have been submitted. The nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies submitted.

2. *Analytical method*. The residue field tests on soybeans used a gas chromatography (GC) method with electron capture detection (ECD), EN-CAS Method ENC-2/93. This GC/ECD method is adequate for determining residues in or on soybeans with a limit of quantitation (LOQ) of 0.01 ppm.

3. *Magnitude of residues*. In 27 tests on soybeans conducted in Arkansas, Illinois, Louisiana, Missouri, and Tennessee, residues of 2,4-D were nondetectable (<0.01 ppm) in/on all samples of forage and seeds from soybeans treated with a preplant application of 2,4-D (acid, ester, or amine) at 0.5, 1.25, and 2.75 lb active ingredient per acre at lx, 2.5x, and 5.5x rates. Residues of 2,4-D were also nondetectable (<0.01 ppm) in/on 21 of 27 hay samples from the same tests. Hay samples with detectable residues of 0.01-0.04 ppm only came from 2.5x and 5.5x applications of the 2,4-D 2-ethylhexyl ester (2-EHE). Since the label restriction against feeding/grazing soybean forage and hay is not proposed for deletion at this time, no tolerances are necessary for these feed items. Since data from the 5.5x application demonstrate that 2,4-D residues on soybean seeds are nondetectable or >0.05 ppm, a soybean processing study is not required. Based on the residue data for seeds from soybeans, a tolerance of 0.02 ppm in or on the raw agricultural commodity soybeans is appropriate.

B. Toxicological Profile

1. *Acute toxicity*. The oral LD_{50} of 2,4-D acid is 699 mg/kg in the rat. The dermal LD_{50} in the rabbit is >2,000 mg/kg. The acute inhalation LC_{50} in the rat is >1.8 mg/liter. A primary eye irritation study in the rabbit showed severe irritation. A dermal irritation study in the rabbit showed moderate irritation. A dermal sensitization study in the guinea pig showed no skin sensitization. An acute neurotoxicity study in the rat produced a no observed adverse effect level (NOAEL) of 227 milligram/kilograms (mg/kg) for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kg with a lowest observed adverse effect level (LOAEL) of 227 mg/kg.

2. *Genotoxicity*. Mutagenicity studies including gene mutation, chromosomal aberrations, and direct DNA damage tests were negative for mutagenic effects.

3. *Reproductive and developmental toxicity*. A 2–generation reproduction study was conducted in rats with NOAELs for parental and developmental toxicity of 5 mg/kg/day. The LOAELs for this study are established at 20 mg/kg/day based on reductions in body weight gain in F_0 and F_{2b} pups, and reduction in pup weight at birth and during lactation. A teratology study in rabbits given gavage doses at 0, 10, 30, and 90 mg/kg on days 6 through 18 of gestation was negative for developmental toxicity at all doses tested. A teratology study in rats given gavage doses at 0, 8, 25, and 75 mg/kg on days 6 through 15 of gestation showed maternal toxicity only at 75 mg/kg. A NOAEL for fetotoxicity was established at 25 mg/kg/day based on delayed ossification at the 75 mg/kg dose level. The effects on pups occurred in the presence of parental toxicity.

4. *Subchronic toxicity*. A subchronic dietary study was conducted with mice

fed diets containing 0, 1, 15, 100, and 300 mg/kg/day with a NOAEL of 15 mg/kg/day. The (LOAEL) was established at 100 mg/kg/day based on decreased glucose and thyroxine levels, increases in absolute and relative kidney weights, and histopathological lesions in the liver and kidneys. A 90–day dietary study in rats fed diets containing 0, 1, 15, 100, or 300 mg/kg/day resulted in a NOAEL of 15 mg/kg/day and an LOAEL of 100 mg/kg/day. The LOAEL was based on decreases in body weight and food consumption, alteration in clinical pathology, changes in organ weights, and histopathological lesions in the kidney, liver, and adrenal glands of both sexes of rats. A 90–day feeding study was conducted in dogs fed diets containing 0, 0.3, 1, 3, and 10 mg/kg/day with a NOAEL of 1 mg/kg/day. The LOAEL was established at 3 mg/kg/day based on histopathological changes in the kidneys of male dogs.

5. *Chronic toxicity*. A 1–year dietary study was conducted in the dog using doses of 0, 1, 5, and 7.5 mg/kg/day. The NOAEL was 1 mg/kg/day and the LOAEL was 5 mg/kg/day based on clinical chemistry changes and histopathological lesions in the liver and kidney. A 2–year feeding/carcinogenicity study was conducted in mice fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/kg/day. The systemic LOAEL was established at 15 mg/kg/day based on increased kidney and adrenal weights and homogeneity of renal tubular epithelium due to cytoplasmic vacuoles. No carcinogenic effects were observed under the conditions of the study at any dosage level tested.

A second 2–year oncogenicity study was conducted in mice fed diets containing 0, 5,62.5, and 125 mg/kg/day (males) and 0, 5, 150, and 300 mg/kg/day (females). The NOAEL was 5 mg/kg/day and LOAEL was 62.5 (M) and 150 (F) mg/kg/day based on increases in absolute and/or relative kidney weights and histopathological lesions in the kidneys. No treatment-related oncogenicity was observed.

A 2–year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg kg/day. Although there appeared to be a slight treatment-related incidence of benign brain tumors (astrocytomas) in male rats fed diets containing 45 mg/kg/ day, two different statistical evaluations found no strong statistical evidence of carcinogenicity in male rats. There were no carcinogenic effects observed in female rats.

A second 2–year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 5, 75, and 150 mg/kg/day. The NOAEL was 5 mg/kg/day and the LOAEL was 75 mg/kg/day based on decreased body weight, body weight gain, and food consumption; clinical chemistry changes; organ weight changes and histopathological lesions. No treatment-related carcinogenic effects or increased incidences of astrocytomas were observed.

6. *Animal metabolism*. The metabolism of phenyl ring labeled ^{14}C-2,4-D was studied in the rat following a single intravenous or oral dose of approximately 1 mg/kg/day. At 48 hours after treatment, recovery of radioactivity in urine was in excess of 98%. Parent 2,4-D was the major metabolite (72.9% to 90.5%) found in the urine.

7. *Metabolite toxicology*. Because 2,4-D is rapidly excreted without significant metabolism, the toxicology data on the parent compound adequately represents metabolite toxicology.

8. *Endocrine disruption*. Although tests explicitly designed to evaluate the potential endocrine effects of 2,4-D have not been conducted, a large and diverse battery of toxicology studies is available including acute, subchronic, chronic, reproductive, and developmental toxicity tests. The results of these studies do not provide a pattern of effects suggestive of endocrine modulated toxicity.

C. Aggregate Exposure

1. *Dietary exposure*. Residues are below the limit of quantification (LOQ = 0.01 ppm) in soybeans. Tolerances have been established (40 CFR 180.142) for residues of 2,4-D as the acid or various of its salts and esters, in or on a variety of raw agricultural commodities. In addition, there are also tolerances for 2,4-D for meat, milk, and eggs.

2. *Drinking water*. 2,4-D is soluble in water. The average field half-life is 10 days. The chemical is potentially mobile, but rapid degradation in soil and removal by plant uptake minimizes leaching. A Maximum Contaminant Level (MCL) of 0.07 mg/L has been established. In addition, the following Health Advisories have been established: For a 10-kg child, a range of 1 mg/L from 1–day exposure to 0.1 mg/L for longer-term exposure up to 7 years; for a 70 kg adult, a range of 0.4 mg/L for longer-term exposure to 0.07 mg/L for lifetime exposure.

3. *Non-dietary exposure*. 2,4-D is currently registered for use on the following residential non-food sites: Ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. 2,4-D is a commonly-used pesticide in non-agricultural settings. There are chemical-specific and site-specific data available to determine the potential risks associated with residential exposures from the registered uses of 2,4-D. Dislodgeable residues taken from ten 2,4-D turf transferable residue studies showed low dislodgeable percent of application, 0.9% at 1 hour, 0.8% at 8 hours and 0.7% at 24 hours following applications. No detectable residues were found in urine samples supplied by volunteers exposed to sprayed turf 24 hours following application. Intermediate-term postapplication exposure is thus not expected.

D. Cumulative Effects

There are no available data to determine whether 2,4-D has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 2,4-D does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population*. For chronic dietary exposure, EPA has established the Reference Dose (RfD) for 2,4-D at 0.01 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1–year oral toxicity study in dogs with a NOAEL of 1 mg/kg/day and an uncertainty factor of 100. In the most recent final rule establishing tolerances for 2,4-D (time-limited tolerance in soybeans at 64 FR 11792 on March 10, 1999), EPA calculated aggregate risks for the existing uses of 2,4-D at that time (including soybeans and all other existing uses). Since those uses have not changed in the interim, it is appropriate to utilize the same calculations to support extension of the time-limited tolerance in or on soybeans. Chronic dietary exposure estimates (from Dietary Exposure Evaluation Model) used mean consumption (3 day average) and anticipated or tolerance-level residues for all commodities. Exposure estimates used 25.6% of the RfD for the general U.S. population (48 states) and 49.2% of the RfD for the most exposed population of non-nursing infants (less than 1 years old). Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA did not expect the aggregate exposure to exceed 100% of the RfD.

For acute dietary exposure, the NOAEL of 67 mg/kg/day from the rat acute neurotoxicity study should be used for risk assessment. As

neurotoxicity is the effect of concern, the acute dietary risk assessment should evaluate acute dietary risk to all population subgroups. Again, relying upon the EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, EPA calculated acute aggregate risk taking into account anticipated residues or tolerance level residues on all treated crops, which is a significant over estimation of dietary exposure. For the U.S. population, the acute dietary margin of exposure (MOE) is 321 and it is 399 for females 13+ years. These figures do not exceed EPA's level of concern for acute dietary exposure.

Regarding dietary cancer risk assessment, EPA's Cancer Peer Review Committee has classified 2,4-D as a Group D chemical (not classifiable as to human carcinogenicity) on the basis that, the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

2. *Infants and children*. The data base on 2,4-D relative to prenatal and postnatal toxicity is complete with respect to current data requirements. Since the developmental NOAELs for rats and rabbits are 25-fold greater and 90-fold greater, respectively, than the RfD NOAEL of 1 mg/kg/day in the 17–year oral toxicity study in dogs, an additional uncertainty factor to protect infants and children is not warranted.

Using conservative EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, aggregate acute MOEs for exposure to 2,4-D from food are 214 for infants less than 1 years old and 399 for females 13 and older. The maximum estimated concentrations of 2,4-D in surface and ground water are less than EPA's Drinking Water Level of Comparison (DWLOC) figures for 2,4-D as a contribution to acute aggregate exposure. EPA concluded with reasonable certainty that residues of 2,4-D in drinking water do not contribute significantly to the aggregate acute human health risk.

Using the same conservative assumptions described earlier to estimate chronic risk from aggregate chronic exposure to 2,4-D from food, 11.4% of the RfD is utilized for nursing infants less than 1 years old up to 49.2% of the RfD for non-nursing infants less than 1 years old. Further refinement using additional anticipated residue values in crops and percent crop-treated information would result in lower chronic dietary (food) exposure estimates, thus reducing the aggregate risk estimate. Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA concluded that it did not expect the aggregate exposure to exceed 100% of the RfD.

F. International Tolerances

There are no Codex, Canadian, or Mexican maximum residue limits for use of 2,4-D on soybeans.

[FR Doc. 01–26534 Filed 10–23–01; 8:45 am]

BILLING CODE 6560–S

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Special Meeting of the Sub-Saharan Africa Advisory Committee (SAAC) of the Export-Import Bank of the United States (Export-Import Bank)

SUMMARY: The Sub-Saharan Africa Advisory Committee was established by Pub. L. 105–121, November 26, 1997, to advise the Board of Directors on the development and implementation of policies and programs designed to support the expansion of the Bank's financial commitments in Sub-Saharan Africa under the loan, guarantee and insurance programs of the Bank. Further, the committee shall make recommendations on how the Bank can facilitate greater support by U. S. commercial banks for trade with Sub-Saharan Africa.

Time and Place: Wednesday, November 7, 2001, at 9:30 a.m to 12 p.m. The meeting will be held at the Export-Import Bank in room 1143, 811 Vermont Avenue, NW, Washington, DC 20571.

Agenda: This meeting will focus on improving deal flow for transactions in sub-Saharan Africa. SAAC members and the Bank staff will discuss opportunities in various markets and sectors and will also discuss actions that the Bank can take to increase transactions.

Public Participation: The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to November 1, 2001, Teri Stumpf, Room 1215, 811 Vermont Avenue, NW, Washington, DC 20571, voice: (202) 565–3502 or TDD (202) 565–3377.

FOR FURTHER INFORMATION CONTACT: For further information, contact Teri Stumpf, Room 1215, 811 Vermont Avenue, NW, Washington, DC 20571, (202) 565–3502.

Peter B. Saba,

General Counsel.

[FR Doc. 01–26786 Filed 10–23–01; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 4300F.
Name: American Intercargo Express Inc.
Address: One World Trade Center, Suite 4667, New York, NY 10048.
Date Revoked: September 13, 2001.
Reason: Failed to maintain a valid bond.

License Number: 15644N.
Name: Amerilines, Inc.—New York.
Address: 7 Dey Street, Suite 1501, New York, NY 10007.
Date Revoked: September 28, 2001.
Reason: Failed to maintain a valid bond.

License Number: 11238N.
Name: Arrow Cargo Express, Inc.
Address: 2254–B Landmeier Road, Elk Grove Village, IL 60007.
Date Revoked: September 26, 2001.
Reason: Failed to maintain a valid bond.

License Number: 16341N.
Name: Dit (USA), Inc.
Address: 1805 W. Hovey Ave., Suite B, Normal, IL 61761.
Date Revoked: August 17, 2001.
Reason: Surrendered license voluntarily.

License Number: 2430F.
Name: Emigdio S. Ledesma dba Jack Ledesma International Forwarder.
Address: 729 83rd Avenue North, Suite 204, St. Petersburg, FL 33702.
Date Revoked: September 20, 2001.
Reason: Failed to maintain a valid bond.

License Number: 2338NF.
Name: Kamden International Shipping, Inc.
Address: 179–02 150th Avenue, Jamaica, NY 11434.
Date Revoked: September 23, 2001.
Reason: Failed to maintain a valid bond.

License Number: 4238F.
Name: Land Ocean Management, Inc.
Address: 825 20th, Suite 310, Portland, OR 97232.
Date Revoked: September 8, 2001.
Reason: Failed to maintain a valid bond.

License Number: 3964F.
Name: Logistic Excel Corporation.
Address: 1521 West Magnolia, Suite B, Burbank, CA 91506.
Date Revoked: September 16, 2001.
Reason: Failed to maintain a valid bond.

License Number: 16715F.
Name: Nasser Massry dba Maromax Industries.
Address: 417 Pisgah Church Road, Greensboro, NC 27455.
Date Revoked: September 11, 2001.
Reason: Failed to maintain a valid bond.

License Number: 4374F.
Name: Richard T. Freeman.
Address: 2441 Foxwood Road South, Orange Park, IL 32073.
Date Revoked: September 22, 2001.
Reason: Failed to maintain a valid bond.

License Number: 3415NF.
Name: TCX International, Inc. dba Land Joy.
Address: 3101 N.W. 74th Avenue, Miami, FL 33122.
Date Revoked: September 28, 2001.
Reason: Failed to maintain a valid bond.

License Number: 16633N.
Name: Transworld Lines, Incorporated.
Address: 9950 W. Lawrence Avenue, Schiller Park, IL 60176.
Date Revoked: August 24, 2001.
Reason: Surrendered license voluntarily.

Ronald D. Murphy,
Deputy Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 01–26803 Filed 10–23–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary license has been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR 515.

License No.	Name/Address	Date reissued
14503N	Hana Worldwide Shipping Co., Inc., 20435 S. Western Avenue, Torrance, CA 90501	September 12, 2001.

Ronald D. Murphy,
Deputy Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 01–26801 Filed 10–23–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for licenses as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicants

Sea-Big Express, Inc., 24404 S. Vermont Avenue, #305, Harbor City, CA 90710, Officer: Jung Hyun Lee, President (Qualifying Individual)

Pibe, Inc., 6909 NW 52nd Street, Miami, FL 33166, Officers: Luis Rocha, General Manager (Qualifying Individual), Edward Rocha, Vice President

HJM Int'l Corp., Cargo Bldg. 80, Suite 204, Jamaica, NY 11430, Officer: Henry Mandil, President (Qualifying Individual)

Best Raider Cargo Express, Ltd., 147–11 182nd Street, Jamaica, NY 11434, Officers: Danny J. Chen, President (Qualifying Individual), Raymond Chen, Vice President

On My Way, Inc., 8510 NW. 72nd Street, Miami, FL 33166, Officers: Maria Sardi (Gaby), Vice President (Qualifying Individual), Luis Aldaya, President

Inter-Cargo Systems LLC, 5200 Mitchelldale, Suite D–8 Houston, TX 77092, Officers: Richard Kershaw, Vice President (Qualifying Individual), Khurram Iqbal, President

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

Direct Shipping Line 9550 Flair Dr., #5031, El Monte, CA 91731, Officer: Phuong Lam, President (Qualifying Individual),

Benefitor Logistics Inc., 7323 Parkwood Court, #302, Falls Church, VA 22042, Officers: Min Liu, Shipping Manager (Qualifying Individual), Kong Ng, Director

Quisqueya Lines, Inc., 3780 N.W. South River Drive, Miami, FL 33142, Officers: Milagros Abreu, Vice President (Qualifying Individual), Jose Abreu, President

Access Freight Forwarders Inc., 8220 N.W. 30th Terrace, Miami, FL 33122, Officers: Marcelo V. Leal, President, Isabella Riddell, Secretary (Qualifying Individuals)

Interconn, Inc. 15565 Northland Drive, Suite 708W, Southfield, MI 48075, Officers: Anthony Heath, President/CEO (Qualifying Individual), Aaron S. Heath, Vice President

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants

Grizzard Customs Brokers, Inc., 4158 Old Dixie Road, Hapeville, GA 30354, Officer: Michael R. Grizzard, President (Qualifying Individual)

Hub Air Intl. Ltd., 140 Eastern Avenue, Chelsea, MA 02150, Officer: Barry F. Curran, President (Qualifying Individual)

Armstrong Export, Inc., 2001 N.W. 93rd Avenue, Miami, FL 33172, Officers: Lewis R. Armstrong, President (Qualifying Individual), Evelyn S. Armstrong, Secretary

Dated: October 19, 2001.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 01–26802 Filed 10–23–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center Web site at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 7, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Associated Banc-Corp, Green Bay, Wisconsin; to acquire Signal Finance Company, Mendota Heights, Minnesota (Signal Finance), and engage in extending credit and servicing loans, pursuant to § 225.28(b)(1) of Regulation Y, and acting as agent or broker for insurance directly related to extensions of credit of Signal Finance, pursuant to § 225.28(b)(11)(ii) of Regulation Y, and to acquire Signal Trust Company, N.A., Mendota Heights, Minnesota, and engage in trust company functions, pursuant to § 225.28(b)(5) of Regulation Y.

Board of Governors of the Federal Reserve System, October 18, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–26732 Filed 10–23–01; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35) and 5 CFR 1320.05. The following are those information collections recently submitted to OMB.

1. Surveys of SCHIP Enrollees and Disenrollees for the Congressionally Mandated Evaluation of the State Children's Health Insurance Program—NEW—As part of the evaluation of the State Children's Health Insurance Program (SCHIP), the Office of the Assistant Secretary for Planning and Evaluation is proposing to conduct surveys about children currently and previously covered by the program. These surveys, to be conducted in ten states, will provide detailed description of the children's characteristics, their movement in and out of the program, access to care, service use and experiences with the program. A supplemental survey about Medicaid children will be conducted in two states. *Respondents:* individuals or households; Burden Information for SCHIP Survey—*Number of Respondents:* 18,000; *Frequency of Response:* once; *Average Burden per Response:* .59 hours; *Burden for SCHIP Survey:* 10,620 hours—Burden Information for Medicaid Survey—*Number of Respondents:* 3,600; *Frequency of Response:* once; *Average Burden per Response:* .59 hours; *Burden for Medicaid Survey:* 2,124 hours—*Total Burden*—12,744 hours.

OMB Desk Officer: Allison Herron Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: October 16, 2001.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 01–26758 Filed 10–23–01; 8:45 am]

BILLING CODE 4154–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel meeting.

The Health Care Policy and Research Emphasis Panel is a list of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ) and agree to be available, to conduct, on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not meet regularly and do not serve for fixed or long terms. Rather, they are asked to serve for particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for Independent Scientist Award are to be reviewed and discussed at this meeting. These discussions are likely to include personal information concerning individuals associated with these applications. This information is exempt from mandatory disclosure under the above-cited statutes.

1. *SEP Meeting on:* Independent Scientists Award (K02).

Date: November 1, 2001 (Open on November 1 from 3 p.m. to 3:10 p.m. and closed for remainder of the meeting).

Place: 2101 East Jefferson Street, Suite 400W, Rockville, MD 20852.

Contact Person: Anyone wishing to obtain a roster of members or minutes of this

meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594–1846.

Agenda items for this meeting are subject to change as priorities dictate.

This notice is being published less than 15 days prior to the November 1 meeting due to the time constraints of reviews.

Dated: October 18, 2001.

John M. Eisenberg,

Director

[FR Doc. 01–26730 Filed 10–23–01; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02011]

Cooperative Agreements for the Development and Improvement of Population-Based Birth Defects Surveillance Programs and the Integration of Surveillance Data With Public Health Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for developing and improving birth defects surveillance and integrating surveillance data with other public health programs. This program addresses the ''Healthy People 2010'' focus area of Maternal, Infant, and Child Health.

The purpose of the program is to support: (1) The development, implementation, expansion, and evaluation of population-based birth defects surveillance systems; (2) the development and implementation of population-based programs to prevent birth defects; and (3) the development and implementation or expansion of activities to improve the access of children with birth defects to health services and early intervention programs.

B. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

Recipients funded under CDC Program Announcement 00094 (Cooperative Agreements for the Development of State-Based Birth Defect Surveillance Programs and the Use of the Surveillance Data for Public Health Programs) and Program Announcement 96043 (Centers of Excellence to Provide Surveillance, Research, Services, and Evaluation Aimed at Prevention of Birth Defects) are not eligible. See Attachment I in the Application Kit for a list of the States currently funded under these program announcements.

The eligible States are: Alabama, Alaska, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia and Wyoming.

Applicants may apply under one of two categories:

Category 1—States/territories/tribes with no birth defects surveillance systems; or

Category 2—States/territories/tribes with newly implemented or ongoing surveillance systems.

Note: Title 2 of the United States Code, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

C. Availability of Funds

Approximately $2,400,000 is available in FY 2002 to fund approximately 4–8 awards in Category 1, and 8–10 awards in Category 2. It is expected that the awards will range from $50,000 to $250,000. The average award will be $100,000 for Category 1 States and $200,000 for Category 2 States. The awards will begin on or about March 1, 2002, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

These awards may be used for personnel services, equipment, travel, and other costs related to project activities. Project funds may not be used to supplant State funds available for birth defects surveillance or prevention, health care services, patient care, construction, nor lease/purchase of facilities or space.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient activities for States with no birth defects surveillance systems; or 2. Recipient activities for States with newly implemented or ongoing surveillance systems; and CDC will be responsible for the activities under 3. CDC activities.

1. Recipient Activities for States with no birth defects surveillance systems:

a. Develop and begin implementation of a population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects.

c. Develop and implement a plan to evaluate the surveillance methodology used.

d. Involve the appropriate partners within the State to develop a plan and begin implementation of a birth defects prevention program (i.e., Neural Tube Defects (NTD) occurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Develop a plan to evaluate the prevention activities.

f. Involve the appropriate partners within the State to develop a plan and begin implementation of activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (e.g., establish linkages with other programs like Children with Special Health Care Needs).

g. Develop a plan to evaluate the identification of and/or timeliness of referral to services among eligible children or families.

2. Recipient Activities for States with newly implemented or ongoing surveillance systems:

a. Broaden methodologies and approaches which will improve, sustain, and expand the capacity of the existing population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects (e.g., publish a report on the surveillance data).

c. Evaluate the surveillance methodology used.

d. Involve the appropriate additional partners within the State to expand birth defects prevention programs (i.e., Neural Tube Defects (NTD) occurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Evaluate the prevention progress.

f. Involve the appropriate partners within the State to expand activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (e.g., establish linkages with other programs like Children with Special Health Care Needs).

g. Evaluate the progress on improving access to services (e.g., identification of children and families eligible for services; evaluate the timeliness of referral to services).

3. CDC Activities:

a. Assist, if requested, in designing, developing, and evaluating methodologies and approaches used for population-based birth defects surveillance.

b. Assist, if requested, in analyzing surveillance data related to birth defects.

c. Assist, if requested, in designing plans for prevention programs and plans to improve the access of children with birth defects to health services and intervention programs.

d. Provide, if requested, a reference point for sharing regional and national data and information pertinent to the surveillance and prevention of birth defects.

E. Content

Letter of Intent (LOI)

A LOI is requested for this program. The LOI will not be used to eliminate potential applicants, but it will enable CDC to determine the level of interest and plan the review more efficiently. The narrative should be no more than two, double-spaced pages, printed on one side, with one inch margins and 12 point font. The LOI should include the following information: this program announcement number; applicant's name and address; project director's name, phone number, and email; identification of the category for which the applicant is applying (Category 1 or Category 2); a brief description of the number of state-wide births and current birth defect surveillance system; and a brief description of the planned statement of work.

Applications

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in describing the program plan.

The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities. The application must contain the following:

1. *Cover Letter:* A one page cover letter should indicate whether the applicant is applying for Category 1 or Category 2.

2. A one-page, single-spaced, typed abstract in 12 point font must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director and telephone number. The abstract should clearly state which option the applicant is applying for: Category 1 or Category 2. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicant's organization structure. The abstract should precede the program narrative. A table of contents that provides page numbers for each of the following sections should be included. All pages must be numbered.

3. *Narrative:* The narrative should be no more than 25 double-spaced pages printed on one side, with one inch margins, and unreduced font (12 point). The required detailed budget and detailed budget justification are not considered to be part of the program narrative. The narrative should specifically address item 1 or 2 in the ''Program Requirements'' and should contain the following sections:

a. Understanding of the Public Health Impact of Birth Defects;

b. Impact on Population-Based Birth Defects Surveillance;

c. Use of Surveillance Data for Prevention Activities;

d. Use of Surveillance Data for Improving Access to Health Services and Early Intervention Programs;

e. Organizational and Program Personnel Capability; and

f. Human Subjects Review

4. Budget and Budget Justification—Provide a detailed budget which indicates the anticipated costs for personnel, fringe benefits, travel, supplies, contractual, consultants, equipment, indirect, and other items.

F. Submission and Deadline

Letter of Intent (LOI)

On or before November 16, 2001, submit the LOI to the officials designated for programmatic technical assistance identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are available in the application kit and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm.*

On or before December 7, 2001, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC as they relate to the applicant's response to either item 1 or 2 in the ''Program Requirements'' section.

1. Applicant's understanding of the public health impact of birth defects (5 points):

The extent to which the applicant has a clear, concise understanding of the requirements, objectives, and purpose of the cooperative agreement. The extent to which the application reflects an understanding of the public health impact of birth defects in their State and the purpose and complexities of birth defects surveillance as it relates to their State.

2. Impact on population-based birth defects surveillance (20 points):

The extent to which the applicant describes the anticipated level of impact this cooperative agreement will have on birth defects surveillance activities in the State. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

(1) Plans for developing population-based birth defects surveillance;

(2) Methods of case ascertainment;

(3) Timeliness of case ascertainment;

(4) Level of coverage of the population;

(5) Specific birth defects ascertained;

(6) Plans for analyzing and reporting surveillance data to appropriate State, local, and federal health officials;

(7) Plans for evaluating the surveillance methodology and the quality of the surveillance data; and

(8) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

(1) Ability to improve/expand population-based birth defects surveillance;

(2) Methods of case ascertainment;

(3) Timeliness of case ascertainment;

(4) Level of coverage of the population;

(5) Specific birth defects ascertained;

(6) Analyzing and reporting surveillance data to appropriate State, local, and federal health officials;

(7) Evaluating the surveillance methodology and quality of the surveillance data; and

(8) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

3. Use of the surveillance data for prevention activities (30 points):

The extent to which the applicant describes the plans for using surveillance data to develop and implement or expand existing programs to prevent birth defects. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (e.g., provide letters of support, Memorandums of Agreement/Understanding); and

(2) Plan for using the surveillance data to develop prevention programs; and/or Plan for sharing surveillance data (e.g., personal identifiers and contact information) with programs or agencies so that children or families can be enrolled in prevention programs.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (e.g., provide letters of support, Memorandums of Agreement/Understanding);

(2) Use of surveillance data to expand prevention programs; and/or sharing of surveillance data (e.g., personal identifiers and contact information) with programs or agencies so that children or families are enrolled in prevention programs; and

(3) Evaluation of progress made in the prevention of birth defects.

4. Use of surveillance data for improving access to health services and early intervention programs (30 points). The extent to which the applicant describes the plans to develop and implement or expand existing activities to improve the access of children with birth defects to health services and early interventions. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

(1) Identification of appropriate programs within the State for referral to health services (e.g., provide letters of support, Memorandums of Agreement/Understanding);

(2) Plan for linking programs or developing other approaches to increase identification of children or families eligible for health services; and

(3) Plan to evaluate the implementation process.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

(1) Ability to integrate programs within the State (e.g., provide letters of support, Memorandums of Agreement/Understanding, documentation of numbers of eligible children or families referred for and percent receiving services);

(2) Improve and expand approaches to increase identification of children or families eligible for health services; and

(3) Plan for evaluating outcomes of children who receive services.

5. Organizational and program personnel capability (15 points):

a. The extent to which the applicant has the experience, skills, and ability to develop and improve birth defects surveillance and use surveillance data to develop prevention programs and improve access to health services or early intervention programs.

b. The adequacy of the present staff and/or the capability to assemble competent staff to either implement or improve upon a birth defects surveillance system and develop programs for prevention or improving access to health services and early intervention programs. If it is necessary to hire staff to conduct program activities, provide plans for identifying and hiring qualified applicants on a timely basis. Also, provide plans for how work on program activities will be conducted prior to hiring necessary staff.

c. To the extent possible, the applicant shall identify all current and potential personnel who will work on this cooperative agreement including qualifications and specific experience as it relates to the requirements set forth in this announcement.

6. Human Subjects Review (not scored):

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks are so inadequate as to make the entire application unacceptable.)

7. Budget justification and adequacy of facilities (not scored):

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant shall describe and indicate the availability of

facilities and equipment necessary to carry out this project.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment II in the Application Kit.

AR–1—Human Subjects Requirements
AR–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7—Executive Order 12372 Review
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 311 and 371 (C) of the Public Health Service Act [42 U.S.C. 241(a), 243, and 247 (b–4)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Virginia Hall-Broadnax, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02011, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2761, E-mail address: *vdh2@cdc.gov.*

Programmatic technical assistance may be obtained from:

Larry D. Edmonds or Amanda S. Brown, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., Atlanta, GA 30341–3724, Telephone: (770) 488–7171, E-mail address: *LEdmonds@cdc.gov* or *ABrown2@cdc.gov.*

Dated: October 18, 2001.

Rebecca B. O'Kelley,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–26743 Filed 10–23–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02018]

New York Emergency Disaster Relief Related to Asthma; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of funds for a cooperative agreement program for New York Emergency Disaster Relief Related to Asthma. The purpose of the program is to assist the New York State Department of Human Services in assessing public health threats and addressing public health issues related to asthma, as a result of the terrorist attack of September 11, 2001. This program addresses the ''Healthy People 2010'' focus areas of Environmental Health and Public Health Infrastructure.

B. Eligible Applicant

Eligible applicant is Health Research, Inc./New York State Department of Health. No other applications are solicited.

This project is authorized by H.R. 2888, 2001 Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States.

C. Availability of Funds

Approximately $5,200,000 is available to fund this award. The award is expected to be made for a 12-month budget period within a 5 year project period. As long as funds are continued or directed for this applicant continuation funding will be made available for up to 5 years. Funding estimates may vary and are subject to change.

At the request of the applicant, Federal personnel, equipment, or supplies may be provided in lieu of a portion of the financial assistance.

D. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharon Robertson, Lead Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2740, E-mail address: *sqr2@cdc.gov.*

For program technical assistance, contact: Liane Hostler, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE (MS E–17), Atlanta, GA 30333, Telephone number: (404) 498–1009, E-mail address: *lch2@cdc.gov.*

Dated: October 18, 2001.

Rebecca O'Kelley,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–26742 Filed 10–23–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10051]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or

other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Evaluation of the MassHealth Insurance Partnership; *Form No.:* CMS–10051 (OMB# 0938–NEW); *Use:* This collection will be used to evaluate the Massachusetts' 1115 Waiver Demonstration, including Insurance Partnership program, offering subsidies to small employers to encourage them to offer health insurance coverage to employees. The purpose of the survey is to determine the factors influencing an employer's decision to participate or not, in the IP program and their respective characteristics.; *Frequency:* Other: One-time; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Farms; *Number of Respondents:* 2,016; *Total Annual Responses:* 2,016; *Total Annual Hours:* 336.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.hcfa.gov/regs/prdact95.htm*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willinghan, CMS–10051, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 17, 2001.

John P. Burke III,

CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–26720 Filed 10–23–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10048]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Flexibility and Accountability Section 1115 Model Waiver; *Form No.:* CMS–10048 (OMB# 0938–0848); *Use:* This Health Insurance Flexibility and Accountability (HIFA) Section 1115 Model Demonstration will enable states to use Medicaid and SCHIP funds in concert with private health insurance options to expand coverage to low-income uninsured individuals, with a focus on those with income at or below 200 percent of the Federal poverty level. The model demonstration application will facilitate State efforts in designing programs to cover the uninsured; *Frequency:* Other: 5 years after initial submission; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 250.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.hcfa.gov/regs/prdact95.htm,* or e-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS–10048, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 17, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–26783 Filed 10–23–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0476]

Electronic Interchange Standard for Digital ECG and Similar Data; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to collect information regarding the content and format of electrocardiographic (ECG) data to be submitted to the agency in support of applications. The agency is interested in obtaining ECG waveform data in digital format from the full spectrum of ECG devices (i.e., standard 12-lead ECGs, Holter monitors, transtelephonic monitors, and implanted devices) along with annotations for events (e.g., standard ECG interval measurements, arrhythmic events).

DATES: The public meeting will be held on November 19, 2001, from 10 a.m. to 4 p.m. Submit registration requests by November 6, 2001. Written or electronic comments on ECG data standards are welcome at any time.

ADDRESSES: The public meeting will be held at FDA's Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Norman L. Stockbridge, Center for Drug

Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5329, e-mail: *stockbridgen@cder.fda.gov;* or Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, e-mail: *levinr@cder.fda.gov.*

SUPPLEMENTARY INFORMATION: FDA is holding a public meeting to discuss potential data standards for digital ECG waveform data to be submitted in support of applications to FDA. Topics for discussion will include: (1) Scope of ECG datasets (i.e, what information should be included); (2) logical organization of a dataset supporting multiple recording sessions, multiple recording epochs within a session, and multiple leads; (3) logical organization supporting the annotation of data in one or more leads with the submitter's assessment of the locations of events of interest, including standard ECG intervals, arrhythmic events, and other information; and (4) realization of the data in extensible markup language (XML) or other open formats.

Although the agency is considering updating guidance documents on related drug evaluation standards (i.e., arrhythmic potential, electronic submission of clinical trial data, including electronic ECG data), the use of ECG data in support of applications will not be the topic for this meeting. The purpose of this meeting is to get public input on the following questions related to the technical issues of transmitting digital ECG data:

- What information is needed to make ECG datasets easy to interpret?
- Is the data structure complex enough that the standard should be implemented in XML or some other format?
- Are the datasets so large that the data standards should be implemented in binary format?
- What tools can be used to review digital ECG data?

An agenda and other materials, including a proposed data standard, will be available on the Internet at *http://www.fda.gov/cder/regulatory/ersr/default.htm* before the meeting. Although there is no registration fee, preregistration by November 6, 2001, is recommended for those individuals who wish to attend this meeting. Participation is limited to the first 100 registrants. To accommodate the greatest number of interested parties, registration is limited to people outside FDA, and no more than two individuals from a company should attend. To register, send an e-mail message to Wendy Lail (*lailw@cder.fda.gov*) with the names of one or two individuals who wish to attend and the name of their company.

The location of the meeting is 5630 Fishers Lane, Rockville, MD (next to the Parklawn Bldg). Registrants should use the lower entrance, which faces Parklawn Dr. Visitors' badges will be held at the guards' station at the entrance to the building, and participants will need picture identification to pick up their badges. Public parking is not available at the 5630 Fishers Lane location. A public parking lot (for a fee) is available on Fishers Lane across from the Parklawn Bldg. Additional public parking (for a fee) is available at the Twinbrook Metro Station, which is located several blocks west of the meeting location.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on standards for digital ECG data. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–26821 Filed 10–19–01; 4:12 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Voluntary Customer Satisfaction Surveys to Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)

OMB No. 0930–0197; Extension—Executive order 12862 directs agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse agencies, through a range of mechanisms, including publications, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances. The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/ Respondent	Hours/response	Total hours
Focus group	150	1	2.50	375

Type of data collection	Number of respondents	Responses/ Respondent	Hours/re-sponse	Total hours
Mail/telephone.e-mail survey	30,000	1	.33	10,000
Total	30,150			10,375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Lauren Wittenberg, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 17, 2001

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–26744 Filed 10–23–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Invasive Species Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of public meetings of the Invasive Species Advisory Committee.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given of meetings of the Invasive Species Advisory Committee. The purpose of the Advisory Committee is to provide advice to the National Invasive Species Council, as authorized by Executive Order 13112, on a broad array of issues related to preventing the introduction of invasive species and providing for their control and minimizing the economic, ecological, and human health impacts that invasive species cause. The Council is Co-chaired by the Secretary of the Interior, the Secretary of Agriculture, and the Secretary of Commerce. The duty of the Council is to provide national leadership regarding invasive species issues. The purpose of a meeting on November 5–6, 2001 is to convene the full Advisory Committee and discuss implementation of action items outlined in the National Invasive Species Management Plan, which was finalized on January 18, 2001.

DATES: Meeting of Invasive Species Advisory Committee: 9:30 a.m., Monday, November 5, 2001 and 8:30 a.m., Tuesday, November 6, 2001.

ADDRESSES: American Institute of Architects, 1735 New York Avenue, N.W., Washington, DC 20006. Meetings on both days will be held in the AIA Boardroom.

FOR FURTHER INFORMATION CONTACT: Kelsey Passé, National Invasive Species Council Program Analyst; e-mail: *kelsey_passe@ios.doi.gov;* phone: (202) 208–6336; fax: (202) 208–1526.

Dated: October 2, 2001.

Lori Williams,

Executive Director, National Invasive Species Council.

[FR Doc. 01–26825 Filed 10–19–01; 4:15 pm]

BILLING CODE 4310–RK–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

ACTION: Notice of receipt of applications.

SUMMARY: The following applicants have applied for a scientific research permit to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Permit No. TE–048598

Applicant: Gary McDaniel, Spring Branch, Texas

Applicant requests a permit for presence/absence surveys and collection of the following karst invertebrates species in Bexar County, Texas: Helotes Mold Beetle (*Batrisodes venyivi*), Robber Baron Cave harvestman (*Texella cokendolpheri*), Madla's Cave spider (*Cicurina madla*), Robber Baron Cave spider (*Cicurina baronia*), Vesper Cave spider (*Cicurina vespera*), Government Canyon Cave spider (*Neoleptoneta microps*), as well as another cave spider (*Cicurina venii*) and two cave beetles (*Rhadine exilis* and *Rhadine infernalis*) that do not have common names. Applicant requests presence/absence surveys and collection of the following karst invertebrates species in Travis County, Texas: Kretschmarr Cave Mold beetle (*Texamaurops reddelli*), Tooth Cave Ground beetle (*Rhadine persephone*), Tooth Cave pseudoscorpion (*Tartarocreagris texana*), Bee Creek Cave harvestman (*Texella reddelli*), Bone Cave harvestman (*Texella reyesi*), and Tooth Cave spider (*Neoleptoneta myopica*). Applicant requests presence/absence surveys and collection of the following karst invertebrates species in Williamson County Texas: Coffin Cave Mold beetle (*Batrisodes texanus*), Tooth Cave Ground beetle (*Rhadine persephone*), and Bone Cave harvestman (*Texella reyesi*). Applicant also requests presence/absence surveys and collection for Peck's Cave amphipod (*Stybobromus pecki*) in Comal County, Texas and presence/absence surveys for Texas Blind Salamander (*Typhlomolge rathbuni*) in Hays County, Texas. There may be possible disturbance to the Mexican long-nosed bat (*Leptonycteris nivalis*) in Brewster County, Texas.

Permit No. TE–020661

Applicant: Janine Spencer, Prescott, Arizona.

Applicant requests an amendment to an existing permit to allow presence/absence surveys for the Black-footed ferret (*Mustela nigripes*) within New Mexico and Arizona.

Permit No. TE–048609

Applicant: Michael Rigney, Wickenburg, Arizona.

Applicant requests a permit for recovery purposes to conduct presence/absence surveys for the Southwestern willow flycatcher (*Empidonax traillii extimus*) within the Hassayampa River Preserve, Maricopa County, Arizona.

Permit No. TE–048464

Applicant: Joanne M. Kirchner, Sierra Vista, Arizona.

Applicant requests a permit for recovery purposes to conduct presence/absence surveys for the following species: Cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*), Lesser long-nosed bat (*Leptonycteris curasoae yerbabuenae*), Black-footed ferret (*Mustela nigripes*), and Yuma clapper rail *Rallus longirostris yumanensis).* Applicant also requests a permit to conduct presence/absence surveys, capture, band, and collect blood samples from the Mexican spotted owl (*Strix occidentalis lucida*). Further, applicant requests a permit to conduct presence/absence surveys, capture, band, nest monitor, and collect feathers from the Southwestern willow flycatcher (*Empidonax traillii extimus*). These activities will be conducted within Arizona.

Permit No. TE–048806

Applicant: U.S. Fish and Wildlife Service, Austwell, Texas.

Applicant requests a permit for individuals to possess and/or ship dead Whooping cranes or their parts, including eggs, feathers, semen and blood; capture, band, radio-tag, raise, breed, and administer health care to captive birds; and re-introduce and rehabilitate Whooping cranes (*Grus americana*) throughout North America from the Rocky Mountains to the east coast. This will be for the Whooping crane Recovery Program.

Permit No. TE–048579

Applicant: Kathlene Meadows, Tucson, Arizona.

Applicant requests a permit for recovery purposes to conduct presence/absence surveys for the Cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*) within Arizona.

Permit No. TE–048907

Applicant: Elizabeth Davis, San Marcos, Texas.

Applicant requests a permit to collect plant materials for research and recovery purposes from the Texas wild-rice plant (*Zizania texana*) within Texas.

DATES: Written comments on these permit applications must be received on or before November 23, 2001.

ADDRESSES: Written data or comments should be submitted to the Chief, Endangered Species Division, Ecological Services, P.O. Box 1306, Room 4102, Albuquerque, New Mexico 87103; (505) 248–6649; Fax (505) 248–6788. Documents will be available for public inspection by written request, by appointment only, during normal business hours (8 to 4:30) at the U.S. Fish and Wildlife Service, Albuquerque, New Mexico. Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

FOR FURTHER INFORMATION CONTACT: Chief, Endangered Species Division, Albuquerque, New Mexico, at the above address. Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice, to the address above.

Steven M. Chambers,

Acting Assistant Regional Director, Ecological Services, Region 2, Albuquerque, New Mexico.

[FR Doc. 01–26745 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address below) and must be received within 30 days of the date of this notice.

PRT–048761

Applicant: Kevin Gross, Claremont, CA

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–048784

Applicant: Zoological Society of Philadelphia, PA

The applicant request a permit to re-export one captive born male giant otter (*Pteronura brasiliensis*) to the Fundacao Polo Ecologico de Brasilia (Brasilia Zoo) in Brazil for the purpose of enhancement of the survival of the species.

PRT–039276

Applicant: Chicago Zoological Park (Brookfield Zoo), Brookfield, IL

The applicant requests a permit to import biological samples from captive-held/captive-born Goeldi's monkey (*Callimico goeldii*) from the University of Zurich, Zurich, Switzerland, for scientific research.

Marine Mammals

The public is invited to comment on the following application(s) for a permit to conduct certain activities with marine mammals. The application(s) was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

Written data, comments, or requests for copies of these complete applications or requests for a public hearing on these applications should be submitted to the Director (address below) and must be received within 30 days of the date of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

PRT–048671

Applicant: Benjamin Robson, Whittier, CA

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Lancaster Sound polar bear population in Canada for personal use.

PRT–048768

Applicant: Ralph Gitz, Berwick, PA

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Lancaster Sound polar bear population in Canada for personal use.

The U.S. Fish and Wildlife Service has information collection approval from OMB through March 31, 2004, OMB Control Number 1018–0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203, telephone 703/358–2104 or fax 703/358–2281.

Dated: October 9, 2001.

Monica Farris,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 01–26800 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Issuance of Permit for Marine Mammals

On August 14, 2001, a notice was published in the **Federal Register** (66 FR 42676), that an application had been filed with the Fish and Wildlife Service by Sead Dizdarevic for a permit (PRT–043241) to import one polar bear taken from the Lancaster Sound population, Canada for personal use.

Notice is hereby given that on September 24, 2001, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

Documents and other information submitted for these applications are available for review by any party who submits a written request to the U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203, telephone (703) 358–2104 or fax (703) 358–2281.

Dated: October 5, 2001.

Monica Farris,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 01–26799 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–690–01–1610–JP–064B, C00–0927 WHA–ADR]

Temporary Closure to Camping of Selected Federal Lands in Imperial County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to camping east of sand dunes on selected federal lands in Imperial County, California.

DATES: The temporary closure was approved October 18, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, El Centro Field Office, 1661 S. 4th Street, El Centro, CA 92243.

FOR FURTHER INFORMATION CONTACT: Roxie Trost, BLM, El Centro Field Office, 1661 S. 4th Street, El Centro, CA 92243, telephone (760) 337–4400. The camp closure area east of the sand dunes is posted in the El Centro Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the El Centro Field Office as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary camping closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 18, 2001 and will remain in effect until a Record of Decision is signed on the North Eastern Colorado Deserts Bio-regional Plan, which is expected to be signed September 2002.

Exceptions to this closure include government vehicles conducting official business shall be allowed inside the closed areas as authorized. Official business may include public service emergencies, resource monitoring/research, other dunes operations and management activities, and other actions authorized by BLM's El Centro Field Office Manager.

Notice of the proposed closure was published in the **Federal Register** August 10, 2001 (66 FR 42234).

Dated: October 19, 2001.

Henri Bisson,

Assistant Director for Renewable Resources and Planning.

[FR Doc. 01–26826 Filed 10–22–01; 9:33 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–690–01–1610–JP–064B, C00–927 WHA–ADR]

Temporary Motorized Vehicle use Closure on Selected Federal Lands in San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands Edwards Bowl area in San Bernardino County, California.

DATES: The temporary closure was approved October 17, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311

FOR FURTHER INFORMATION CONTACT: Tim Read, BLM, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311. The closure is posted in the Barstow Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Barstow Field Office as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 17, 2001 and will remain in effect until a Record of Decision is signed on the West Mojave Plan, which is expected to be signed June 2003.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Barstow Field Office Manager.

Notice of the proposed closure was published in the **Federal Register** July 20, 2001 (66 FR 32639–32640).

Dated: October 19, 2001.

Henri Bisson,

Assistant Director Renewable Resources and Planning.

[FR Doc. 01–26827 Filed 10–22–01; 9:33 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–670–01–1610–JP–064B, C00–0927 WHA–ADR]

Temporary Closure to Motorized Vehicles on Selected Routes of Travel or Areas Known as NECO Wash in San Bernardino, Riverside, and Imperial Counties, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicles on selected routes of travel or areas in San Bernardino, Riverside, and Imperial Counties, CA.

DATES: The temporary closure was approved October 17, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, California Desert District Office, 6221 Box Springs Boulevard, Riverside, CA 92507.

FOR FURTHER INFORMATION CONTACT: Richard Crowe, BLM, California Desert District Office, 6221 Box Springs Boulevard, Riverside, CA 92507, telephone (909) 697–5216. The NECO wash closure is posted in the California Desert District Office, and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the

California Desert District Office, as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to Title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 17, 2001 and will remain in effect until a Record of Decision is signed on the North Eastern Colorado Deserts Bio-regional Plan, which is expected to be signed September 2002.

Exceptions to this closure include government vehicles conducting official business shall be allowed inside the closed areas as authorized. Official business may include public service emergencies, resource monitoring/research, other dunes operations and management activities, and other actions authorized by BLM's California Desert District Office Manager.

Notice of the proposed closure was published in the **Federal Register** June 15, 2001 (66 FR 32639–32640).

Dated: October 19, 2001.

Henri Bisson,

Assistant Director for Renewable Resources and Planning.

[FR Doc. 01–26828 Filed 10–22–01; 9:33 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–690–01–1610–JP–064B, C00–0927 WHA–ADR]

Temporary Motorized Vehicle Use Closure on Selected Federal Lands in San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands in Red Mountain area in San Bernardino County, California

DATES: The temporary closure was approved October 19, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Ridgecrest Field Office, 300 S. Richmond Rd, Ridgecrest, CA 93555

FOR FURTHER INFORMATION CONTACT: Hector Villalobos, BLM, Ridgecrest Field Office, 300 South Richmond Rd, Ridgecrest, CA 93555, telephone (760) 384–5400. The Red Mountain closure is posted in the Ridgecrest Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Ridgecrest Field Office as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 19, 2001 and will remain in effect until a Record of Decision is signed on the WEMO Plan, which is expected to be signed June 2003.

Exceptions to the closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Ridgecrest Field Office Manager.

Dated: October 19, 2001.

Henri Bisson,

Assistant Director for Renewable Resources and Planning.

[FR Doc. 01–26829 Filed 10–23–01; 9:44 pm]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–670–01–1610–JP–064B, C00–0927 WHA–ADR]

Temporary Closure of Selected Routes of Travel in Lower Chemehuevi Valley, San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicles on selected routes of travel or areas in San Bernardino, County, California.

DATES: The temporary closure was approved October 18, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, California Desert District Office, 6221 Box Springs, Boulevard, Riverside, CA 92507.

FOR ADDITIONAL INFORMATION CONTACT: Richard Crowe, BLM, California Desert District Office, 6221 Box Springs Boulevard, Riverside, CA 92507, telephone (909) 697–5216. The closure is posted in the California Desert District Office, and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the California Desert District Office, as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 18, 2001 and will remain in effect until a Record of Decision is signed on the Northern and Eastern Colorado Desert (NECO) Plan, an amendment to the California Desert Conservation Area Plan, which is expected to be signed September 2002.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized. Official business may include public service emergencies, resource monitoring/research, other dunes operations and management activities, and other actions authorized by BLM's California Desert District Office Manager.

Notice of the proposed closure was published in the **Federal Register** on July 30, 2001, (66 FR 39332–39333).

Dated: October 19, 2001.

Henri Bisson,

Assistant Director Renewable Resources and Planning.

[FR Doc. 01–26869 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–680–02–1610–JP–064B]

Temporary Motorized Vehicle Use Closure and Establish an Interim Motorized Vehicle Access Network on Selected Federal Lands in Western San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands in San Bernardino County, California and establish an interim motorized vehicle access network. The area encompasses 81,585 acres in the Newberry-Rodman subregion.

DATES: The temporary closure was approved October 19, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Barstow Field Office, 2601 Barstow Rd, Barstow, CA 92311

FOR ADDITIONAL INFORMATION CONTACT: Tim Read, BLM, Barstow Field Office 2601 Barstow Rd, Barstow, CA 92311, telephone (760) 252–6000. The closure is posted in the Barstow Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Barstow Field Office as

well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to Title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 18, 2001 and will remain in effect until a Record of Decision is signed on the West Mojave Coordinated Management Plan (WEMO Plan), which is expected to be signed June 2003.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized and an interim route network signed as open routes on the ground and identified on the map. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Barstow Field Office.

Dated: October 19, 2001.

Henri Bisson,

Assistant Director of Renewable Resources and Planning.

[FR Doc. 01–26830 Filed 10–22–01; 9:44 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–680–02–1610–JP–064B]

Temporary Motorized Vehicles Use Closure and Establish an Interim Motorized Vehicle Access Network on Selected Federal Lands in Western San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands in San Bernardino County, California and establish an interim motorized vehicle access network. The area encompasses 271,528 acres in the Superior subregion.

DATES: The temporary closure was approved October 19, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311.

FOR FURTHER INFORMATION CONTACT: Tim Read, BLM, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311, telephone (760) 252–6000. The closure is posted in the Barstow Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Barstow Field Office as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 18, 2001 and will remain in effect until a Record of Decision is signed on the West Mojave Coordinated Management Plan (WEMO Plan), which is expected to be signed June 2003.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized and an interim route network signed as open routes on the ground and identified on the map. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Barstow Field Office.

Dated: October 19, 2001.

Henri Bisson,

Assistant Director for Renewable Resources and Planning.

[FR Doc. 01–26831 Filed 10–22–01; 9:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–680–02–1610–JP–064B]

Temporary Motorized Vehicles Use Closure and Establish an Interim Motorized Vehicle Access Network on Selected Federal Lands in Western San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands in San Bernardino County, California and establish an interim motorized vehicle access network. The area is known as Helendale/Silver Lakes adjacent to the community of Silver Lakes.

DATES: The temporary closure was approved October 19, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311.

FOR FURTHER INFORMATION CONTACT: Tim Read, BLM, Barstow Field Office, 2601 Barstow Rd., Barstow, CA 92311, telephone (760) 252–6000. The closure is posted in the Barstow Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Barstow Field Office as well as on the Bureau of Land Management (BLM) California Web site at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved October 18, 2001 and will remain in effect until a Record of Decision is signed on the West Mojave Coordinated Management Plan (WEMO Plan), which is expected to be signed June 2003.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized and an interim route network signed as open routes on the ground and identified on the map. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Barstow Field Office.

Dated: October 19, 2001.

Henri Bisson,

Assistant Director for Renewable Resources and Planning.

[FR Doc. 01–26832 Filed 10–22–01; 9:44 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

National Park Service

Concessions Management Advisory Board Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting of Concessions Management Advisory Board.

SUMMARY: In accordance with the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770, 5 U.S.C. App. 1, Section 10), notice is hereby given that the Concessions Management Advisory Board will hold its sixth meeting October 31 and November 1, 2001, at the Pisgah Inn on the Blue Ridge Parkway in North Carolina. The meeting will be in the Rhododendron Room at the Pisgah Inn located at Mile Marker 408.6 on the Blue Ridge Parkway. The meeting will convene at 8:30 a.m. on Wednesday, October 31, and will conclude in the afternoon on November 1.

SUPPLEMENTARY INFORMATION: The Advisory Board was established by Title IV, Section 409 of the National Park Omnibus Management Act of 1998, November 13, 1998 (Public Law 105–391). The purpose of the Board is to advise the Secretary and the National Park Service on matters relating to management of concessions in the National Park System.

The advisory board will meet at 8:30 a.m. for the regular business meeting to discuss the following subjects.

- Approval of Minutes of Previous Meeting 5/30–5/31/01
- Report of findings by the handcraft subcommittee
- Rate Approval Program
- Discussion and Preparation of outline for report to the Congress
- Agenda for next meeting
- Date for next meeting

The meeting will be open to the public, however, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come-first-served basis.

Assistance to Individuals With Disabilities at the Public Meeting

The meeting site is accessible to individuals with disabilities. If you plan to attend and will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least 2 weeks before the scheduled meeting date. Attempts will be made to meet any request(s) we receive after that date, however, we may not be able to make the requested auxiliary aid or service available because of insufficient time to arrange for it.

In light of the events which took place on September 11, 2001, and a recent attempt to relocate National Park Service administrative personnel and offices affecting the publication of notices this notice could not be published at least 15 days prior to the meeting date. The National Park Service regrets these events, but is compelled to hold the meeting as scheduled because of the significant sacrifice re-scheduling would require of committee members who have adjusted their schedules to accommodate the proposed meeting dates, and the high level of anticipation by all parties who will be affected by the outcome of the Board's actions.

Anyone may file with the Board a written statement concerning matters to be discussed. The Board may also permit attendees to address the Board, but may restrict the length of the presentations, as necessary to allow the Board to complete its agenda within the allotted time.

Interested persons may make oral/written presentations to the Advisory Board during the business meeting or file written statements. Such requests should be made to the Director, National Park Service, Attention: Manager, Concession Program, at least 7 days prior to the meeting. Further information concerning the meeting may be obtained from National Park Service, Concession Program, 1849 C Street NW, Room 7313, Washington, DC 20240, Telephone, 202/565–1210.

Draft minutes of the meeting will be available for public inspection approximately 6 weeks after the meeting, in room 7313, Main Interior Building, 1849 C Street, NW, Washington, DC.

Fran P. Mainella,

Director, National Park Service.

[FR Doc. 01–26757 Filed 10–23–01; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

Office of Community Oriented Policing Services

Agency Information Collection Activities; Proposed Collection; Comments Requested

ACTION: 30-day notice of information collection under review; new collection; Tribal Resources Grant Program Application.

The Department of Justice (DOJ), (Office of Community Oriented Policing Services (COPS)) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (Volume 66, Number 147, pages 39537) on July 31, 2001, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until November 23, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202)–395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of information collection:* New collection.

(2) *The title of the form/collection:* Tribal Resources Grant Program Application.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form: None. Office of Community Oriented Policing Services, U.S. Department of Justice.

(4) *Affected public who will be asked to required to respond, as well as a brief abstract:* Primary: Federally Recognized Tribal Governments.

Other: None. The information collected will be used by the COPS Office to determine whether Federally recognized Tribal Governments are eligible for three year grants specifically targeted to meet the most serious needs of law enforcement in Indian communities. The grants are meant to enhance law enforcement infrastructures and community policing efforts in these communities.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: 200 respondents at 8 hours per response. The information will be collected annually from each respondent.

(6) An estimate of the total public burden (in hours) associated with the collection: There are 1800 annual burden hours associated with this information collection.

If additional information is required contact: Brenda E. Dyer, Department Deputy Clearance Officer, Information

Management and Security Staff, Justice Management Division, United States Department of Justice, 601 D Street NW, Patrick Henry Building, Suite 1600, NW, Washington, DC 20530.

Dated: October 16, 2001.

Brenda E. Dyer,

Department Deputy Clearance Officer, Department of Justice.

[FR Doc. 01–26707 Filed 10–23–01; 8:45 am]

BILLING CODE 4410–AT–M

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Meeting of the CJIS Advisory Policy Board

AGENCY: Federal Bureau of Investigation (FBI).

ACTION: Meeting notice.

SUMMARY: The purpose of this notice is to announce the meeting of the Criminal Justice Information Services (CJIS) Advisory Policy Board (APB). The CJIS APB is responsible for reviewing policy issues, uniform crime reports, and appropriate technical and operational issues related to the programs administered by the FBI's CJIS Division and thereafter, make appropriate recommendations to the FBI Director. The topics to be discussed will include the Justice Consolidated Network, Applicability of Compact Council ''rules, procedures, or standards'' to Nonparty States and to Law Enforcement Agencies, CJIS System of Systems Enhancements Status, request for Dissemination of NCIC Vehicle File Information by the National Insurance Crime Bureau to For-Profit, Non-Criminal Justice Agencies, Access to National Vehicle Registration Data to Combat Vehicle Cloning, Discussion of ''Criminal Justice'' and the Possible Expansion of the Term as Defined in the Code of Federal Regulations (CFR) and the United States Code (U.S.C.), and Emergency Response to National Disasters. Discussion will also include the status on the National Crime Prevention and Privacy Compact, the DOJ Global and Information Sharing Project, and other issues related to the Integrated Automated Fingerprint Identification System, NCIC, Law Enforcement Online, National Instant Criminal Background Check System and Uniform Crime Reporting Programs.

The meeting will be open to the public on a first-come first-seated basis. Any member of the public wishing to file a written statement concerning the FBI's CJIS Division programs or wishing to address this session should notify the Designated Federal Employee, Mr. Roy G. Weise, Programs Development Section, (304) 625–2730, at least 24 hours prior to the start of the session.

The notification should contain the requestor's name, corporate designation, and consumer affiliation or government designation along with a short statement describing the topic to be addressed and the time needed for the presentation. A requestor will ordinarily be allowed no more than 15 minutes to present a topic.

DATES: The Advisory Policy Board will meet in open session from 9 a.m. until 5 p.m. on December 12–13, 2001.

ADDRESSES: The meeting will take place at the W New Orleans Hotel, 333 Poydras Street, New Orleans, Louisiana, telephone (504) 525–9444.

FOR FURTHER INFORMATION CONTACT: Inquiries may be addressed to Mr. Randall R. Hissam, Management Analyst, Advisory Groups Management Unit, Programs Development Section, FBI CJIS Division, Module C3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306–0149, telephone (304) 625–2705, facsimile (304) 625–5090.

Dated: October 12, 2001.

Roy G. Weise,

Designated Federal Employee, Criminal Justice Information Services Division, Federal Bureau of Investigation.

[FR Doc. 01–26784 Filed 10–23–01; 8:45 am]

BILLING CODE 4410–02–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Refuse Piles and Impounding Structures, Recordkeeping and Reporting Requirements

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or containing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

DATES: Submit comments on or before December 24, 2001.

ADDRESSES: Send comments to Gordon J. Burke, Jr., Director, Administration and Management, 4015 Wilson Boulevard, Room 615, Arlington, VA 22203–1984. Commenters are encouraged to send their comments on a computer disk, or via Internet E-mail to Burke-Gordon@msha.gov, along with an original printed copy. Mr. Burke can be reached at (703) 235–13830 (voice), or (703) 235–1563 (facsimile).

FOR FURTHER INFORMATION CONTACT: Charlene N. Barnard, Regulatory Specialist, Records Management Division, U.S. Department of Labor, Mine Safety and Health Administration, Room 725, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Ms. Barnard can be reached at *barnard-charlene@msha.gov* (Internet E-mail), (703) 235–1470 (voice), or (703) 235–1563 facsimile).

SUPPLEMENTARY INFORMATION:

I. Backgound

The Coal Mine Health and Safety Act of 1969 was amended by the Federal Mine Safety and Health Act of 1977 after the Buffalo Creek dam failure in 1972 in West Virginia. The refuse pile and impound standards, Title 30 CFR sections 77.215 and 77.216 had been enacted earlier in 1975 and were incorporated into the Act. Additional parts of these Sections were promulgated and enacted in 1992.

The standards require that the agency approve prudently engineered design plans for dams and their impoundments, as well as the plans for hazardous refuse piles that are routinely constructed by coal mine operators. Plan revisions are also required to be submitted for approval. In addition, the standards also require plans when one of these sites is to be abandoned. And plans are required when spontaneous fires erupt and need to be extinguished at the burning site. Records of weekly inspections and instrument monitoring are also required to ensure that the sites remain safe. Finally, the mine operators are also required to submit an annual status report and certification that guarantees that the site is being constructed in accordance with the approved plan, and the site has not been altered during the construction year.

II. Desired Focus of Comments

Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the proposed extension of the information collection related to Refuse Piles and Impound Structures, Recordkeeping and

Reporting Requirements. MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

A copy of the proposed information collection request may be viewed on the Internet by accessing the MSHA homepage (*http://www.msha.gov*) and selecting ''Statutory and Regulatory Information'' then ''Paperwork Reduction Act submission (*http://www.msha.gov/regspwork.htm*)'', or by contacting the employee listed above in the **FOR FURTHER INFORMATION CONTACT** section of this notice for a hard copy.

III. Current Actions

There are approximately 750 coal mine impounding structures, of which at least 250 are high-hazard sites. In addition, there are hundreds of refuse piles, and of these, it is estimated that 25 are hazardous. All impoundments and hazardous refuse piles are required by the standards to be constructed and operated in an approved manner. In addition, coal mine operators frequently revise construction plans to accommodate mining conditions, cycles or markets. Since these revisions to the structures can adversely affect a great number of people, such changes are required to be planned in a prudent manner and approved by the agency.

Fire extinguishing plans are only required from an operator when a spontaneous combustion has occurred, and the operator is directed to extinguish the fire.

Inspections on a weekly basis, or inspections at a longer interval for long-established and stable impoundments (after the regulation changes in 1992), are required to ensure that precipitation, seismic activity, or perhaps an unknown construction flaw, has not adversely affected any part of the dam site. The annual status report and certification ensures that the company's engineers confirm that the site is in accordance with the approved engineering plan.

An abandonment plan approved by the agency, ensures that a hazardous site is not left in place after all mining activity has ceased.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

Title: Impounding Safety and Refuse Piles, Reporting Requirements, Certifications and Record keeping.

OMB Number: 1219–0015.

Record keeping: 3 years.

Affected Public: Business or other for-profit.

Cite/Reference/Form/etc: 30 CFR Sections 77.215 and 77.216.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintaining): None.

Cite/reference	Total respondents	Frequency	Total responses	Average time per response (in hours)	Burden hours
77.215 New Refuse Piles	50	Annually	50	16	800
Fire Ext. Plans	1	Annually	1	4	4
Abandonment Plans	25	Annually	25	8	200
Certification	15	Annually	15	2	30
77.16 New Impoundments	50	Annually	50	1,300	65,000
Revisions	100	Annually	100	5	500
Annual Certification	115	Annually	115	2	230
Inspections w/monitoring Instruments	285	On Occasion	4,845	3	14,535
w/o Monitoring Instruments	426	On Occasion	7,242	2	14,484
Totals	755		12,428	8	95,753

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: October 17, 2001.

Gordon J. Burke, Jr.,

Director, Administration and Management.

[FR Doc. 01–26738 Filed 10–23–01; 8:45 am]

BILLING CODE 4510–43–M

COMMISSION ON OCEAN POLICY

Public Meeting

AGENCY: Commission on Ocean Policy.

ACTION: Notice of public meeting.

SUMMARY: The Commission on Ocean Policy is an independent Federal commission appointed by the President and authorized by the Oceans Act of 2000 (Public Law 106–256).

The Commission on Ocean Policy is hereby announcing the Commission's second public meeting to be held on Tuesday and Wednesday, November 13 and 14, 2001. The meeting will begin at 9 a.m. on November 13, and conclude at 5 p.m. The Commission will reconvene at 9 a.m. on November 14 and meet until 5 p.m. The meeting will be held in the Naval Memorial and Heritage Center auditorium, 701 Pennsylvania Avenue NW, Suite 123, Washington, DC.

The Commission on Ocean Policy is holding this second public meeting pursuant to requirements under the Oceans Act of 2000 (Public Law 106–256, Section 3(e)(1)(E)). The agenda will include welcoming remarks, presentations by invited guests representing Congress, various Federal agencies and national non-governmental organizations, opportunity for comment from the public and any required administrative discussions and executive sessions. Further information, including a draft agenda, will be available at the Commission's Web site, *http://oceancommission.gov.*

FOR FURTHER INFORMATION CONTACT: Terry Schaff, Commission on Ocean Policy, 2300 Clarendon Boulevard, Suite 1350, Arlington, Virginia, 22201, 703–588–0851; *TSchaff@nsf.gov.*

Dated: October 16, 2001.

James D. Watkins,

Chairman, Commission on Ocean Policy.

[FR Doc. 01–26734 Filed 10–23–01; 8:45 am]

BILLING CODE 6820–WM–P

RAILROAD RETIREMENT BOARD

Proposed Data Collection Available for Public Comment and Recommendations

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection

Railroad Separation Allowance or Severance Pay Report

Section 6 of the Railroad Retirement Act provides for a lump-sum payment to an employee or the employee's survivors equal to the Tier II taxes paid by the employee on a separation allowance or severance payment for which the employee did not receive credits toward retirement. The lump-sum is not payable until retirement benefits begin to accrue or the employee dies. Also, Section 4(a–1)(iii) of the Railroad Unemployment Insurance Act provides that a railroad employee who is paid a separation allowance is disqualified for unemployment and sickness benefits for the period of time the employee would have to work to earn the amount of the allowance. In order to calculate and provide payments, the Railroad Retirement Board (RRB) must collect and maintain records of separation allowances and severance payments which were subject to Tier II taxation from railroad employers. The RRB uses Form BA–9 to obtain, on a quarterly basis, the information needed from railroad employers concerning the separation allowances and severance payments made to railroad employees and/or the survivors of railroad employees. All reports contain a one-line entry for each such payment or adjustment. Completion is mandatory. Responses are requested quarterly. The RRB proposes non-burden impacting editorial changes to Form BA–9.

Estimate of Annual Respondent Burden

The estimated annual respondent burden is as follows:

Form #	Annual responses	Time (min)	Burden (hrs)
BA–9	1,009	75	1,262

Additional Information or Comments

To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092. Written comments should be received within 60 days of this notice.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 01–26721 Filed 10–23–01; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 45, SEC File No. 270–164, OMB Control No. 3235–0154

Rule 52, SEC File No. 270–326, OMB Control No. 3235–0369

Rule 53, SEC File No. 270–376, OMB Control No. 3235–0426

Rule 54, SEC File No. 270–376, OMB Control No. 3235–0427

Rule 57(b) and Form U–33–S, SEC File No. 270–376, OMB Control No. 3235–0429

Rule 58 and Form U–9C–3, SEC File No. 270–400, OMB Control No. 3235–0457

Rule 71, Form U–12(I)–A, and Form U–12(I) –B, SEC File No. 270–161, OMB Control No. 3235–0173

Part 257, SEC File No. 270–252, OMB Control No. 3235–0306

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (Commission) has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information, under the Public Utility Holding Company Act of 1935 (Act), as discussed below.

Rule 45 imposes a filing requirement on registered holding companies and their subsidiaries under Section 12(b) of the Act. Under the requirement, the companies must file a declaration seeking authority to make loans or otherwise extend credit to other companies in the same holding company system. Among others, the rule exempts from the filing requirement the performance of payment obligations under consolidated tax agreements. The 15 recordkeepers together incur about 46 annual burden hours to comply with these requirements.

There is no recordkeeping requirement for this information collection. Companies that are subject to Rule 45 are under a mandatory duty to provide the Commission with the required information. There is no requirement to keep the information confidential because it is public information.

Rule 52 permits public utility subsidiary companies of registered holding companies to issue and sell certain securities without filing a declaration if certain conditions are met. The Commission estimates that the total annual reporting and recordkeeping burden of collection under Rule 52 is 33 hours (33 responses × one hour = 33 burden hours).

There is no recordkeeping requirement for this information collection. It is mandatory that qualifying companies provide the information required by Rule 52. There is no requirement to keep to information

confidential because it is public information.

Sections 32 and 33 of the Act as amended, and Rules 53, 54 and 57(b) under the Act, permit among other things, utility holding companies registered under the Act to make direct or indirect investments in exempt wholesale generators (''EWGs'') and foreign utility companies (''FUCOs''), as defined in Sections 32 and 33 of the Act, respectively, without the prior approval of the Commission, if certain conditions are met. Rules 53 and 54 do not create a reporting burden for respondents. These rules do, however, contain recordkeeping and retention requirements. As required by Congress, the Commission mandates the maintenance of certain books and records identifying investments in and earnings from all subsidiary EWGs or FUCOs in order to measure their financial effect on the registered systems.

The Commission estimates that the total annual recordkeeping and record retention burden under Rule 53 will be a total of 160 hours (10 hours per respondent × 16 respondents = 160 burden hours). It is estimated that there will be no burden hours associated with Rule 54.

Under Rule 57(b) there is an annual requirement for any public utility company that owns one or more FUCOs to file Form U–33–S. The information contained in Form U–33–S allows the Commission to monitor overseas investments by public utility companies.

The Commission estimates that the total annual reporting burden under Rule 57(b) will be 30 hours (3 hours per respondent × 10 filings = 30 hours).

Rules 53, 54, 57(b) each impose a mandatory recordkeeping requirement of this information collection. It is mandatory that qualifying companies provide the information required by Rules 53, 54 and 57(b). There is no requirement to keep the information confidential because it is public information.

Rule 58 under the Act allows registered holding companies and their subsidiaries to acquire energy-related and gas-related companies. Acquisitions are made, within certain limits, without prior Commission approval under Section 10 of the Act. However, within sixty days after the end of the first calendar quarter in which any exempt acquisition is made, and each calendar quarter thereafter, the registered holding company is required to file with the Commission a Certificate of Notification on Form U–9C–3 containing the information prescribed by that form. The Commission uses this information to determine the existence of financial detriment, regarding the acquisition of certain energy-related companies, to the interests the Act is designed to protect. The Commission estimates that the total annual reporting burden is 1,008 hours to comply with these requirements (63 respondents × 16 = 1,008 burden hours).

Rule 71 requires that certain information be filed by employees of registered holding companies who represent the companies' interests before Congress, the Commission or the Federal Energy Regulatory Commission on either Form U–12(I)–A or Form U–12(I)–B. The filings must provide, among other things, the identity of the representative, the person's position and compensation, and a quarterly statement of those expenses not incurred in the ordinary course of business. Employees appearing for the first time must file this information on Form U–12(I)–A within ten days of an appearance. Employees appearing on a regular basis may file the information in advance on Form U–12(I)–B, which will remain valid for the remainder of the year in which it was first filed and for the following two calendar years. Thereafter, it may be renewed for additional three-year periods within thirty days of the expiration of the prior filing.

The information collection prescribed by Form U–12(I)–A and Form U–12(I)–B is required by Rule 71 under the Act. Rule 71 implements section 12(i) of the Act, which expressly requires the filing of the prescribed disclosure information with the Commission in the interest of investors and consumers. The Commission estimates that the total annual reporting burden of collections under Rule 71 is 167 hours (250 responses × forty minutes = 167 burden hours).

Part 257 generally mandates the preservation, and provides for the destruction, of books and records of registered public utility holding companies subject to Rule 26 under the Act and service companies subject to Rule 93. Part 257 prescribes which records must be maintained for regulatory purposes and which media methods may be used to maintain them. Further, it sets a schedule for destroying particular documents or classes of documents.

The Commission estimates that there is an associated recordkeeping burden of 25 hours in connection with the record preservation programs administered by registered holding companies under Part 257 (25 recordkeepers × 1 hour = 25 burden hours).

It is mandatory that records subject to Part 257 be maintained by the holding companies and their service companies for the prescribed period. There is no requirement to keep the information related to Part 257 confidential, because it is public information.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms.

It should be noted that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct general comments regarding the above information to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; and (ii) Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: October 12, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26725 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 25214; 812–11928]

Clearwater Investment Trust and Clearwater Management Co., Inc.; Notice of Application

October 18, 2001.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act.

SUMMARY OF APPLICATION: The requested order would permit applicants, Clearwater Investment Trust (the ''Trust'') and Clearwater Management Co., Inc. (the ''Adviser''), to enter into and materially amend investment subadvisory agreements without obtaining shareholder approval.

FILING DATES: The application was filed on January 6, 2000, and amended on

April 10, 2000, and August 13, 2001, and amended on October 3, 2001.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 13, 2001, and should be accompanied by proof of service on the applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW, Washington, DC 20549–0609; Applicants, c/o Richard T. Holm, Esq., Clearwater Management Co., Inc., 332 Minnesota Street, Suite 2100, St. Paul MN 55101–1394.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 942–0574, or Nadya Roytblat, Assistant Director, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulations).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, NW, Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicants' Representations

1. The Trust, a Massachusetts business trust, is registered under the Act as an open end management investment company. The Trust is comprised of three separate series, each with its own distinct investment objectives, policies, and restrictions (each, a ''Fund'').[1]

2. The Adviser is registered under the Investment Advisers Act of 1940 (''Advisers Act''). The Trust, on behalf of each Fund, has entered into investment advisory agreements with the Adviser (each, an ''Advisory Agreement''), pursuant to which the Adviser serves as the investment adviser to the Funds. Each Advisory Agreement has been approved by the Funds' initial shareholder and by a majority of the Trust's board of trustees (the ''Board''), including a majority of the trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Trust or the Adviser (''Independent Trustees'').

3. Under the Advisory Agreements, the Adviser, subject to Board oversight, provides each Fund with investment research, advise, and supervision, and furnishes an investment program for each Fund. The Advisory Agreements also provide that the Adviser may delegate its responsibility for providing investment advise and making investment decisions for a particular Fund to one or more subadvisers (''Subadvisers''). The Adviser selects Subadvisers based on the Adviser's continuing evaluation of their skills in managing assets pursuant to particular investment styles. The Adviser screens potential new Subadvisers and engages in an on-going analysis of the continued advisability as to the retention of its existing Subadvisers. From time to time, the Adviser may recommend to the Board that the services of a Subadviser be terminated. Each Fund pays the Adviser a fee for its services based on the Fund's average daily net assets.

4. The Adviser and each Fund have entered into investment subadvisory agreements (''Subadvisory Agreements'') with each Subadviser. None of the Trust's existing Subadvisers is an ''affiliated person,'' as defined in section 2(a)(3) of the Act, of the Fund or the Adviser (other than by serving as a Subadviser to the Fund). Each Subadviser, and any future Subadviser will be, registered under the Advisers Act or exempt from registration. The Adviser pays each Subadviser's fees out of the fees the Adviser receives from each Fund.

5. Applicants request relief to permit the Adviser to enter into and materially amend Subadvisory Agreements without obtaining shareholder approval. Applicants state that shareholder approval of a Subadvisory Agreement with a Subadviser that is an affiliated person of the Trust or the Adviser (other than by reason of serving as a Subadviser to one or more of the Funds) (''Affiliated Subadviser'') will be obtained.

Applicant's Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except under a written contract approved by a majority of the investment company's outstanding voting shares. Rule 18f–2 under the Act provides that each series or class of stock in a series company affected by a matter must approve the matter if the Act requires shareholder approval.

2. Section 6(c) of the Act authorizes the Commission to exempt persons or transactions from the provisions of the Act, or from any rule thereunder, to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act. Applicants request an exemption under section 6(c) of the Act from section 15(a) of the Act and rule 18f–2 under the Act to permit them to enter into and materially amend Subadvisory Agreements without shareholder approval.

3. Applicants assert that a Fund's investors rely on the Adviser to select and monitor Subadvisers best suited to manage the Fund's portfolio. Applicants submit that, from the perspective of an investor, the role of the Subadvisers is comparable to that of individual portfolio managers employed by other investment company advisory firms. Applicants contend that requiring shareholder approval of Subadvisory Agreements would impose expenses and unnecessary delays on the Funds, and may preclude the Adviser from promptly acting in a manner considered advisable by the Board. Applicants note that the Advisory Agreements will remain subject to section 15(a) of the Act and rule 18f–2 under the Act, including the requirements for shareholder approval.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Fund may rely on the order requested in this application, the operation of the Fund in the manner described in this application will be approved by a majority or the Fund's outstanding voting securities, as defined in the Act, or by its initial shareholder, provided that, in the case of approval by the initial shareholder, the pertinent Fund's shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below. Similarly, before a Future Fund

[1] Applicants also request relief with respect to future Funds and any other registered open-end management investment company and its series that in the future: (a) is advised by the Adviser, or a person controlling, controlled by or under common control (within the meaning of section 2(a)(9) of the Act) with the Adviser; (b) operates in substantially the same manner as the Funds with regard to the Adviser's responsibility to select, evaluate, and supervise Subadvisers; and (c) complies with the terms and conditions in the application (''Future Funds''). The only existing registered open-end management investment company that currently intends to rely on the requested order is named as an applicant. (p. 2, fn. 1) No Fund or Future Fund will incorporate the name of any Subadviser in the Fund's name.

may rely on the order requested in this application, the operation of the Future Fund in the manner described in this application will be approved by its initial shareholder before a public offering of shares of such Future Fund, provided that shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below.

2. Each Fund will disclose in its prospectus the existence, substance, and effect of any order granted pursuant to the application. In addition, each Fund will hold itself out to the public as employing the management structure described in the application. The prospectus will prominently disclose that the Adviser has the ultimate responsibility to oversee Subadvisers and recommend their hiring, termination and replacement.

3. At all times, a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be at the discretion of the then-existing Independent Trustees.

4. The Adviser will not enter into a Subadvisory Agreement with any Affiliated Subadviser without that agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Fund.

5. When a Subadviser change is proposed for a Fund with an Affiliated Subadviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Trust's Board minutes, that the change is in the best interests of the Fund and its shareholders and does not involve a conflict of interest from which the Adviser or the Affiliated Subadviser derives an inappropriate change.

6. Within 90 days of the hiring of any new Subadviser for any Fund, the Fund shareholders will be furnished all relevant information about a new Subadviser that would be contained in a proxy statement, including any change in such disclosure caused by the addition of a new Subadviser. Each Fund will meet this condition by providing shareholders with an information statement meeting the disclosure requirements of Regulation 14C, Schedule 14C, and Item 22 of Schedule 14A under the Securities Exchange Act of 1934 within 90 days of the hiring of a Subadviser.

7. The Adviser will provide general management services to each Fund, including overall supervisory responsibility for the general management and investment of each Fund's portfolio, and, subject to review and approval by the Board, will: (i) Set the Fund's overall investment strategies; (ii) select Subadviser(s); (iii) monitor and evaluate the performance of Subadviser(s); (iv) ensure that the Subadviser(s) comply with each Fund's investment objectives, policies and restrictions by, among other things, implementing procedures reasonably designed to ensure compliance; and (v) allocate and, where appropriate, reallocate a Fund's assets among its Subadvisers when a Fund has more than one Subadviser.

8. No trustee or officer of the Trust or director of officer of the Adviser will own, directly or indirectly (other than through a pooled investment vehicle that is not controlled by that trustee, director or officer), any interest in a Subadviser, except for: (i) Ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser; or (ii) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly-traded company that is either a Subadviser or any entity that controls, is controlled by, or is under common control with a Subadviser.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26753 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–25213; File No. 812–12140]

United Life & Annuity Insurance Company, et al.

October 17, 2001.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order pursuant to Section 26(c) of the Investment Company Act of 1940 (''1940 Act'').

APPLICANTS: United Life & Annuity Insurance Company (''United Life'') and United Life & Annuity Separate Account One (''Separate Account One'', and together with United Life, ''Applicants'').

SUMMARY OF APPLICATION: Applicants seek an order approving the substitution of shares of the Limited Maturity Bond Portfolio of Neuberger Berman Advisers Management Trust for shares of the Fixed Income Portfolio of Credit Suisse Warburg Pincus Trust II held by Separate Account One to find certain variable annuity contracts and certificates (''Contracts'') issued by United Life.

FILING DATE: The application was filed on June 26, 2000, and amended on April 4, 2001 and October 9, 2001.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 13, 2001, and be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Applicants, Linda E. Senker, United Life & Annuity Insurance Company, c/o ING Variable Annuities, 1475 Dunwoody Drive, West Chester, PA 19380.

FOR FURTHER INFORMATION CONTACT: Kenneth C. Fang, Attorney, or Keith E. Carpenter, Branch Chief, at (202) 942–0670, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the Commission, 450 Fifth Street, NW, Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicant's Representations

1. United Life is a stock life insurance company organized in 1955. United Life was originally domiciled in Louisiana. On December 18, 1998, United Life was re-domesticated to Texas. United Life is authorized to conduct business in 47 states, the District of Columbia and Puerto Rico. On July 24, 1996, Pacific Life and Accident Insurance Company (PLAIC) acquired one hundred percent ownership of United Life. PLAIC is a wholly-owned subsidiary of PennCorp Financial Group, Inc. On April 30, 1999, ING America Insurance Holdings, Inc. (''ING America'') acquired United Life. ING America's ultimate parent is ING Groep N.V. (The Netherlands) (''ING''). ING, based in the Netherlands, is a global financial services holding company.

2. Separate Account One is a separate account of United Life which was authorized by United Life's Board of Directors under Louisiana insurance law on November 2, 1994. Separate Account One is registered as a unit investment trust under the 1940 Act (File No. 811–09026) for the purpose of funding the Contracts that invest in the Neuberger Berman Advisers Management Trust, Credit Suisse Warburg Pincus Trust II and other underlying mutual funds. Security interests under the Contracts have been registered under the Securities Act of 1933 (''1933 Act'') (File Nos. 33–91362 and 33–95778).

3. Separate Account One is currently divided into sub-accounts, each of which reflects the investment performance of a corresponding portfolio of the Neuberger Berman Advisers Management Trust, Credit Suisse Warburg Pincus Trust II and other underlying mutual funds.

4. The Fixed Income Portfolio is a portfolio of the Credit Suisse Warburg Pincus Trust II (formerly, Warburg Pincus Trust II), a registered open-end management company. The Fixed Income Portfolio's investment objective is to seek total return consistent with prudent investment management. The Fixed Income Portfolio invests primarily in fixed-income securities. The Fixed Income Portfolio normally maintains a weighted average portfolio maturity of 10 years or less.

5. Credit Suisse Asset Management, LLC (''CSAM''(, 466 Lexington Avenue, New York, NY 10017, a registered investment adviser and indirect wholly-owned U.S. subsidiary of Credit Suisse Group, provides overall management of the investment strategies and policies of the Fixed Income Portfolio as investment adviser to the Credit Suisse Warburg Pincus Trust II.

6. CSAM receives an annual management fee of .50% of the Fixed Income Portfolio's average daily net assets (before any waivers). The total expenses, after all expense reimbursements for the Fixed Income Portfolio for the year ended December 31, 2000 were 1.29% of its average net assets. Without regard to such expense reimbursements or credits, the total expenses for the year ended December 31, 2000 were 3.11%.

7. On December 31, 2000, the Fixed Income Portfolio had approximately $1,572,000 in net assets.

8. The Limited Maturity Bond Portfolio's investment objective is to seek the highest current income consistent with liquidity and low risk to principal. Total return is a secondary goal. The Limited Maturity Bond Portfolio invests primarily in investment-grade bonds and other debt securities from U.S. government and corporate issuers such as mortgage- and asset-backed securities.

9. Neuberger Berman Management Inc., (''NBM''), 605 Third Avenue, 2nd Floor, New York, New York 10158, a registered investment adviser, is the overall adviser to Neuberger Berman Advisers Management Trust. Neuberger Berman LLC, 605 Third Avenue, New York, New York 10158, is the sub-adviser of the Limited Maturity Bond Portfolio. Neuberger Berman LLC is an affiliate of NBM. United Life is not affiliated with the Limited Maturity Bond Portfolio of Neuberger Berman Advisers Management Trust, NBM or Neuberger Berman LLC.

10. NBM receives an annual fee of 0.65% of the Limited Maturity Bond Portfolio's average net assets. The total expenses of the Limited Maturity Bond Portfolio for the year ended December 31, 2000 were 0.76% of its average net assets.

11. On December 31, 2000 the Limited Maturity Bond Portfolio had approximately $214,400,000 in net assets.

12. For those Contract Owners who continue to have any of their Contract Values invested in shares of the Fixed Income Portfolio on the effective date of the Substitution, United Life proposes to substitute shares of the Limited Maturity Bond Portfolio for shares of the Fixed Income Portfolio on the following basis. As of the effective date of the Substitution, United Life would redeem the shares of the Fixed Income Portfolio representing Contract values. On the same day, United Life would use the proceeds to purchase the appropriate number of shares of the Limited Maturity Bond Portfolio. The Substitution will be a cash transaction (*i.e.,* no securities will be exchanged in the transaction). The Substitution will take place at relative net asset values of the Portfolios, with no change in the amount of any Contract Owner's Contract values or in the dollar value of his or her investment in Separate Account One.

13. United Life will pay all expenses and transactions costs of the Substitution, including any applicable brokerage commissions. United Life will schedule the Substitution to occur as soon as practicable following the issuance of the Order so as to maximize the benefits to be realized from the Substitution. Within five (5) days after the completion of the Substitution pursuant to the Order of the Commission approving the Substitution, United Life will send to the affected Contract Owners written notice of the Substitution (the ''Notice'') stating that shares of the Fixed Income Portfolio have been eliminated and that the shares of the Limited Maturity Bond Portfolio have been substituted. United Life will include in such mailing the supplement to the prospectuses of Separate Account One, which describes the Substitution.

14. Contract Owners will be advised in the Notice that for a period of thirty (30) days from the mailing of the Notice, they may transfer all assets, as substituted, to any other available subaccount, without limitation and without charge. The period from the date of the supplement to thirty (30) days from the mailing of the Notice is referred to as the ''Free Transfer Period.'' Transfers made by Contract Owners during the Free Transfer Period will not count in determining the transfer fee. Following the Substitution, Contract Owners will be afforded the same Contract rights, including surrender and other transfer rights with regard to amounts invested under the Contracts, as they currently have.

Applicant's Legal Analysis and Conditions

1. Section 26(c) (formerly, Section 26(b)) of the 1940 Act provides, in pertinent part, that ''[i]t shall be unlawful for any depositor or trustee of a registered unit investment trust holding the security of a single issuer to substitute another security for such security unless the Commission shall have approved such substitution.'' The purpose of Section 26(c) is to protect the expectation of investors in a unit investment trust that the unit investment trust will accumulate the shares of a particular issuer and to prevent unscrutinized substitutions which might, in effect, force shareholders dissatisfied with the substituted security to redeem their shares, thereby possibly incurring either a loss of the sales load deducted from initial purchase payments, an additional sales load upon reinvestment of the redemption proceeds, or both. Section 26(c) affords this protection to investors by preventing a depositor or trustee of a unit investment trust holding the shares of one issuer from substituting for those shares the shares of another issuer, unless the Commission approves that substitution.

2. The purposes, terms and conditions of the Substitution are consistent with the principles and purposes of Section 26(c) and do not entail any of the abuses that Section 26(c) is designed to prevent. Warburg Pincus notified United Life that it intends to close the Fixed Income Portfolio once there is no

longer Contract Owner money invested in it. United Life has no other choice but to effect a Substitution.

3. The Substitution will not result in the type of costly forced redemption that Section 26(c) was intended to guard against and is consistent with the protection of investors and the purposes fairly intended by the 1940 Act for the following reasons: (a) The Substitution is of shares of the Limited Maturity Bond Portfolio whose objectives, policies, and restrictions are similar to the objectives, policies, and restrictions of the Fixed Income Portfolio so as to continue fulfilling the Contract Owners' objectives and risk expectations; (b) the total annual expenses of the Limited Maturity Bond Portfolio as a percentage of net assets are lower than the Fixed Income Portfolio; (c) if a Contract Owner so requests, during the Free Transfer Period, assets will be reallocated for investment in a Contract Owner-selected sub-account; (d) the Substitution will, in all cases, be effected at net asset value of the respective shares, without the imposition of any transfer or similar charge; (e) United Life has undertaken to assume the expenses and transaction costs, including among others, legal and accounting fees and any brokerage expenses, relating to the Substitutions in a manner that attributes transaction costs to United Life; (f) the Substitution will in no way alter the insurance benefits to Contract Owners or the contractual obligations of United Life; (g) the Substitution will in no way alter the tax benefits to Contract Owners; (h) Contract Owners may choose simply to withdraw amounts credited to them following the Substitution under the conditions that currently exist, subject to any applicable contingent deferred sales charge; and (i) the Substitution is expected to confer certain economic benefits to Contract Owners by virtue of the enhanced asset size and lower total expenses, as described below.

4. United Life, on the basis of the following facts and circumstances, has determined that it is in the best interests of Contract Owners to substitute shares of the Limited Maturity Bond Portfolio for shares of the Fixed Income Portfolio:

(a) The investment objectives and programs of the Limited Maturity Bond Portfolio and the Fixed Income Portfolio are sufficiently similar so as to continue fulfilling the Contract Owner's objectives and risk expectations.

(b) The total expenses of the Limited Maturity Bond Portfolio are lower than the total expenses of the Fixed Income Portfolio.

(c) On December 31, 2000, the Fixed Income Portfolio had approximately $1,572,000 in net assets. On December 31, 2000, the Limited Maturity Bond Portfolio had approximately $214,400,000 in net assets.

(d) The larger size of the Limited Maturity Bond Portfolio lends itself to greater flexibility in purchasing attractive investments and consequently the Limited Maturity Bond Portfolio can more readily react to changes in market conditions. Contract Owners would benefit in the long run through the more effective management of a larger portfolio such as the Limited Maturity Bond Portfolio.

5. United Life does not currently receive (and will not receive for 3 years from the date of the Commission order requested herein) any direct or indirect benefit from the Limited Maturity Bond Portfolio of Neuberger Berman Advisers Management Trust or Neuberger Berman Management Inc. (and their affiliates including Neuberger Berman LLC and its affiliates) that would exceed the amount that United Life had received from the Fixed Income Portfolio of the Credit Suisse Warburg Pincus Trust II or Credit Suisse Asset Management LLC (or their affiliates), including without limitations, 12b–1, shareholder service, administrative or other service fees, revenue sharing or other arrangements, either with respect to specific reference to the Limited Maturity Bond Portfolio or as part of an overall business arrangement.

Conclusion

Applicants submit, for all of the reasons stated herein, that the requested Order under Section 26(c) of the 1940 Act meets the standards of that section.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26754 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [66 FR 53272, October 19, 2001].

STATUS: Open meeting.

PLACE: 450 Fifth Street, NW, Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Thursday, October 25, 2001 at 2:30 p.m.

CHANGE IN THE MEETING: Additional item.

The following item has been added to the open meeting scheduled for Thursday, October 25, 2001:

The Commission will consider extending the comment periods for the joint proposed rules relating to Customer Margin for Security Futures (File No. S7–16–01) and Applicability of CFTC and SEC Customer Protection, Recordkeeping, Reporting, and Bankruptcy Rules and the Securities Investor Protection Act of 1970 to Accounts Holding Security Futures Products (File No. S7–17–01).

For further information, contact Jennifer Colihan at 202 942–0735.

Commissioner Unger, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 942–7070.

Dated: October 22, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–26962 Filed 10–22–01; 4:01 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44946; File No. SR–GSCC–2001–01]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Order Granting Approval of a Proposed Rule Change Relating to the Redesign of Comparison Rules

October 17, 2001.

On January 16, 2001, the Government Securities Clearing Corporation (''GSCC'') filed with the Securities and Exchange Commission (''Commission'') and on April 11 and August 17, 2001,[1] amended the proposed rule change (File No. SR–GSCC–2001–01) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[2] Notice of the proposal was published in the **Federal Register** on May 16, 2001.[3] No comment letters were received. For the reasons discussed below, the

[1] The August 17, 2001, amendment withdrew a portion of the proposed rule change which was reflected by GSCC in a subsequent proposed rule change. Securities Exchange Act Release No. 44907 (October 4, 2001), 66 FR 51988 (October 11, 2001) [File No. SR–GSCC–2001–09]. As such, republication of notice was not required.

[2] 15 U.S.C. 78s(b)(1).

[3] Securities Exchange Act Release No. 44282 (May 8, 2001), 66 FR 27190.

Commission is granting approval for the proposed rule change.

I. Description

The purpose of the filing is to redesign GSCC's comparison rules in order to implement real-time interactive services. In a white paper distributed to all members in early 1997, GSCC outlined its long-range plans to provide straight-through processing and a point-of-trade guarantee to its members primarily through the implementation of real-time interactive services. Last years, GSCC announced that it would implement its interactive services in three phases. Phase 1 will introduce interactive messaging to support real-time comparison; phase 2 will introduce interactive messaging to support netting; and phase 3 will introduce support of same-day settlement of repo start legs.

During the latter part of 2000, GSCC implemented the necessary technical changes to its automated system to implement the first phase of its interactive processing service (*i.e.,* making available the interactive messaging facility to support real-time comparison). Up until this point, GSCC's processing experience has been essentially batch. Members now have the ready ability, from a technological perspective, to submit trade input on an automated basis to GSCC intraday as trades are executed. While GSCC will continue to support its existing batch input and output facilities initially, it plans to eventually stop supporting these older formats. Members will be encouraged to make the shift from batch to interactive processing as soon as it is feasible for them to do so. At some point in time, once a sufficient nucleus of members has begun processing interactively, GSCC will implement disincentives to discourage members from continuing to submit and receive data via the old batch formats.[4]

Concurrent with this development, GSCC has been redesigning its matching and comparison procedures to better meet the needs of its members during their transition from batch to an interactive environment. This redesign is the subject of this proposed rule change. GSCC's central goal in this redesign is to provide straight-through processing by allowing for the easy identification and resolution of trades intraday to achieve 100 percent comparison. GSCC believes that interactive messaging and enhanced real-time matching processing are critical steps in helping to reduce risk by ensuring that more transactions are compared earlier in the day and then eventually also netted and guaranteed through GSCC so that intraday credit exposure to counterparties is minimized.

In the current environment, with the exception being certain locked-in trades, most trades such as members' Federal Reserve auction purchases are compared within the GSCC system as a result of bilateral comparison. To facilitate real-time comparison while still providing members with the flexibility to transition from batch to interactive submission according to a timeframe suitable to their own needs and resources, GSCC is proposing to: (i) Amend its rules to provide for three types of trade comparison: (a) bilateral comparison, (b) demand comparison, and (c) locked-in comparison; and (ii) make certain other related rules changes as further discussed below.

Bilateral Comparison

Bilateral comparison, which is the traditional method of comparison, will continue to require that the two trade counterparties (or if one or both of the counterparties are not GSC members, the members acting on their behalf) submit trades to GSCC in which certain mandatory details either match or fall within predefined parameters to effect a match. Bilateral comparison will remain the primary comparison type for dealer-to-dealer trades and will be available in both real-time and batch. Members may elect to submit interactively regardless of whether their trade counterparties do so.

A new feature of bilateral comparison will be the ability for members to ''DK'' any trades they ''do not know''. The proposed rule change introduces the term ''DK Notice'' to GSCC's rules. If a member determines that a request for comparison is invalid or incorrect, it can send a DK notice to GSCC which will be forwarded to the original submitter. The receipt of the DK notice by GSCC will prevent the trade from comparing on GSCC's system. If a member that sent a DK notice determines that it did so erroneously, the member will be able to remove the DK and enable comparison to occur if it does so within the timeframes prescribed by GSCC for such purpose.

Demand Comparison

Demand comparison is a new type of comparison that has been designed to provide members with flexibility and control over the comparison process for trades executive via intermediaries. Demand comparison strikes a balance between bilateral comparison, where the member is required to submit trade data in order for its trade to compare, and locked-in comparison (discussed in more detail below), where the trade has essentially been operationally compared before being submitted to GSCC.

Demand trades will be submitted by approved intermediaries (*e.g.,* brokers) that will be called ''demand trade sources.'' Demand trade sources must be able to communicate with GSCC interactively. In order for GSCC to accept trades from a demand trade source on a member's behalf, the member must provide GSCC with prior written authorization. The intermediary must also be approved and authorized by GSCC to be a demand trade source.

GSCC will deem a demand trade compared upon receipt of the trade data from the demand trade source. However, if a member does not know a trade submitted on its behalf by a demand trade source, the member will be able to submit a DK notice to GSCC. The receipt of a DK notice by GSCC will cause the demand trade to no longer be eligible for comparison. If a member that sent a DK notice determines that it did so erroneously, the member will be able to remove the DK and enable comparison to occur if it does so within the timeframes prescribed by GSCC for such purpose.

GSCC is making incidental rules changes to Rules 11, 16, 18, 21, 22, and 39 to take into account the introduction of demand trades.

Locked-In Comparison

Locked-in comparison will be similar to that currently provided for in GSCC's rules. Locked-in comparison presumes that a member would elect not to submit corresponding trade details to affect a match because the trade has been precompared by the trade source. An example of a trade appropriate for locked-in comparison would be one executed through a ''pure'' electronic trading system that is terminal-driven and that no discretion over trade details is exercised once the trade is submitted.

In order to participate, the locked-in trade source must be authorized by both the members of whose behalf it will be submitting trade data and by GSCC. With the exception of some current locked-in sources, such as the Federal Reserve banks, locked-in trade sources will be expected to communicate interactively with GSCC.

Locked-in trades will be deemed compared upon receipt by GSCC. The DK feature will also be available for locked-in trades. However, unlike the case of demand trades, a DK of a locked-in trade will be treated by GSCC as a

[4] GSCC will file with the Commission pursuant to Section 19 of the Act proposed rule changes with respect to any fees intended as disincentives to discourage members from using batch formats.

request for cancellation to the locked-in trade source. In order to actually cancel the trade on GSCC's system, the locked-in trade source will have to respond to the request by submitting a trade cancellation. The locked-in trade source can modify the trade in response to a DK notice.

Submission Methods

In order to set forth the concept of a member submitting interactively versus submitting in one of the batch modes, GSCC is adding three new definitions to its rules: ''interactive submission method,'' ''multiple batch submission method,'' and ''single batch submission method.'' The proposed rules changes make clear which submission type is required for each type of comparison. In addition, GSCC is adding a definition of ''real time'' in its rules to be used to indicate when a particular process (*e.g.,* the enhanced comparison processes set forth in Rule 10) will be performed by GSCC in real time as opposed to at end of day.

Submission of Full-Sized Trades

GSCC is permitting members to submit full-sized trades. Currently, non-GCF Repo trades are submitted in $50 million increments. Because members' internal systems tend to reflect the full size of each trade (as opposed to the pieces that they submit to GSCC), the submission of full-sized trades will permit members to better reconcile their trading activity. GSCC recognizes that not all members will be able to begin processing full-sized trades immediately. Therefore, GSCC will not require that members exercise this option.

Timing of Key Processes of GSCC

GSCC's key processes are comparison, netting, novation, and guaranty of settlement. GSCC is changing the timing of the comparison and guaranty of settlement processes.

With respect to the timing of comparison, GSCC's rules currently provide that it occurs when GSCC makes its comparison output available to members. GSCC is amending its rules to state that, while comparison will continue to occur upon issuance of the comparison message by GSCC with respect to trades submitted for bilateral comparison, comparison will be deemed to occur upon receipt of trade data from the authorized trade source with respect to trades submitted for demand comparison and locked-in comparison.

With respect to the timing of netting, GSCC's rules currently provide that netting occurs upon issuance of the report of or output on net settlement positions by GSCC. This will continue to be the case. Similarly, GSCC's rules currently provide that novation, the process by which GSCC becomes the substituted counterparty to trades submitted to it, occurs upon the issuance of the report of or output on net settlement positions by GSCC. This will also remain unchanged.

With respect to the timing of GSCC's guaranty of settlement, GSCC's current rules provide that GSCC guarantees the settlement of a netting-eligible trade upon issuance of the report/output that sets forth the member's net settlement position.[5] The proposed rule changes will move the timing of GSCC's guaranty to the point of comparison. This means that a netting-eligible trade submitted for bilateral comparison will be guaranteed upon issuance of the comparison message by GSCC, and a netting-eligible trade submitted for demand or locked-in comparison will be guaranteed upon receipt of trade, data from the authorized trade source. If a trade is DKed (and with respect to a locked-in trade cancelled by the locked-in trade source), GSCC's guaranty will no longer be in effect with respect to that trade. As a transition measure that recognizes that members may need some time to switch to interactive processing, GSCC is proposing that it maintain its policy of guaranteeing blind brokered repo trades entered into in good faith upon trade execution through the year 2001.

General Responsibilities of Members

GSCC's comparison rule contains a provision that requires members to review documents that they receive from GSCC. GSCC desires to expand the provision to cover any type of communication provided to members by GSCC and to require members to inform GSCC promptly, but in no event later than ten calendar days upon receipt of the communication, if there is any error, omission, or other problem with respect to the communication. GSCC's netting rule contains a similar provision with respect to which GSCC is adding the ten-day requirement. GSCC believes that the ten-day time frame will provide members with a sufficient amount of time within which to detect problems in a communication from GSCC.

[5] The exception to this rule is GSCC's policy of guaranteeing blind brokered repos entered into in good faith upon trade execution. GSCC adopted this policy in order to comfort dealers that have intraday credit exposure to brokers through whom they execute such transactions. The policy only applies to such transactions that are entered into in good faith, which means, for example, that GSCC would not honor it in the event that a dealer entered into a transaction knowing that the counterparty was insolvent.

Amendments to Schedules

GSCC is making incidental changes to certain of its Schedules for clarification purposes and to bring them into conformity with the proposed rules changes discussed above. Specifically, GSCC is expanding the output time slot in its ''Schedule of Timeframes'' from ''midnight to 2:00 a.m.'' to ''8:00 p.m. to 2:00 a.m.'' This change reflects the fact that GSCC may be able to provide certain output earlier given the implementation of real-time trade matching and also the recent shift to the 8:00 p.m. trade submission deadline.

GSCC is also adding language to make clear that the 10:30 a.m. deadline for satisfaction of a clearing fund deficiency call is approximate because members have two hours after a call is made to fulfill their obligation.

GSCC is also updating its ''Schedule of Required Match Data,'' ''Schedule of Required Data Submission Items,'' and its ''Schedule of Required Data Submission Items for a Right of Substitution'' to make clear that the only locked-in trades to which those schedules do not apply are Treasury/Federal Reserve auction purchases and GCF repo transactions.

GSCC is also amending its fee structure to set fees for demand trades which will be the same as those currently imposed on locked-in trades.

II. Discussion

Section 17A(b)(3)(F)[6] of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in the custody or control of GSCC. The rule change, which allows GSCC to implement interactive messaging to support real-time comparison, will enable GSCC to reduce risk by enabling firms to know earlier of any trades which do not compare and to have more time to resolve the problems. This should reduce the number of failed trades at GSCC. The rule change also provides for more efficient procedures in the comparison process thereby facilitating prompt and accurate clearance and settlement of securities at GSCC. Therefore, the Commission finds that the rule change is consistent with Section 17A and the rules and regulations thereunder.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the

[6] 15 U.S.C. 78q–1(b)(3)(F).

requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It is Therefore Ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–GSCC–2001–01) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26727 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44955; File No. SR–ISE–2001–18]

Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change, and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 4 to Proposed Rule Change, by the International Securities Exchange LLC, Relating to Priority Principles on Complex Orders

October 18, 2001.

I. Introduction

On May 25, 2001, the International Securities Exchange LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish priority and order handling principles for complex orders. Notice of the proposed rule change and Amendment Nos. 1, 2 and 3 thereto was published for comment in the **Federal Register** on August 13, 2001.[3] No comments were received.

On October 16, 2001, the ISE filed Amendment No. 4 to the proposed rule change. In Amendment No. 4, the Exchange added text to proposed new Rule 722(b)(5) to provide that the right to facilitate or cross up to 40% of a customer's complex order without exposing the order for 30 seconds, as is otherwise required by ISE rules, would be limited to those complex orders where at least one leg of the order was for at least 50 contracts.[4]

This order approves the proposed rule change as amended, accelerates approval of Amendment No. 4, and solicits comment from interested persons on that amendment.

II. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[5] In particular, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act,[6] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors and the public interest.

The Commission notes that the rules of other options exchanges allow similar procedures for the execution of complex orders.[7] In general, such rules serve to reduce the risk of incomplete or inadequate executions, while increasing efficiency and competitive pricing. At the same time, they protect the priority of orders of public customers by permitting the legs of complex orders to trade ahead of bids and offers established in the marketplace only under restrictions such as those proposed here. Although the ISE's proposal would apply to more types of orders than the rules of other options exchanges, such as box spread and collar orders, the Commission believes that these types of orders are of a similar degree of complexity to those approved in the past for special priority rules, and it is therefore appropriate to accord them the same treatment.

As originally proposed, the new rule would have allowed a firm to execute immediately up to 40% of a complex order, either as principal (''facilitation'') or against an order it has solicited (''crossing''), as opposed to first exposing the order to the market for 30 seconds, as is otherwise required by paragraphs (d) and (e) of ISE Rule 717. In Amendment No. 4 to the proposed rule change, the ISE limited this allowance to orders where at least one leg of the transaction was for at least 50 contracts.[8]

The Commission finds that Amendment No. 4 is consistent with the Act, and finds good cause to approve it prior to the thirtieth day after the date of publication of notice of its filing in the **Federal Register.** Amendment No. 4 conforms the proposed rules to existing ISE Rules 716 and 717, which permit similar execution procedures for other orders, provided that they are for 50 contracts or more. The Commission believes that limiting such facilitation or crossing rights to orders of this size should help to adequately protect competitive pricing for smaller orders. Finally, the Commission notes that a broker who accepts a customer's order has a fiduciary duty toward that order.

Therefore, the Commission finds good cause to approve Amendment No. 4 to the proposed rule change on an accelerated basis.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 4, including whether Amendment No. 4 is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 USC 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–ISE–2001–18 and should be submitted by November 14, 2001.

IV. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–ISE–2001–18), as amended, be, and it hereby is, approved.

[1] 15 USC 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 44659 (August 6, 2001), 66 FR 42575 (August 13, 2001) (''Notice'').

[4] *See* letter from Jennifer Lamie, Assistant General Counsel, ISE, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated October 15, 2001 (''Amendment No. 4'').

[5] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 USC 78(c)(f).

[6] 15 USC 78f(b)(5).

[7] *See* Chicago Board Options Exchange Rule 6.45; American Stock Exchange Rule 950(d), Commentary .01; Philadelphia Stock Exchange Rule 1033; Pacific Exchange Rule 6.75.

[8] *See* fn. 4, *supra.*

[9] 15 USC 78s(b)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26755 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44631A; File No. SR–NASD–00–38]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 2 to the Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Application of NASD Rules and Interpretive Materials to Exempted Securities; Corrections

October 17, 2001.

In FR Document No. 01–19700, beginning on page 41283, column 3, for Tuesday, August 7, 2001, a sentence was incorrectly stated. Specifically, footnote 10 should be revised to delete references to National Association of Securities Dealers, Inc. (''NASD'') Rule 2440, ''Fair Prices and Commissions,'' and to IM–2440, ''Mark-Up Policy.''

Footnote 10 is revised to read as follows:

[10] *See* Securities Exchange Act Release No. 37588 (August 20, 1996), 61 FR 44100 (August 27, 1996) (order approving File No. SR–NASD–95–39) (''1996 Order''). The 1996 Order approved the application of the following NASD rules to exempted securities, including government securities but not municipal securities: NASD Rule 2110, ''Standards of Commercial Honor and Principles of Trade;'' NASD Rule 2120, ''Use of Manipulative, Deceptive or Other Fraudulent Devices;'' NASD Rule 2210, ''Communications with the Public;'' IM–2210–2, ''Communications with the Public about Collateralized Mortgage Obligations;'' IM–2210–2, ''Communications with the Public about Variable Life Insurance and Variable Annuities;'' IM–2210–3, ''Use of Rankings in Investment Companies Advertisements and Sales Literature;'' NASD Rule 2250, ''Disclosure of Participation or Interest in Primary or Secondary Distribution;'' NASD Rule 2270, ''Disclosure of Financial Condition to Customers;'' NASD Rule 2310, ''Recommendations to Customers (Suitability);'' IM–2310–2, ''Fair Dealing with Customers;'' IM–2310–3, ''Suitability Obligations to Institutional Customers;'' NASD Rule 2320, ''Best Execution and Interpositioning;'' NASD Rule 2330, ''Customers' Securities or Funds;'' IM–2330, ''Segregation of Customers' Securities;'' NASD Rule 2340, ''Customer Account Statements;'' NASD Rule 2430, ''Charges for Services Performed;'' NASD Rule 2450, ''Installment or Partial Sales;'' NASD Rule 2510, ''Discretionary Accounts;'' NASD Rule 2520, ''Margin Accounts;'' NASD Rule 2521, ''Margin Requirements—Exception for Certain Members'' (formerly NASD Rule 2520(a); NASD Rule 2522, ''Definitions Related to Options, Currency Warrants Currency Index Warrants and Stock Index Warrants Transactions'' (formerly NASD Rule 2520(b); NASD Rule 2770, ''Disclosure of Price in Selling Agreements'' (applicable only to traditional underwriting arrangements); NASD Rule 2780, ''Solicitation of Purchases on an Exchange to Facilitate a Distribution of Securities;'' NASD Rule 2910, ''Disclosure of Financial Condition to Other Members;'' NASD Rule 3010, ''Supervision;'' NASD Rule 3020, ''Fidelity Bonds;'' NASD Rule 3030, ''Outside Business Activities of an Associated Person;'' NASD Rule 3040, ''Private Securities Transactions of an Associated Person;'' NASD Rule 3050, ''Transactions for or by Associated Persons;'' NASD Rule 3060, ''Influencing or Rewarding Employees of Others;'' NASD Rule 3070, ''Reporting Requirements;'' NASD Rule 3120, ''Use of Information Obtained in a Fiduciary Capacity;'' NASD Rule 3110, ''Books and Records;'' IM–3110, ''Customer Account Information;'' NASD Rule 3130, ''Regulation of Members Experiencing Financial and/or Operational Difficulties;'' IM–3130, ''Restrictions on a Member's Activity;'' NASD Rule 3131, ''Regulation of Activities of Section 15C Members Experiencing Financial and/or Operational Difficulties;'' NASD Rule 3140, ''Approval of Change in Exempt Status under SEC Rule 15c3–3;'' NASD Rule 3230, ''Clearing Agreements;'' NASD Rule 3310, ''Publication of Transactions and Quotations;'' IM–3310, ''Manipulative and Deceptive Quotations;'' NASD Rule 3320, ''Offers at Stated Prices;'' IM–3320, ''Firmness of Quotations;'' NASD Rule 3330, ''Payment Designed to Influence Market Prices, Other than Paid Advertising;'' NASD Rule 8110, ''Availability to Customers of Certificate, By-Laws, and Rules;'' NASD Rule 8120, ''Complaints by Public Against Members for Violations of Rules;'' NASD Rule 8130, ''Complaints by District Business Conduct Committees;'' NASD Rule 8140, ''Complaints by the Board of Governors;'' NASD Rule 8210, ''Reports and Inspections of Books for Purpose of Investigating Complaints;'' NASD Rule 8220, ''Suspension of Members for Failure to Furnish Information Duly Requested;'' NASD Rule 8310, ''Sanctions for Violation of the Rules;'' IM–8310–1, ''Effect of a Suspension, Revocation, or Bar;'' IM–8310–2, ''Release of Disciplinary Information;'' NASD Rule 8320, ''Payment of Fines, Other Monetary Sanctions, or Costs;'' and NASD Rule 8330, ''Cost of Proceedings.'' As discussed more fully below, Amendment No. 2 clarifies NASD Regulation's reasons for including NASD Rules 2521, 2522, 2910, 8220 (which was expanded to include current NASD Rules 8221 through 8227), and IM–8310–2 in its list of rules and interpretative materials applicable to exempted securities, including government securities, other than municipal securities. *See* Amendment No. 2, *supra* note 4.

[10] 17 CFR 200.30–3(a)(12).

In addition, in FR Document No. 01–19700, beginning on page 41284, column 1, a sentence in footnote 12 was incorrectly stated. Specifically, footnote 12 should be changed to delete references to NASD Rule 2300 and to IM–8310 and to add a reference to IM–2522.

Footnote 12 is revised to read as follows:

[12] Specifically, NASD Rule 0116(b) states that, unless otherwise indicated within a particular provision, the following NASD rules and interpretative materials apply to transactions and business activities relating to exempted securities but not municipal securities, conducted by members and associated persons: 2110, 2120, 2210, IM–2210–1, IM–2210–2, IM–2210–3, 2250, 2270, 2310, IM–2310–2, IM–2310–3, 2320, 2330, IM–2330, 2340, 2430, 2450, 2510, 2520, 2521, 2522, IM–2522, 2770, 2780, 2820(g), 2910, 3010, 3020, 3030, 3040, 3050, 3060, 3070, 3110, IM–3110, 3120, 3130, IM–3130, 3131, 3140, 3230, 3310, IM–3310, 3320, IM–3320, 3330, 8110, 8120, 8210, 8221, 8222, 8223, 8224, 8225, 8226, 8227, 8310, IM–8310–1, IM–8310–2, 8320, and 8330. *See* Amendment No. 2, *supra* note 4.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26728 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44943; File No. SR–NYSE–2001–39]

Self-Regulatory Organizations; New York Stock Exchange, Inc., Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. To Amend Rule 123

October 16, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–b–4 thereunder,[2] notice is hereby given that on October 8, 2001, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'' the proposed rule change as described in Items, I, II and III below, which Items have been prepared by the NYSE. The text of the proposed rule change is available for inspection and copying at

[1] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the places specified in Item IV below. 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 proposed rule change consists of amendments to NYSE Rule 123. The text of the proposed rule change is available at the Office of the Secretary, NYSE, 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, the NYSE included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This proposed rule change was originally filed as a one-month pilot in SR–NYSE–2001–36.[3] With this proposed rule change, the NYSE seeks permanent approval to the amendments to NYSE Rule 123.

The Exchange has adopted requirements for the electronic capture of orders at the point of sale (front end systemic capture, or ''FESC'')[4] and at the point of receipt (order tracking system, or ''OTS''). The purpose of the requirements is to create a complete systemic record of orders handled by members and member organizations. The Exchange believes that these requirements will provide benefits both to the Exchange and members in terms of recordkeeping, surveillance and order processing.

However, due to the time sensitivity of bona fide arbitrage orders and orders to offset transactions made in error, the Exchange is proposing to carve out two exceptions to NYSE Rule 123(e). These orders may be initiated by a member on the Floor pursuant to SEC Rule 11a–1 and NYSE Rule 111, and a requirement that such orders be first entered into FESC may result in a lost arbitrage opportunity, or the covering of an error at additional loss to the member. With respect to bona fide arbitrage orders,[5] a member may execute such order before entering the order into FESC. However, such member must enter such order into FESC no later than 60 seconds after the execution of such order.

Similarly, with respect to orders to offset transactions made in error, a member may, upon discovering such error within the same trading session, effect an offsetting transaction without first entering such order into FESC. However, such member must enter such order into FESC no later than 60 seconds after the execution of such order.

2. Statutory Basis

The Exchange believes that the basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) of the Act[6] that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change is designed to accomplish these ends by strengthening the Exchange's ability to surveil the Floor activities of members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and subparagraph (f)(6) of Rule 19b–4 thereunder.[8] At any time within 60 days of the filing of the proposed rule change, as amended, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Commission notes that under Rule 19b–4(f)(6)(iii),[9] the proposal does not become operative for 30 days after date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the five-day pre-filing requirement and designate that the proposed rule change become operative immediately to permit the continued implementation of the amendments to NYSE Rule 123, as begun on September 10, 2001, for a one-month pilot. The NYSE believes it is consistent with investor protection and the public interest. In particular, the Exchange believes the proposed rule change will enable members to execute bona fide arbitrage orders and orders to offset transactions made in error quickly without having to enter the order into the FESC. The proposed rule will still require that these be entered into the FESC within 60 seconds after the execution of the respective order.

The Commission believes that it is consistent with the protection of investors and the public interest to waive the five-day pre-filing require and designate the proposed rule change

[3] *See* Securities Exchange Act Release No. 44783 (September 10, 2001), 66 FR 48304 (September 19, 2001).

[4] *See* Securities Exchange Act Release No. 43689 (December 7, 2000), 65 FR 79145 (December 18, 2000) (Order approving amendments to NYSE Rule 123 providing for the systemic capture of order information on the Exchange floor).

[5] In Securities Exchange Act Release No. 15533 (January 29, 1979), 44 FR 6084 January 31, 1979), the Commission defined ''bona fide arbitrage'' as an ''activity undertaken by market professionals in which essentially contemporaneous purchases and sales are effected in order to 'lock in' a gross profit or spread resulting from a current differential in pricing.'' The Commission further stated that it ''understands that many transactions currently being undertaken by those who are regularly engaged in arbitrage involve some limited, intentional delay (usually a matter of minutes or hours but sometimes, under extraordinary circumstances, as long as a day or even two days) in between the transaction in which the first leg of the arbitrage is established and the subsequent transaction in which the second, offsetting, leg is completed.'' With respect to the latter, each ''leg'' of an arbitrage would be considered an ''order'' for purposes of the bona fide arbitrage exception under Exchange Rule 123(e). Thus, a member would be required to enter such order into FESC no later than 60 seconds after the execution of each ''leg'' of the arbitrage.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] 17 CFR 240.19b–4(f)(6).

immediately operative.[10] Accelerating the operative date and waiving the pre-filing requirement will permit the Exchange to continue implementation of NYSE Rule 123(e) without interruption. For this reason, the Commission finds good cause to designate that the proposed rule change become operative immediately.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549–0609.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room.

Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to the File No. SR–NYSE–2001–39 and should be submitted by November 14, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26729 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

[10] For purposes of accelerating the operative date of this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44947; File No. SR–Phlx–2001–90]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Registration Fees for Registered Representatives

October 17, 2001.

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 October 5, 2001, the Philadelphia Stock Exchange, Inc. (''Plx'' and ''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 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

Pursuant to Rule 19b–4 under the Act, the Phlx proposes to amend its fee schedule for Registered Representative registration. Specifically, the Phlx proposes to increase the initial Registered Representative registration fee from $45 to $55 and to increase both the maintenance and transfer registration fee for Registered Representatives from $45 to $50. The proposed effective date of the increase is January 1, 2002.

The text of the proposed rule change appears below. Next text is italics; deletions are in brackets.

Phlx Fee Schedule

* * * * *

Registered Representative Registration

	Delections	New text
Initial	[$45.00]	*$55.00*
Maintenance	[1] 45.00]	[1] *50.00*
Transfer	[45.00]	*50.00*

[1] Annual.

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 Items IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 increase the Exchange's initial Registered Representative registration fee from $45 to $55 and to increase its maintenance and transfer Registered Representative registration fee from $45 to $50. These fees, which were adopted in 1993,[3] and subsequently adjusted in 1995;[4] 1997,[5] 1999 [6] and 2000 [7] are payable by member organizations that apply for, maintain, and transfer Registered Representative registration.[8] The Proposed fee increases will be effective January 1, 2002. The Phlx intends that, on its behalf, the National Association of Securities Dealers, Inc. (''NASD'') will bill for the year 2002 fees in November 2001 and will thereafter collect the fees for the Exchanges.[9] The proposed fees will apply to year 2002 registrations. Any initial registration in 2001 will continue to be subject to the current $45 initial registration fee. Any maintenance and transfer fees incurred for calendar year 2001 will continue to be subject to the $45 maintenance or transfer fee. The purpose of the proposed rule change is to address the increased costs associated with maintaining surveillance and regulatory programs in an increasingly sophisticated trading environment. The Exchange continues to believe that strong surveillance and regulatory

[3] *See* Securities Exchange Act Release No. 32833 (September 14, 1993), 58 FR 48922 (September 20, 1993) (order approving File No. SR–Phlx–93–24).

[4] *See* Securities Exchange Act Release No. 36348 (October 14, 1993), 58 FR 48922 (September 20, 1993) (order approving File No. SR–Phlx–93–24).

[5] *See* Securities Exchange Act Release No. 39044 (September 10, 1997), 62 FR 48914 (September 17, 1997) (notice of filing and immediate effectiveness of File No. SR–Phlx–97–41).

[6] *See* Securities Exchange Act Release No. 42122 (November 10, 1999), 64 FR 63098 (November 18, 1999) (notice of filing and immediate effectiveness of File No. SR–Phlx–99–34).

[7] *See* Securities Exchange Act Release No. 43547 (November 13, 2000), 65 FR 69980 (November 21, 2000) (notice of filing and immediate effectiveness of File No. SR–Phlx–00–95).

[8] The Phlx originally implemented the fees to offset regulatory costs based on the number of Registered Representative registrations maintained by member organizations.

[9] The Exchange has represented that initial, transfer, and maintenance Registered Representative registration fees traditionally have been billed and collected by the NASD. Under the proposal, as noted above, the NASD will continue to bill for and collect these fees. Telephone conversation between Murray L. Ross, Vice President and Security, Phlx, to Yvonne Fraticelli, Special Counsel, Division of Market Regulation, Commission, on October 15, 2001.

programs are essential to the ability of the Exchange to maintain a fair and orderly market for the investment community.

According to the Phlx, the general costs associated with the Exchange's surveillance and regulatory programs have continued to rise. The Phlx notes that since the last Registered Representative fee increase in 2000,[10] costs associated with the Exchange's surveillance and regulatory programs have increased. The Phlx attributes the increase in costs to, among other things, inflationary and competitive pressures upon the cost of staffing, equipment, and computer technology, as well as the expansion of the Exchange surveillance and regulatory programs in response to increased market share. Moreover, the Exchange has listed, and will likely continue to list, new issues and products, which trigger significant additional surveillance and regulatory costs.

(2) Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(4),[12] in particular, in that is provides for the equitable allocation of reasonable dues, fees, and offer charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change establishes or changes a due, fee, or charge imposed by the Exchange and, therefore, has become effective upon filing pursuant to Rule 19(b)(3)(A)(ii) of the Act[13] and Rule 19b–4(f)(2) hereunder.[14] The Exchange intends to implement the fees effective as of January 1, 2002. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purpose 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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Phlx–2001–90 and should be submitted by November 14, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[15]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–26726 Filed 10–23–01; 8:45 am]

BILLING CODE 8010–01–M

[10] *See supra* note 7.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78(s)(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3347]

State of Texas; Amendment #7

In accordance with a notice received from the Federal Emergency Management Agency, dated October 17, 2001, the above-numbered Declaration is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to October 31, 2001.

All other information remains the same, i.e., the deadline for filing applications for loans for economic injury is March 8, 2002.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: October 18, 2001.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 01–26733 Filed 10–23–01; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Region VII Regulatory Fairness Board; Meetings

The Small Business Administration Region VII Regulatory Fairness Board and the SBA Office of the National Ombudsman, will hold a Public Roundtable Thursday, November 1, 2001 at 1 p.m. at the Carlsen Center, Room 232, Johnson County Community College, 12345 College Boulevard, Overland Park, Kansas 66313, to provide small business owners and representatives of trade associations with an opportunity to share information concerning the regulatory enforcement and compliance environment.

Anyone wishing to attend or to make a presentation must contact Ms. Barbara Caldwell, Public Information Officer, in writing by letter or fax no later than October 31st , 2001, in order to be put on the agenda. Barbara Caldwell, Public Information Officer, Kansas City District Office, U.S. Small Business Administration, 323 W. 8th Street, Lucas Place, Suite 501 Kansas City, MO 64105, Phone (816) 374–6762 (ext. 244), fax (816) 374–6759.

Steve Tupper,

Committee Management Officer.

[FR Doc. 01–26739 Filed 10–23–01; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Region III Regulatory Fairness Board; Meeting

The Small Business Administration Region III Regulatory Fairness Board and the SBA Office of the National Ombudsman, will hold a Public Roundtable November 13, 2001, at 1 p.m. at Harrisburg City Council, 10 North 2nd Street, Room 101, Harrisburg, PA 17101, to provide small business owners and representatives of trade associations with an opportunity to share information concerning the regulatory enforcement and compliance environment.

Anyone wishing to attend or to make a presentation must contact Ms. Susan Harris, in writing by letter or fax no later than November 6, 2001, in order to be put on the agenda. Susan Harris,

Philadelphia District Office, U.S. Small Business Administration, Robert N C Nix Sr., Federal Building 900 Market Street, 5th Floor, Philadelphia, PA 19107, Phone (215) 580–2709, Fax (215) 580–2759.

Steve Tupper,

Committee Management Officer.

[FR Doc. 01–26740 Filed 10–23–01; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 3821]

Privacy Act of 1974: Creation of a New System of Records

Notice is hereby given that the Department of State proposes to create a new system of records, STATE–32, pursuant to the provisions of the Privacy Act of 1974, as amended [5 U.S.C. 552a(r)], and the Office of Management and Budget Circular No. A–130, Appendix I. The Department's report was filed with the Office of Management and Budget on October 04, 2001.

STATE–32 is being implemented by the Department of State to facilitate its responsibility for managing the Department's Child Care Subsidy Program.

Any persons interested in commenting on this new system of records may do so by submitting comments in writing to Margaret Peppe, Chief; Programs and Policies Division; Office of IRM Programs and Services; A/RPS/IPS/PP; U.S. Department of State, SA–2; Washington, DC 20522–6001.

This system of records will be effective 40 days from the date of publication, unless we receive comments that will result in a contrary determination.

This new system description, ''Child Care Subsidy Program Records, STATE–32'' will read as set forth below.

Dated: October 4, 2001.

William A. Eaton,

Assistant Secretary for the Bureau of Administration, Department of State.

STATE–32

SYSTEM NAME:

Child Care Subsidy Program Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Department of State, SA–14, 2401 E Street, NW; Washington, DC 20520; and the Federal Employees Education and Assistance Fund (FEEA), 8441 W. Bowles Avenue, Suite 200, Littleton, CO 80123–9501.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the Department of State who voluntarily apply for a child care subsidy, their spouses and children.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application forms for a child care subsidy contain personal information including employee's (parent/guardian) name, Social Security Number, position grade, home phone number, home address, total income, number of dependent children, and number of children on whose behalf the parent is applying for a subsidy, information on any tuition assistance received from state/county/local child care subsidy, and information on child care providers used, including their name, address, provider license number, and state of license issued, tuition cost, provider tax identification number, and copies of Internal Revenue Form 1040 for verification purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Consolidated Appropriations Act of 2001, Pub. L. 106–544.

PURPOSE(S):

Information contained in the Child Care Subsidy Program Records is collected and maintained by the Bureau of Human Resources in the administration of its responsibility for managing the Department's Child Care Subsidy Program. The primary use of the records maintained in this system is to establish and verify Department of State employees' eligibility for child care subsidies in order to provide monetary assistance to them. Other uses of the records in the system include verifying the eligibility of child care centers and compliance with regulations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The information in this system is used by:

(1) Experts, consultants or contractors of the Department who determine eligibility and/or payment of child care subsidies;

(2) Child care providers in order to verify a covered child's dates of attendance at the provider's facility;

(3) The Bureau of Finance and Management Policy (FMP) of the Department of State, responsible for wages, compensation and allowances;

(4) The Department of Justice, or a court, adjudicative or other administrative body, or a party in litigation before a court or adjudicative or administrative body, when:

(a) One of the following is a party to the proceeding or has an interest in the proceeding:

(1) The Department or any component of the Department;

(2) Any Departmental employee acting in his or her official capacity;

(3) Any Departmental employee acting in his or her individual capacity where the Department of Justice has agreed to represent the employee, or

(4) The United States, when the Department determines that the Department is likely to be affected by the proceeding; and

(b) The Department deems the disclosure to be relevant and necessary to the proceedings.

STORAGE:

Electronic media, hard copy.

RETRIEVABILITY:

Individual name and Social Security Number.

SAFEGUARDS:

All employees of the Department of State have undergone a thorough background security investigation. Access to the Department and its annexes are controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All records containing personal information are maintained in secured file cabinets or in restricted areas, access to which is limited to authorized personnel and contractors; and Federal Employees Education and Assistance Fund employees and contractors. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage.

RETENTION AND DISPOSAL:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with published record schedules of the Department of State and as approved by the National Archives and Records Administration. More specific information may be obtained by writing to the Director; Office of IRM Programs and Services; SA–2; Department of State; 515 22nd Street, NW; Washington, DC 20522–6001.

SYSTEM MANAGER AND ADDRESS:

The Director General of the Foreign Service and Director of Human Resources, Department of State; 2201 C Street, NW; Washington, DC 20520.

NOTIFICATION PROCEDURE:

Individuals who have reason to believe that the Bureau of Human Resources might have records pertaining to themselves should write to the Director; Office of IRM Programs and Services; SA–2; Department of State; 515 22nd Street, NW; Washington, DC 20522–6001. The individual must specify that he/she wishes the Child Care Subsidy Program Records to be checked. At a minimum, the individual should include: name; date and place of birth; current mailing address and zip code; signature; and preferably his/her Social Security Number; a brief description of the circumstances that caused the creation of the record, and the approximate dates which give the individual cause to believe that the Bureau of Human Resources has records pertaining to him/her.

RECORD ACCESS AND AMENDMENT PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Director, Office of IRM Programs and Services (address above).

RECORD SOURCE CATEGORIES:

Information is provided by Department of State employees who apply for child care subsidies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–26771 Filed 10–23–01; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2001–10862]

Towing Safety Advisory Committee

AGENCY: Coast Guard, DOT.

ACTION: Notice of public meeting.

SUMMARY: The License Implementation Working Group of the Towing Safety Advisory Committee (TSAC) will meet to discuss and develop the performance criteria to be used with the Towing Officer Assessment Record (TOAR). The meetings are open to the public.

DATES: The Working Group will meet on Wednesday, November 14, 2001, from 1 p.m. to 5 p.m., and on Thursday, November 15, 2001, from 8:30 a.m. to 3:30 p.m. These meetings may close early if all business is finished. Requests to make oral presentations should reach the Coast Guard on or before November 7, 2001.

ADDRESSES: The Working Group will meet in the 7th Floor, All-Hands Conference Room at Coast Guard's National Pollution Fund Center; 4200 Wilson Blvd.; Arlington, VA. Send written materials and requests to make oral presentations to Mr. Gerald P. Miante, Commandant (G–MSO–1); Room 1210, U.S. Coast Guard Headquarters; 2100 Second Street, SW; Washington, DC 20593–0001. This notice is available on the Internet at *http://dms.dot.gov.*

Security notice: All non-military/government participants MUST first go to the 10th floor and sign in with a photo ID (driver's license). You will then receive a 2-day pass for the meetings.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald P. Miante, Assistant Executive Director, TSAC, telephone 202–267–0229, fax 202–267–4570, or e-mail at: gmiante@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. The performance criteria to be discussed at this working group meeting, when developed, will be announced in the **Federal Register** and made available for review and comment. Sample TOARs were published on May 21, 2001, as part of the Navigation and Vessel Inspection Circular 4–01 (NVIC 4–01) entitled ''Licensing and Manning for Officers of Towing Vessels.'' This NVIC provides guidance on the implementation of a recent interim rule with request for comments published in the **Federal Register** on April 26, 2001 (66 FR 20931; Licensing and Manning for Officers of Towing Vessels, Docket Number: USCG 1999–6224). The NVIC is available on the Internet at *http://www.uscg.mil/hq/g-m/nvic/4–01/n4–01.pdf.* The rulemaking history is also available on the Internet at *http://dms.dot.gov* under the same Docket Number.

Agenda of Meeting

The agenda includes the Working Group's review of the TOARs and the drafting of performance criteria proposals that will be presented to the full Committee for approval at a later date.

Procedural

This meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Assistant Executive Director on or before November 7, 2001.

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 the Assistant Executive Director as soon as possible.

Dated: October 17, 2001.

Joseph J. Angelo,

Director of Standards, Marine Safety and Environmental Protection.

[FR Doc. 01–26815 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Camden and Gloucester Counties, NJ

AGENCY: Federal Highway Administration (FHWA), USDOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for improvements at the interchange of Routes I–295/I–76/NJ 42 in Camden and Gloucester Counties, to enhance the traffic flow within the interchange.

FOR FURTHER INFORMATION CONTACT: Lourdes Castaneda, Area Engineer, or Amy Fox, Environmental Coordinator, Federal Highway Administration, 840 Bear Tavern Road, Suite 310, West Trenton, NJ 08628.

SUPPLEMENTARY INFORMATION: Pursuant to title 23, Code of Federal Regulations, part 771, Environmental Impact Statement and Related Procedures, the FHWA, in cooperation with the New Jersey Department of Transportation (NJDOT), will prepare an environmental impact statement (EIS) in accordance with the National Environmental Policy Act (NEPA) for a proposal to improve the interchange of Routes I–295/I–76/NJ 42 in Camden and Gloucester Counties.

Improvements to the interchange are considered necessary to provide a safer and more efficient roadway. Several alternatives including a ''No-Build'' Alternative (continuation of the existing condition) will be analyzed.

Letters describing the action and soliciting comments will be sent to appropriate Federal, State, and Local

agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A series of public meetings will be held during the development of this document. Public notice will be given of the time and place of the meetings and hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing. A formal scoping meeting will be conducted.

To ensure that the full range of issues relating to this proposed action are addressed and all significant issues are identified, written comments, suggestions or questions should be directed to the FHWA at the address provided above or directed to: Mr. Andras Fekete, Manager, Bureau of Environmental Services, New Jersey Department of Transportation, 1035 Parkway Avenue, Trenton, NJ 08625–0600, telephone: (609) 530–2824.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding inter-governmental consultation on Federal programs and activities apply to this program)

Issued on: October 12, 2001.

Randell Prescott,

Program Operations Director, FHWA—New Jersey Division, Trenton.

[FR Doc. 01–26785 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: St. Louis County and the City of St. Louis, MO

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for proposed improvements to I–64 in St. Louis County and the City of St. Louis, Missouri.

FOR FURTHER INFORMATION CONTACT: Ms. Peggy Casey, Environmental Projects Engineer, FHWA Division Office, 209 Adams Street, Jefferson City, MO 65101, Telephone: (573) 638–2620 or Mr. Dave Nichols, Director of Project Development, Missouri Department of Transportation, P.O. Box 270, Jefferson City, MO 65102, Telephone: (573) 751–4586.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Missouri Department of Transportation (MoDOT), will prepare an EIS for a proposal to reconstruct the existing I–64 (U.S. Route 40) facility with new interchange configurations and appurtenant roadways/structures in St. Louis County and the City of St. Louis, Missouri. It is intended that the reconstructed facility will meet current standards. A location study will run concurrently with the preparation of the EIS and will provide definitive reasonable alternatives for evaluation in the EIS. The proposed action will accomplish several goals: (1) Replace the deteriorating facility and substandard interchanges, (2) improve safety (and capacity between Spoede Road and I–170), (3) improve operation and decrease congestion, and (4) promote community redevelopment.

The proposed project which includes work on I–170 from south of Brentwood Boulevard to I–64, begins west of Spoede Road in St. Louis County and continues easterly to west of Sarah Street in the City of St. Louis. The project is approximately 12 miles in length. Known potential impacts include residential and/or commercial relocations, acquisition of National Register of Historic Places-eligible properties, access changes, and likely impacts to parkland at the City of St. Louis' Forest Park and Richmond Heights' A.B. Green Athletic Field Complex, both eligible for protection under Section 4(f) of the Department of Transportation Act of 1966. A Department of the Army Section 404 permit and a floodplain development permit from the State Emergency Management Agency may be required.

Alternatives under consideration include (1) no build, (2) build alternatives, and (3) transportation system management options.

To date, substantial preliminary coordination has occurred with local officials and other interested parties. As part of the scoping process, an interagency coordination meeting will be held with all appropriate federal, state, and local agencies. In addition, public information meetings and further meetings with community officials will be held to solicit public and agency input on the reasonable range of alternatives. A location public hearing will be held to present the findings of the Draft EIS. Public notice will be given announcing the time and place of all public meetings and the public hearing. The Draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues are identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA or MoDOT at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: October 15, 2001.

Peggy J. Casey,

Environmental Projects Engineer, Jefferson City.

[FR Doc. 01–26722 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2001–10578]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption from the vision standard; request for comments.

SUMMARY: This notice announces the FMCSA's receipt of applications from 37 individuals for an exemption from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). If granted, the exemptions will enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the vision standard prescribed in 49 CFR 391.41(b)(10).

DATES: Comments must be received on or before November 23, 2001.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590, or submit electronically at *http://dmses.dot.gov/submit*. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard, or you may print the acknowledgment page that appears after submitting comments electronically.

FOR FURTHER INFORMATION CONTACT: For information about the vision exemptions in this notice, Ms. Sandra Zywokarte, Office of Bus and Truck Standards and Operations, (202) 366–2987; for information about legal issues related to this notice, Mr. Joseph Solomey, Office of the Chief Counsel, (202) 366–1374, FMCSA, Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may see all the comments online through the Document Management System (DMS) at: *http://dmses.dot.gov/submit*.

Background

Thirty-seven individuals have requested an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Under 49 U.S.C. 31315 and 31136(e), the FMCSA may grant an exemption for a renewable 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' Accordingly, the agency will evaluate the qualifications of each applicant to determine whether granting the exemptions will achieve the required level of safety.

Qualifications of Applicants

1. Loa M. Boggs

Mr. Boggs, age 50, has amblyopia of the left eye. His aided acuity is 20/20 with the right eye and 20/200 with the left. An optometrist who examined him in 2000 stated, ''In my opinion, he has sufficient vision to continue operating a commercial vehicle.'' Mr. Boggs submitted that he has driven straight trucks for 21 years, accumulating 577,000 miles. He holds a Class D driver's license from West Virginia. His driving record shows he has had no accidents or convictions for traffic violations in a CMV for the last 3 years.

2. Anthony Brandano

Mr. Brandano, 35, has amblyopia in his right eye. His corrected vision is 20/40-in the right eye and 20/20 in the left eye. Following an examination in 2001, his ophthalmologist concluded, ''It is my opinion patient has sufficient vision to drive a commercial vehicle.'' Mr. Brandano reported that he has operated straight trucks for 2 years, traveling 100,000 miles, and tractor-trailer combinations for 6 years, traveling 750,000 miles. He holds a Class A CDL from New York, and his driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

3. Jerald D. Davis

Mr. Davis, 58, is blind in the left eye due to trauma in 1959. His best-corrected visual acuity is 20/20 in the right eye. An ophthalmologist examined him in 2001 and affirmed, ''In my medical opinion he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Davis submitted that he has driven tractor-trailer combinations for 27 years, accumulating 4.0 million miles. He holds a Class A CDL from Texas. His driving record shows he has had no accidents and one conviction for a moving violation—Speeding—in a CMV during the last 3 years. He exceeded the speed limit by 13 mph.

4. Vernon J. Dohrn

Mr. Dohrn, 65, has amblyopia in his right eye. The corrected vision in his right eye is 20/80- and in the left eye, 20/20. His optometrist examined him in 2001 and certified, ''In my opinion, this patient can safely perform the visual tasks required to operate a commercial vehicle even with the vision deficiency in his right eye.'' Mr. Dohrn stated in his application that he has driven tractor-trailer combination vehicles for 31 years, accumulating 2.7 million miles, and straight trucks for 7 years, accumulating 280,000 miles. He holds a Minnesota Class A CDL. His driving record shows he has had no accidents and one conviction for a moving violation—Drive and/or Pass on Shoulder—in a CMV during the past 3 years.

5. Stanley E. Elliott

Mr. Elliott, 47, has amblyopia in his left eye. His corrected vision is 20/20 in the right eye and $20/70^{-2}$ in the left eye. Following an examination in 2001, his optometrist concluded, ''It is my opinion that Mr. Elliott can perform all driving tasks related to operating a commercial vehicle.'' According to Mr. Elliott's application, he has 4 years of experience driving straight trucks, totaling 150,000 miles, and 12½ years of experience driving tractor-trailers, totaling 312,500 miles. He holds a Utah Class A CDL and has had no accidents or moving violations in a CMV for the past 3 years, according to his driving record.

6. Elmer E. Gockley

Mr. Gockley, 56, has had a corneal scar in his right eye since age 6. His best-corrected visual acuity in the right eye is counting fingers at 2 feet and in the left eye 20/20. An ophthalmologist examined him in 2001 and certified, ''I verify that Mr. Gockley has sufficient vision to perform the driving tasks required to operate a commercial vehicle at this time.'' Mr. Gockley submitted that he has driven straight trucks for 11 years, traveling 220,000 miles, and tractor-trailer combinations for 40 years, traveling 4.2 million miles. He holds a Class A CDL from Pennsylvania, and his driving record for the past 3 years shows no accidents or convictions for moving violations in a CMV.

7. Paul C. Gruenberg

Mr. Gruenberg, 53, is blind in the left eye due to an injury at the age of 12. The corrected visual acuity in his right eye is 20/15. An ophthalmologist examined him in 2001 and stated, ''He should have no problem operating commercial vehicle(s).'' Mr. Gruenberg reported he has 3 years' and 240,000 miles' experience driving tractor-trailer combinations. He holds a Class A CDL from Florida, and his driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

8. Tommy D. Habben

Mr. Habben, 36, has amblyopia in his left eye. His corrected vision in the right eye is $20/25^{-2}$ and in the left, 20/100. An optometrist examined him in 2001 and certified, ''It is my opinion that Mr. Habben has sufficient vision to perform driving tasks required to operate a commercial vehicle.'' Mr. Habben reported that he has driven straight trucks for 15 years, accumulating 750,000 miles. He holds a Class D driver's license from Tennessee and has no accidents or convictions for moving violations in a CMV on his driving record during the last 3 years.

9. Glenn T. Hehner

Mr. Hehner, 53, had a perforation of his right eye in 1963. He has no light perception in the right eye and 20/20 vision, best-corrected, in the left eye. An ophthalmologist examined him in 2000 and certified, ''In my opinion he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Hehner reported that he has 13 years' experience driving straight trucks and has accumulated 1.3 million miles. He holds a Class DMB CDL from Kentucky, and there are no accidents or convictions for moving violations in a CMV on his record for the last 3 years.

10. Carl R. Hunt

Mr. Hunt, 64, has a right eye that is aphakic with a retinal detachment and scar formation. His corrected vision in the right eye is hand motion and in the left, 20/20. Following an examination in 2001, his ophthalmologist stated, ''I certify that it is my medical opinion that Carl R. Hunt has sufficient vision to perform driving tasks required to operate a commercial vehicle since his left eye is in excellent visual shape.'' In his application, Mr. Hunt indicated he has driven straight trucks for 47 years, accumulating 1.4 million miles. He holds a Class E license from the State of Missouri, and his driving record shows he has had no accidents or convictions for moving violations in a CMV during the last 3 years.

11. Shane M. Hunter

Mr. Hunter, 29, has amblyopia in his right eye. His best-corrected visual acuities are 20/60 in the right eye and 20/20 in the left. Following an examination in 2001, his optometrist stated, ''In my opinion, Shane has sufficient vision to operate a commercial vehicle as long as he is wearing glasses or contact lenses to give him optimum driving efficiency.'' In his application, Mr. Hunter indicated he has driven straight trucks for 3 years, accumulating 78,000 miles. He holds an Operator's license from the State of Washington, and his driving record shows he has had no accidents or convictions for moving violations in a CMV during the last 3 years.

12. Thomas M. Ingebretsen

Mr. Ingebretsen, 45, has retinal scars in his left eye due to toxoplasmosis at age 3. His best-corrected visual acuity is 20/20 in the right eye and 20/60 in the left. Following an examination in 2001, his ophthalmologist stated, ''I reiterate my statement on my last letter to you that Mr. Ingebretsen has sufficient vision to operate a commercial vehicle according to the guidelines you have submitted to me.'' Mr. Ingebretsen reported that he has 18 years' experience driving straight trucks, accumulating 409,000 miles, and 12 years' experience driving tractor-trailer combinations, accumulating 420,000 miles. He holds a Class A CDL from California, and his driving record shows he has had no accidents or convictions for moving violations in a CMV over the last 3 years.

13. Lonnie M. Jones

Mr. Jones, 50, is blind in his right eye due to a childhood injury. His best-corrected visual acuity is 20/20 in the left eye. An ophthalmologist examined him in 2001 and affirmed, ''In my medical opinion, this patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Jones submitted that he has driven tractor-trailer combinations for 27 years and straight trucks for 2 years, accumulating 3.2 million miles and 6,000 miles, respectively. He holds a Class A CDL from Georgia. His driving record shows that he has had no accidents and one conviction for a moving violation—Speeding—in a CMV during the last 3 years. He exceeded the speed limit by 17 mph.

14. Martin D. Keough

Mr. Keough, 52, has 20/400 vision in his left eye from an injury over 40 years ago. The visual acuity in his right eye is $20/20^{+}$. An optometrist examined him in 2001 and stated, ''In my professional opinion this patient can drive a motor vehicle and operate a commercial vehicle safely.'' Mr. Keough submitted that he has driven straight trucks and tractor-trailer combinations for 25 years, accumulating 250,000 miles in the former and 125,000 miles in the latter. He holds a Class AM CDL from New York, and his driving record for the last 3 years shows no accidents or convictions for traffic violations in a CMV.

15. Ricky J. Knutson

Mr. Knutson, 46, had his left eye enucleated in 1990 due to a choroidal melanoma. The visual acuity in his right eye is 20/20 with correction. His optometrist examined him in 2001 and certified, ''Rick has sufficient vision to perform any driving tasks to safely operate a commercial vehicle.'' In his application, Mr. Knutson indicated he has driven straight trucks for 13 years, accumulating 195,000 miles, and tractor-trailer combinations for 5 years, accumulating 225,000 miles. He holds a Class A CDL from Minnesota, and his driving record for the past 3 years shows he has had no accidents or convictions for traffic violations in a CMV.

16. Randall B. Laminack

Mr. Laminack, 43, has amblyopia in his right eye. His best-corrected visual acuities are 20/200 in the right eye and 20/20 in the left eye. Following a 2001 examination, his optometrist stated, ''In my medical opinion, Randy has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' According to his application, Mr. Laminack has operated tractor-trailer combinations for 20 years and 2.0 million miles, and straight trucks for 5 years and 500,000 miles. He holds a Class A CDL from Texas, and he has had no accidents or convictions for moving violations in a CMV during the last 3 years.

17. Norman R. Lamy

Mr. Lamy, 49, has amblyopia in his left eye. His best-corrected visual acuity is 20/15 in the right eye and 20/70 in the left eye. An optometrist examined him in 2001 and certified, ''Central and peripheral field results are sufficient for driving tasks required to operate a commercial vehicle.'' Mr. Lamy submitted that he has driven straight trucks for 13 years, accumulating 377,000 miles. He holds a Class B CDL from Massachusetts. His driving record for the last 3 years shows no accidents or convictions for traffic violations in a CMV.

18. James A. Lenhart

Mr. Lenhart, 46, has amblyopia in his right eye. His best-corrected visual acuities are 20/70 in his right eye and 20/20 in his left eye. Following a 2001 examination, his ophthalmologist noted, ''It is my medical opinion that Mr. James Lenhart has sufficient vision to perform driving tasks required to operate a commercial vehicle.'' According to Mr. Lenhart, he has operated straight trucks for 20 years, accumulating 2.0 million miles, and tractor-trailer combinations for 5 years, accumulating 625,000 miles. He holds a West Virginia Class A CDL, and he has no accidents or convictions for moving violations on his driving record for the last 3 years.

19. Dennis L. Lockhart, Sr.

Mr. Lockhart, 55, has amblyopia in his left eye. His corrected vision in the right eye is 20/20 and in the left, 20/400. An optometrist examined him in 2001 and certified, ''His condition is congenital and stable, and should not interfere with operating a commercial vehicle.'' Mr. Lockhart submitted that he has driven tractor-trailer combinations for 15 years traveling 750,000 miles and straight trucks for 7 years traveling 490,000 miles. He holds a Class A CDL from Virginia, and his driving record for the past 3 years shows no accidents or convictions for moving violations in a CMV.

20. Jerry J. Lord

Mr. Lord, 49, has amblyopia in his right eye. His best-corrected visual acuity is 20/25 in the left eye and counting fingers in the right eye. Mr. Lord was examined in 2001 and his ophthalmologist stated, ''I certify that in my medical opinion, Mr. Lord has sufficient vision to perform the driving tasks required to operate a commercial

vehicle.'' Mr. Lord submitted that he has driven straight trucks for 33 years, accumulating 3.3 million miles. He holds a Maryland Class BM CDL, and his driving record for the last 3 years contains no accidents or convictions for moving violations in a CMV.

21. Raymond P. Madron

Mr. Madron, 50, has had scarring of his right eye since birth due to toxoplasmosis. His vision in the right eye is $20/200^{-1}$, not correctable, and in the left eye, 20/20 without correction. Following an examination in 2001, his optometrist affirmed, ''Raymond Madron is able to see to operate a commercial vehicle without a vision correction.'' Mr. Madron holds a Class AM CDL from Maryland and reported that he has driven straight trucks for 7 years, accumulating 105,000 miles, and tractor-trailer combinations for 21 years, accumulating 630,000 miles. His driving record shows no accidents or convictions for moving violations in a CMV for the past 3 years.

22. Ronald S. Mallory

Mr. Mallory, 45, has amblyopia in his left eye. His visual acuity is 20/20+ in the right eye without correction and 20/400 in the left eye, not correctable. An optometrist examined him in 2001 and certified, ''He has sufficient vision required to perform driving tasks with a commercial vehicle.'' Mr. Mallory, who holds a Class A CDL from Oklahoma, reported that he has been driving straight trucks and tractor-trailer combinations for 25 years, accumulating 625,000 miles in the former and 125,000 in the latter. His driving record shows he has had no accidents or convictions for traffic violations in a CMV during the last 3 years.

23. Keith G. McCully

Mr. McCully, 62, has amblyopia in his right eye. His best-corrected visual acuity is 20/200 in the right eye and $20/20^{+}$ in the left eye. Following an examination in 2000, his optometrist certified, ''He does have sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. McCully submitted that he has driven tractor-trailer combinations for 40 years, accumulating 3.2 million miles. He holds a Class A CDL from Montana. His driving record for the last 3 years shows no accidents or convictions for traffic violations in a CMV.

24. Ernest L. McLendon

Mr. McLendon, 51, lost light perception in his right eye in 1985 due to glaucoma. The visual acuity in his left eye is 20/20, best-corrected. An optometrist examined him in 2001 and certified, ''He has sufficient vision to operate a commercial vehicle with no medical condition that would compromise his visual field OS [left].'' Mr. McLendon submitted that he has driven tractor-trailer combinations for 23 years, traveling 2.7 million miles, and straight trucks for 6 years, traveling 480,000 miles. He holds a Class A CDL from Florida, and his driving record for the past 3 years shows no accidents or convictions for moving violations in a CMV.

25. Charles J. Morman

Mr. Morman, 48, has had a chorioretinal lesion of the right eye since birth. His aided visual acuity is 20/400 with the right eye and 20/20 with the left. An optometrist who examined him in 2001 stated, ''In my opinion, Mr. Morman has sufficient vision to operate a commercial motor vehicle.'' Mr. Morman reported that he has 5 years' experience driving straight trucks, accumulating 250,000 miles, and 20 years' experience driving tractor-trailer combinations, accumulating 1.2 million miles. He holds a Class A CDL from Florida, and his driving record shows he has had no accidents or convictions for moving violations in a CMV over the last 3 years.

26. Eugene C. Murphy

Mr. Murphy, 47, has chorioretinal scarring and a retinal detachment in the right eye due to an injury at age 13. His best-corrected visual acuity in the right eye is hand motion at one foot and in the left 20/20. Following an examination in 2001, his ophthalmologist commented, ''In my medical opinion, Mr. Murphy has significant binocular visual acuity as well as horizontal visual field to meet the requirements to operate a commercial vehicle.'' Mr. Murphy indicated he has driven straight trucks for 20 years and 910,000 miles. He holds a Class B CDL from Maine, and his driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

27. Jack E. Potts, Jr.

Mr. Potts, 28, has amblyopia of the left eye. His best-corrected visual acuities are 20/20 in the right eye and 20/200 in the left eye. In 2001 his optometrist examined him and affirmed, ''Upon completion of Jack's most recent visual examination, I have determined that he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Potts submitted that he has 6 years of experience driving straight trucks for 165,000 miles. He holds a Class C license from Pennsylvania, and his driving record for the last 3 years has no accidents or convictions for a moving violation in a CMV.

28. Bernard A. Ranly

Mr. Ranly, 50, has amblyopia of the left eye. The visual acuity of his right eye is 20/20 uncorrected and of the left eye 20/50 corrected. His optometrist examined him in 2001 and certified, ''It is my opinion, since this is a long-term condition, that Mr. Ranly has adapted very well and that Mr. Ranly has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Ranly reported that he has driven tractor-trailer combinations for 29 years, accumulating 3.1 million miles. He holds a Class AM CDL from Texas, and his driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

29. John E. Rogstad

Mr. Rogstad, 50, has amblyopia of the left eye. His aided acuity is 20/20 with the right eye and 20/200 with the left eye. An optometrist who examined him in 2001 stated, ''It is my opinion that Mr. Rogstad has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Rogstad reported that he has driven straight trucks for 30 years, accumulating 360,000 miles. He holds a Class ABCD CDL from Wisconsin, and his driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

30. Jerry W. Russell

Mr. Russell, 55, has had a cataract in his right eye since birth. His vision is light perception only in the right eye and 20/20 in the left eye. His optometrist examined him in 2001 and certified, ''Because Mr. Russell's condition has been present since birth, there is no risks of further changes, and he is safe to perform the task of driving a commercial vehicle.'' Mr. Russell reported that he has driven straight trucks for 7 years, accumulating 218,400 miles. He holds a Class D license from Kentucky. His driving record for the last 3 years shows no accidents and no convictions for moving violations in a CMV.

31. Stephen G. Sniffin

Mr. Sniffin, 52, has amblyopia in his left eye. His best-corrected visual acuity is 20/20 in the right eye and 20/400 in the left. His ophthalmologist examined him in 2000 and noted, ''Patient has

sufficient vision to operate a commercial vehicle.'' Mr. Sniffin submitted that he has driven straight trucks for 32 years, accumulating 1.3 million miles, and buses for 4 years, accumulating 40,000 miles. He holds a Class A CDL, and his driving record shows he has had no accidents or convictions for moving violations in a CMV in the last 3 years.

32. John R. Snyder

Mr. Snyder, 31, has amblyopia in his right eye. His best-corrected vision is 20/80 in the right eye and 20/20 in the left. An ophthalmologist examined him in 2000 and certified, ''It is my opinion that Mr. John Snyder has sufficient vision to perform any driving task required to operate a commercial vehicle.'' Mr. Snyder reported that he has operated tractor-trailer combinations for 8 years and 560,000 miles, and straight trucks for 13 years and 65,000 miles. He holds a Class A license from the State of Washington. His driving record for the last 3 years shows he has had no accidents and one conviction for a moving violation—Failure to Yield Right of Way to Emergency Vehicle—in a CMV.

33. Darwin J. Thomas

Mr. Thomas, 52, has amblyopia in his left eye. His best-corrected visual acuities are 20/25 in the right eye and 20/200 in the left. Following an examination in 2001, his optometrist certified, ''In my medical opinion, Mr. Thomas has sufficient vision to continue to drive his commercial vehicle.'' Mr. Thomas submitted that he has 17 years' and 2.0 million miles' experience operating tractor-trailer combinations, and 2 years' and 12,000 miles' experience operating straight trucks. He holds a Class A CDL from Pennsylvania, and his driving record shows he has had no accidents or convictions for moving violations in a CMV for the last 3 years.

34. Rene R. Trachsel

Mr. Trachsel, 43, has had a macular scar in his left eye since January 1994. The vision in his right eye is 20/20 and in the left eye, 20/200. Following an examination in 2001, his ophthalmologist certified, ''In my opinion, his vision is adequate to perform all tasks required to operate a commercial vehicle, as for practical purposes his central vision is 20/20 by a virtue of the central vision in the right eye, and his peripheral vision is entirely unaffected.'' In his application, Mr. Trachsel stated he has driven tractor-trailer combinations for 15 years, accumulating 122,850 miles. He holds an Oregon Class A CDL. His official driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

35. Stephen D. Vice

Mr. Vice, 46, has amblyopia in his right eye. His best-corrected visual acuities are $20/70^{-1}$ in the right eye and 20/20 in the left. An optometrist examined him in 2001 and certified, ''In my personal opinion, Mr. Vice's vision is adequate to operate a commercial vehicle.'' Mr. Vice submitted that he has driven buses for 4 years, accumulating 35,000 miles, and straight trucks for 2 years, accumulating 20,000 miles. He holds a Class DB Operator/CDL from Kentucky, and his driving record for the last 3 years shows he has had no accidents or convictions for moving violations in a CMV.

36. John H. Voigts

Mr. Voigts, 49, has had a corneal opacity in his left eye since birth. The corrected vision in his right eye is 20/20 and in the left eye, light perception only. Following an examination in 2001, his optometrist certified, ''I feel there is no reason why he cannot continue to drive commercial because of his vision.'' According to his application, Mr. Voigts has operated straight trucks for 30 years, accumulating 2.2 million miles, and tractor-trailer combinations for 27 years, accumulating 2.7 million miles. He holds a Class A CDL from Arizona. His official driving record for the last 3 years shows no accidents or convictions for moving violations in a CMV.

37. Kendle F. Waggle, Jr.

Mr. Waggle, 38, has been aphakic in his right eye since birth. His aided acuity is 20/150 with the right eye and 20/20 with the left eye. An optometrist who examined him in 2001 stated, ''In my medical opinion, since he has driven a commercial vehicle with this vision condition for many years, I feel he has sufficient vision to perform the driving tasks required to operate a commercial vehicle as he has in the past.'' Mr. Waggle submitted that he has driven straight trucks and tractor-trailer combinations for 15 years, accumulating 150,000 miles in the former and 772,500 miles in the latter. He holds a Class A CDL from Indiana, and his driving record for the last 3 years shows no accidents or convictions for traffic violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), the FMCSA is requesting public comment from all interested persons on the exemption petitions and the matters discussed in this notice. All comments received before the close of business on the closing date indicated above will be considered and will be available for examination in the docket room at the above address. Comments received after the closing date will be filed in the docket and will be considered to the extent practicable, but the FMCSA may publish in the **Federal Register** a notice of final determination at any time after the close of the comment period.

Issued on: October 19, 2001.

Brian M. McLaughlin,

Associate Administrator for Policy and Program Development.

[FR Doc. 01–26810 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Motor Theft Prevention Standard; Nissan

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

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the petition of Nissan North America, Inc., (Nissan) for an exemption of a high-theft line (codenamed ''Model M'') from the parts-marking requirements of the Federal motor vehicle theft prevention standard. This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard. Nissan requested confidential treatment for its information and attachments submitted in support of its petition. The agency will address Nissan's request for confidential treatment in a separate letter.

DATES: The exemption granted by this notice is effective beginning with the (confidential) model year.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalind Proctor, Office of Planning and Consumer Programs, NHTSA, 400 Seventh Street, SW, Washington DC 20590. Ms. Proctor's phone number is (202) 366–0846. Her fax number is (202) 493–2290.

SUPPLEMENTARY INFORMATION: In a petition dated June 21, 2001, Nissan North America, Inc. (Nissan), requested exemption from the parts-marking requirements of the theft prevention standard for a motor vehicle line. The nameplate of the line and the model year of introduction are confidential. The petition requested an exemption from parts-marking pursuant to 49 CFR 543, Exemption from Vehicle Theft Prevention Standard, based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Based on the evidence submitted by Nissan, the agency believes that the antitheft device for the Nissan ''Model M'' vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard (49 CFR part 541).

Section 33106(b)(2)(D) of title 49, United States Code, authorized the Secretary of Transportation to grant an exemption from the parts-marking requirements for not more than one additional line of a manufacturer for MYs 1997–2000. However, it does not address the contingency of what to do after model year 2000 in the absence of a decision under Section 33103(d). 49 U.S.C. 33103(d)(3) states that the number of lines for which the agency can grant an exemption is to be decided after the Attorney General completes a review of the effectiveness of antitheft devices and finds that antitheft devices are an effective substitute for parts-marking. The Attorney General has not yet made a finding and has not decided the number of lines, if any, for which the agency will be authorized to grant an exemption. Upon consultation with the Department of Justice, we determined that the appropriate reading of Section 33103(d) is that the National Highway Traffic Safety Administration (NHTSA) may continue to grant parts-marking exemptions for not more than one additional model line each year, as specified for model years 1997–2000 by 49 U.S.C. 33106(b)(2)(C). This is the level contemplated by the Act for the period before the Attorney General's decision. The final decision on whether to continue granting exemptions will be made by the Attorney General at the conclusion of the review pursuant to Section 330103(d)(3).

Nissan's submittal is considered a complete petition, as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6. Nissan requested confidential treatment for the information submitted in support of its petition. The agency will address Nissan's request for confidential treatment in a separate letter.

In its petition, Nissan provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the new line. This antitheft device includes an engine-immobilizer and alarm system. The antitheft device is a passive system, and is activated by turning the ignition switch to the ''OFF'' position using the proper ignition key.

In order to ensure the reliability and durability of the device, Nissan conducted tests based on its own specified standards. Nissan provided a detailed list of tests conducted and believes that its device is reliable and durable since the device complied with its specified requirements for each test.

Nissan compared the device proposed for its vehicle line with devices which NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements. Nissan stated that its proposed device is functionally equivalent to the systems used in previous vehicle lines which were deemed effective and granted exemptions from the parts-marking requirements of the theft prevention standard. Additionally, theft data have indicated a decline in theft rates for vehicle lines that have been equipped with antitheft devices similar to that which Nissan proposes to install on the new line.

On the basis of this comparison, Nissan has concluded that the proposed antitheft device is no less effective than those devices installed on lines for which NHTSA has already granted full exemption from the parts-marking requirements.

Based on the evidence submitted by Nissan, the agency believes that the antitheft device for the Nissan vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR 541).

The agency concludes that the device will provide five of the types of performance listed in § 543.6(a)(3): Promoting activation; attracting attention to the efforts of unauthorized persons; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

As required by 49 U.S.C. 33106 and 49 CFR part 543.6(a)(4) and (5), the agency finds that Nissan has provided adequate reasons for its belief that the antitheft device will reduce and deter theft. This conclusion is based on the information Nissan provided about its device, much of which is confidential. This confidential information included a description of reliability and functional tests conducted by Nissan for the antitheft device and its components.

For the foregoing reasons, the agency hereby grants in full Nissan's petition for exemption for its vehicle line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. Advanced listing, including the release of future product nameplates, is necessary in order to notify law enforcement agencies of new models exempted from the parts-marking requirements of the Theft Prevention Standard. Therefore, since Nissan has been granted confidential treatment for its vehicle line, the confidential status of the vehicle line will be protected until the introduction of its vehicle line into the market place. At that time, Appendix A–1 will be revised to reflect the nameplate of Nissan's exempted vehicle line.

If Nissan decides not to use the exemption for this line, it should formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Nissan wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, part 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes the effects of which

might be characterized as *de minimis*, it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: October 18, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–26811 Filed 10–23–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

October 18, 2001.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before November 23, 2001 to be assured of consideration.

Financial Management Service (FMS)

OMB Number: 1510–0034.

Form Number: POD 315.

Type of Review: Extension.

Title: Depositor's Application to Withdraw Postal Savings.

Description: This form is prepared by the applicant for payment of a Postal Savings Account. This form is used to identify the depositor and ensure that payment is made to the proper person. POD form was formerly used by the Post Office Department for processing payments when payments of accounts were their responsibility.

Respondents: Individuals or households.

Estimated Number of Respondents: 700.

Estimated Burden Hours Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 350 hours.

Clearance Officer: Juanita Holder, Financial Management Service, 3700 East West Highway, Room 144, PGP II, Hyattsville, MD 20782

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 01–26804 Filed 10–23–01; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

October 16, 2001.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before November 23, 2001 to be assured of consideration.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0337.

Recordkeeping Requirement ID Number: ATF REC 5150/1.

Type of Review: Extension.

Title: Usual and Customary Business Records Relating to Denatured Spirits.

Description: Denatured Spirits are used for nonbeverage industrial purposes in the manufacture of personal household products. Records ensure spirits accountability. Tax revenue and public safety are protected.

Respondents: Business or other for-profit, State, Local or Tribal Government.

Estimated Number of Recordkeepers: 3,111.

Estimated Burden Hours Per Recordkeeper: 0.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 1 hour.

OMB Number: 1512–0363.

Recordkeeping Requirement ID Number: ATF REC 5210/6.

Type of Review: Extension.

Title: Tobacco Products Manufacturers—Supporting Records for Removals for the Use of the United States.

Description: Used by tobacco products manufacturers to record removals of tobacco products for use of the United States. Used by ATF to verify that removals were tax exempt. Needed to trace transactions for protection of the revenue.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 101.

Estimated Burden Hours Per Recordkeeper: 5 hours.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 505 hours.

OMB Number: 1512–0373.

Recordkeeping Requirement ID Number: ATF REC 5400/3.

Type of Review: Extension.

Title: RECORDS AND SUPPORTING DATA: Importation, Receipt, Storage, and Disposition by Licensed Explosives Manufacturers, Importers, Dealers, and Users.

Description: These records show daily activities in the importation, manufacture, receipt, storage, and disposition of all explosive materials covered under 18 U.S.C. Chapter 40. The records are used to show where and to whom explosives materials are sent, thereby ensuring that any diversions will be readily apparent and, if lost or stolen, ATF will be immediately notified.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 10,519.

Estimated Burden Hours Per Respondent: 6 minutes.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 132,754 hours.

OMB Number: 1512–0391.

Recordkeeping Requirement ID Number: ATF REC 5210/10.

Type of Review: Extension.

Title: Tobacco—Record of Disposition of More than 60,000 Cigarettes in a Single Transaction.

Description: Records must be maintained by tobacco products manufacturers and cigarette distributors showing details of large cigarette transactions. The records are also used to trace the movement of contraband cigarettes and helps curtail the illicit traffic in cigarettes between states.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 9,500.

Estimated Burden Hours Per Recordkeeper: 120 hours.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 1,140,000 hours.

Clearance Officer: Frank Bowers (202) 927–8930, Bureau of Alcohol,

Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, NW, Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–26805 Filed 10–23–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

October 16, 2001.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before November 23, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1752.

Revenue Procedure Number: Revenue Procedure 2001–42.

Type of Review: Extension.

Title: Modified Endowment Contract Correction Program Extension.

Description: This revenue procedure allows issuers (life insurance companies) to remedy inadvertent non-egregious failures to comply with the modified endowment rules set forth in section 7702A of the Internal Revenue Code.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Burden Hours Per Respondent: 100 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 1,000 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–26806 Filed 10–23–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Advisory Group to the Internal Revenue Service; Meeting

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: The Information Reporting Program Advisory Committee (IRPAC) will hold a public meeting on Thursday, November 1, 2001.

FOR FURTHER INFORMATION CONTACT: Lorenza Wilds, Office of National Public Liaison, CL:NPL:PAC, Room 7565 IR, 1111 Constitution Avenue, NW., Washington, DC 20224. Telephone: 202–622–6440 (not a toll-free number). E-mail address: *public__liaison@irs.gov.*

SUPPLEMENTARY INFORMATION: By notice herein given, pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), a public meeting of the IRPAC will be held on Thursday, November 1, 2001, from 9 a.m. to 4 p.m. in Room 3313, main Internal Revenue Service building, 1111 Constitution Avenue, NW., Washington, DC 20224. Issues to be discussed include: TIN matching system/automatic penalty waiver; questionable W–4s; gross proceeds on periodic payment of principal on debt obligation; affiliate taxpayer sharing W–8/W–9; enforcement of social security card presentation; recommendations to reporting requirements for SEP/SARSEP plans; uniformity of payees copy of schedule K–1 (Form 1065); and attorney reporting regulations. Reports from the four IRPAC sub-groups, Wage & Investment/Small Business/Self Employed, Large and Mid-Size Business, Tax Exempt and Government Entities and Multi-Interest will also be presented and discussed. Last minute agenda changes may preclude advance notice. The meeting room accommodates approximately 50 people, IRPAC members and Internal Revenue Service officials inclusive. Due to limited seating and security requirements, please call Lorenza Wilds to confirm your attendance. Ms. Wilds can be reached at (202) 622–6440. Attendees are encouraged to arrive at least 30 minutes before the meeting begins to allow sufficient time for purposes of security clearance. Please use the main entrance at 1111 Constitution Avenue to enter the building.

Should you wish the IRPAC to consider a written statement, please call (202) 622–6440, or write to: Internal Revenue Service, Office of National Public Liaison, CL:NPL:PAC, 1111 Constitution Avenue, NW., Room 7565 IR, Washington, DC 20224, or e-mail: *public__liaison@irs.gov.*

Dated: October 16, 2001.

Nancy A. Thoma,

Designated Federal Official, Acting Director, National Public Liaison.

[FR Doc. 01–26807 Filed 10–23–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Notice of Open Meeting

ACTION: Notice.

SUMMARY: An open meeting of the Pacific-Northwest Citizen Advocacy Panel will be held in Seattle, Washington.

DATES: The meetings will be held Friday November 16, 2001 and Saturday November 17, 2001.

FOR FURTHER INFORMATION CONTACT: Judi L. Nicholas at 1–888–912–1227 or 206–220–6096.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Citizen Advocacy Panel will be held Friday November 16, 2001, from 9 a.m. to 4:30 p.m. at the Jackson Federal Building located at 915 Second Avenue, Room 3442, Seattle, WA, 98714; Saturday, November 17, 2001, from 9 a.m. to Noon at the Port of Seattle, Pier 69 Commission Chambers located at 2711 Alaskan Way, Seattle, Washington.

The public is invited to make oral comments. Individual comments will be limited to 10 minutes. If you would like to have the CAP consider a written statement, please call 1–888–912–1227 or 206–220–6096, or write Judi L. Nicholas, CAP Office, 915 2nd Avenue, Room 442, Seattle, WA 98174. Due to limited conference space, notification of intent to attend the meeting must be made with Judi L. Nicholas. Ms. Nicholas can be reached at 1–888–912–1227 or 206–220–6096.

The Agenda will include the following: various IRS issue updates and reports by the CAP sub-groups.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: October 1, 2001.

Cindy Vanderpool,

Director, CAP, Communications and Liaison.

[FR Doc. 01–26808 Filed 10–23–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of The Florida Citizen Advocacy Panel

ACTION: Notice.

SUMMARY: An open meeting of the Florida Citizen Advocacy Panel will be held in Sunrise CAP Office, Florida.

DATES: The meeting will be held Friday, November 16, 2001, and Saturday, November 17, 2001.

FURTHER INFORMATION CONTACT: Nancy Ferree at 1–888–912–1227, or 954–423–7973.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Citizen Advocacy Panel will be held Friday, November 16, 2001, from 6 p.m. to 9 p.m. and Saturday, November 17, 2001, from 9 a.m. to 12 p.m, at Sunrise CAP Office, 7771 W Oakland Park Boulevard Suite 225, Sunrise, Florida 33351. The public is invited to make oral comments. Individual comments will be limited to 10 minutes. If you would like to have the CAP consider a written statement, please call 1–888–912–1227 or 954–423–7973, or write Nancy Ferree, CAP Office, 7771 W. Oakland Park Blvd. Rm. 225, Sunrise, FL 33351, or e-mail *firstcapsfl@mindspring.com.* Due to limited conference space, notification of intent to attend the meeting must be made with Nancy Ferree. Ms. Ferree can be reached at 1–888–912–1227 or 954–423–7973, or e-mail *firstcapsfl@mindspring.com.*

The agenda will include the following: various IRS issue updates and reports by the CAP sub-groups.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: October 17, 2001.

Cindy Vanderpool,

Director, CAP, Communications and Liaison.

[FR Doc. 01–26809 Filed 10–23–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and continuing information collections, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3507. The Office of Thrift Supervision within the Department of the Treasury will submit the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. Today, OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before December 24, 2001.

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552; send a facsimile transmission to (202) 906–6518; or send an e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS Internet Site at *www.ots.gov.* In addition, interested persons may inspect comments at the Public Reference Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *publicinfo@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: You can request additional information about this proposed information collection from Deborah Goddard, Program Analyst (Compliance), Compliance Policy and Specialty Examinations, (202) 906–6438, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Comments should address one or more of the following points:

a. Whether the proposed collection of information is necessary for the proper performance of the functions of OTS;

b. The accuracy of OTS's estimate of the burden of the proposed information collection;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collection on respondents, including through the use information technology.

We will summarize the comments that we receive and include them in the OTS request for OMB approval. All comments will become a matter of public record. In this notice, OTS is soliciting comments concerning the following information collection.

Title of Proposal: Loans in Areas Having Special Flood Hazards.

OMB Number: 1550–0088.

Form Number: N/A.

Regulation requirement: 12 CFR 572.

Description: Lending institutions are required by statute and OTS regulations to use the standard flood hazard determination form developed by FEMA when determining whether property securing the loan is or will be located in a special flood hazard and is required to retain a copy of the completed form.

Type of Review: Renewal.

Affected Public: Savings Associations and Savings Banks.

Estimated Number of Respondents: 1,035.

Estimated Frequency of Response: Annually.

Estimated Burden Hours per Response: .25 hours.

Estimated Total Burden: 27,168.75 hours.

Clearance Officer: Sally W. Watts, (202) 906–7380, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

OMB Reviewer: Alexander Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: October 18, 2001.

Deborah Dakin,

Deputy Chief Counsel, Regulations and Legislation Division.

[FR Doc. 01–26735 Filed 10–23–01; 8:45 am]

BILLING CODE 6720–01–P

Federal Register

Wednesday,
October 24, 2001

Part II

Department of Health and Human Services

Food and Drug Administration

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under 21 CFR 10.115(n)(2) of FDA's regulation on Good Guidance Practices (GGPs). This list is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

DATES: We welcome general comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov.dockets/ecomments. We have provided information in the tables below on where to obtain a single copy of any of the guidance documents listed.

FOR FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Office of Policy, Planning, and Legislation (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

We published our final rule on GGPs in the **Federal Register** of September 19, 2000 (65 FR 56468), and they became effective October 19, 2000. GGPs are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance. We committed in the GGPs to publishing annually a comprehensive list of guidance documents. This list updates a comprehensive list published July 21, 2000 (65 FR 45428).

The following comprehensive list identifies all final guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn this year are also listed. We have organized the documents by the issuing Center or Office within FDA, and we have identified the pertinent intended users or regulatory activities. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide information on the tables below.

The following most frequently used Internet sites for agency guidances are provided for future reference:

CBER: http://www.fda.gov/cber/guidelines.htm

CDER: http://www.fda.gov/cder/guidance/index.htm

CDRH: http://www.fda.gov/cdrh/guidance.html

CFSAN: http://www.cfsan.fda.gov/dms/guidance.html

CVM: http://www.fda.gov/cvm/guidance/published.htm#documents

ORA: http://www.fda.gov/ora/compliance—;ref

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Interpretative Guidelines of the Source Plasma (Human) Standards	October 2, 1973	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Guidelines for Reviewing Amendments to Include Plasmapheresis of Hemophiliacs	July 20, 1976	Do	Do
Package Insert: Immune Serum Globulin (Human)	March 30, 1978	Do	Do
Guidelines for Interpretation of Potency Test Results for All Forms of Adsorbed Diphtheria and Tetanus Toxoids	April 12, 1979	Do	Do
Guidelines for Immunization of Source Plasma (Human) Donors With Blood Substances	June 1, 1980	Do	Do
Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes)	January 28, 1981	Do	Do
Platelet Testing Guidelines—Approval of New Procedures and Equipment	July 1, 1981	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Revised Guideline for Adding Heparin to Empty Containers for Collection of Heparinized Source Plasma (Human)	August 1, 1981	Do	Do
Requirements for Infrequent Plasmapheresis Donors	August 27, 1982	Do	Do
Recommendations to Decrease the Risk of Transmitting AIDS From Plasma Donors	March 24, 1983	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products Subject to Licensure	June 20, 1983	Do	Do
Draft PTC in the Production and Testing of Interferon Intended for Investigational Use in Humans (Interferon Test Procedures)	July 28, 1983	Do	Do
Interstate Shipment of Interferon for Investigational Use in Laboratory Research Animals or Tests in Vitro	November 21, 1983	Do	Do
Deferral of Blood Donors Who Have Received the Drug Accutane (Isotretinoin/Roche); 13-cis-retinoic acid)	February 28, 1984	Do	Do
Equivalent Methods for Compatibility Testing	December 14, 1984	Do	Do
Plasma Derived From Therapeutic Plasma Exchange	December 14, 1984	Do	Do
Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology	April 10, 1985	Do	Do
Guidelines for Meningococcal Polysaccharide Vaccines	July 17, 1985	Do	Do
Guideline for the Uniform Labeling of Blood and Blood Components	August 1, 1985	Do	Do
Recommended Methods for Short Ragweed Pollen Extracts	November 1, 1985	Do	Do
Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container	June 2, 1986	Do	Do
To In Vitro Diagnostic Reagent Manufacturers: Guidance on the Labeling of Human Blood Derived in Vitro Diagnostic Devices in Regard to Labeling for HTLV–III/LAV Antibody Testing	December 6, 1986	Do	Do
Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline on General Principles of Process Validation	May 1, 1987	Do	Do
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone	November 25, 1987	Do	Do
Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1, 1987	Do	Do
Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)	December 2, 1987	Do	Do
Extension of Dating Period for Storage of Red Blood Cells, Frozen	December 4, 1987	Do	Do
To Licensed In Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials	December 23, 1987	Do	Do
Recommendations for Implementation of Computerization in Blood Establishments	April 6, 1988	Do	Do
Control of Unsuitable Blood and Blood Components	April 6, 1988	Do	Do
Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines	July 7, 1988	Do	Do
Physician Substitutes	August 15, 1988	Do	Do
To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release	August 26, 1988	Do	Do
Revised Guideline for the Collection of Platelets, Pheresis	October 7, 1988	Do	Do
To Manufacturers of HTLV–I Antibody Test Kits: Antibody to Human T-Cell Lymphotropic Virus, Type I (HTLV–I) Release Panel I	October 18, 1988	Do	Do
Draft Guideline for the Design of Clinical Trials for Evaluation of Safety and Efficacy of Allergenic Products for Therapeutic Uses	November 1, 1988	Do	Do
HTLV–I Antibody Testing	November 29, 1988	Do	Do
Use of Recombigen HIV–1 LA Test	February 1, 1989	Do	Do
Guidelines for Release of Pneumococcal Vaccine, Polyvalent	February 1, 1989	Do	Do
Guidance for Autologous Blood and Blood Components	March 15, 1989	Do	Do
HTLV–I Antibody Testing	July 6, 1989	Do	Do
Use of Recombigen HIV–1 Latex Agglutination (LA) Test	August 1, 1989	Do	Do
Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to Human Immunodeficiency Virus Type 1 (1989)	August 8, 1989	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
PTC in the Collection, Processing and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans	August 22, 1989	Do	Do
Information Relevant to the Manufacture of Acellular Pertussis Vaccine	August 23, 1989	Do	Do
FDA Regulated Industries for Drug Master Files	September 1, 1989	Do	Do
Requirements for Computerization of Blood Establishments	September 8, 1989	Do	Do
Abbott Laboratories' HIVAG–1 Test for HIV–1 Antigen(s) Not Recommended for Requirements for Computerization of Blood Establishments	October 4, 1989	Do	Do
Guideline for Collection of Blood or Blood Products From Donors With PositiveTests for Infectious Disease Markers (''High Risk'' Donors)	October 26, 1989	Do	Do
Guideline for Determination of Residual Moisture in Dried Biological Products	January 1, 1990	Do	Do
Autologous Blood Collection and Processing Procedures	February 12, 1990	Do	Do
Cytokine and Growth Factor Pre-Pivotal Trial Information Package	April 2, 1990	Do	Do
Use of Genetic Systems HIV–2 EIA	June 21, 1990	Do	Do
PTC in the Safety Evaluation of Hemoglobin-Based Oxygen Carriers	August 21, 1990	Do	Do
Guideline on the Preparation of Investigational New Drug Products (Human and Animal)	March 1, 1991	Do	Do
FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by Yersinia Enterocolitica	March 15, 1991	Do	Do
Revision to October 26, 1989, Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers (High Risk Donors)	March 17, 1991	Do	Do
Deficiencies Relating to the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
To Biologic Product Manufacturers—Controlling Materials of Bovine or Ovine Origin	May 3, 1991	Do	Do
FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)	September 10, 1991	Do	Do
Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti-HCV	September 11, 1991	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing	December 12, 1991	Do	Do
Recommended Methods for Blood Grouping Reagents Evaluation	March 1, 1992	Do	Do
Recommended Methods for Evaluating Potency, Specificity and Reactivity of Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products for Further Manufacturing into Blood Grouping Reagent and Anti-Human Globulin	March 1, 1992	Do	Do
Supplement to the PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability	April 6, 1992	Do	Do
Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products	April 23, 1992	Do	Do
Use of Fluorognost HIV–1 Immunofluorescent Assay (IFA)	April 23, 1992	Do	Do
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	April 23, 1992	Do	Do
Exemptions to Permit Persons With a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma; Alternative Procedures, 21 CFR 640.120	April 23, 1992	Do	Do
Changes in Equipment for Processing Blood Donor Samples	July 21, 1992	Do	Do
Nomenclature for Monoclonal Blood Grouping Reagents	September 28, 1992	Do	Do
Volume Limits for Automated Collection of Source Plasma	November 4, 1992	Do	Do
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics	November 25, 1992	Do	Do
Revision of October 7, 1988, Memo Concerning Red Blood Cell Immunization Programs	December 16, 1992	Do	Do
Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals	July 12, 1993	Do	Do
CBER Refusal to File (RTF) Guidance for Product and Establishment License Applications	July 12, 1993	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance on Alternatives to Lot Release for Licensed Biological Products	July 20, 1993	Do	Do
Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products	July 22, 1993	Do	Do
Deferral of Blood and Plasma Donors Based on Medications	July 28, 1993	Do	Do
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	August 19, 1993	Do	Do
Changes in Administrative Procedures	September 9, 1993	Do	Do
To Sponsors of INDs Using Retroviral Vectors	September 20, 1993	Do	Do
Draft Guideline for the Validation of Blood Establishment Computer Systems	September 28, 1993	Do	Do
Methods of the Allergenic Products Testing Laboratory	October 1, 1993	Do	Do
Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice	October 14, 1993	Do	Do
Guideline for Adverse Experience Reporting for Licensed Biological Products	October 15, 1993	Do	Do
Guidance Regarding Post Donation Information Reports	December 10, 1993	Do	Do
To Manufacturers: Bovine Derived Materials (BSE)	December 17, 1993	Do	Do
Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis	December 22, 1993	Do	Do
Compliance Program Guidance Manual (Drugs and Biologics)	1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–605–6050 (NTIS Order No. 94–920699)
Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors	January 3, 1994	Do	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
To Sponsors of INDs for Human Immunoglobulin Products	May 23, 1994	Do	Do
To Manufacturers of Licensed Anti-HIV Test Kits	May 26, 1994	Do	Do
Recommendations for Deferral of Donors for Malaria Risk	July 26, 1994	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Guideline for Industry: Studies in Support of Special Populations	August 1, 1994	Do	Do
OELPS, Advertising and Promotional Labeling Staff Procedural Guidance Document (Draft)	August 1, 1994	Do	Do
ICH Guideline for Industry: Stability Testing of New Drug Substances and Products	September 1, 1994	Do	Do
Guide to Inspections of Blood Banks, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs	September 1, 1994	FDA Personnel	Do
Letter to Manufacturers of Immune Globulin Intravenous (Human) (IGIV), Aseptic Meningitis Syndrome	October 3, 1994	FDA Regulated Industry	Do
Guidance on Alternatives to Lot Release for Licensed Biological Products	October 27, 1994	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1994	Do	Do
Recommendations to Users of Medical Devices That Test for Infectious Disease Markers by Enzyme Immunoassay (EIA) Test Systems	December 20, 1994	Do	Do
To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin	December 27, 1994	Do	Do
Timeframe for Licensing Irradiated Blood Products	February 3, 1995	Do	Do
Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV–1 and/or HIV–2) Antibody Testing; Revisions to Previous Guidance	February 23, 1995	Do	Do
ICH Guideline for Industry: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: HCV RNA Testing by PCR	March 3, 1995	Do	Do
Revision of 8/27/82 FDA Memo: Requirements for Infrequent Plasmapheresis Donors	March 10, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: Additional Information Regarding HCV RNA Testing by PCR	March 13, 1995	Do	Do
To Health Professionals: Implementation of Testing for HCV RNA by PCR for Immune Globulin Products for Intramuscular Administration	March 14, 1995	Do	Do
To All Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma	March 14, 1995	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes and Source Plasma	June 8, 1995	Do	Do
Guideline for Quality Assurance in Blood Establishments	July 11, 1995	Do	Do
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products	July 11, 1995	Do	Do
Disposition of Products Derived From Donors Diagnosed With, or at Known High Risk for, Creutzfeldt-Jakob Disease	August 8, 1995	Do	Do
Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma or Source Leukocytes Obtained From Donors With Elevated Levels of Alanine Aminotransferase (ALT)	August 8, 1995	Do	Do
Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products	August 8, 1995	Do	Do
Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	August 8, 1995	Do	Do
PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals	August 22, 1995	Do	Do
Informed Consent for Plasmapheresis/Immunization	October 1, 1995	FDA Personnel	Do
Draft Reviewers' Guide: Changes in Personnel	October 1, 1995	FDA Personnel	Do
Disease Associated Antibody Collection Program	October 1, 1995	FDA Personnel	Do
Guidance Concerning Conversion to FDA-Reviewed Software Products	November 13, 1995	FDA Regulated Industry	Do
Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 4, 1995	Do	Do
Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products	December 8, 1995	Do	Do
Dear Colleague: Regarding Reverse Transcriptase Activity in Viral Vaccines Produced in Chicken Cells	January 4, 1996	Do	Do
Requesting All Manufacturers Immediately to Revise Warning Section for Package Insert on Thrombin	January 4, 1996	Do	Do
ICH Final Guideline: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Dervied Protein Products	February 23, 1996	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Study of Pharmaceuticals	March 1, 1996	Do	Do
Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	March 14, 1996	Do	Do
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	March 26, 1996	Do	Do
ICH Guideline on the Detection of Toxicity to Reproduction for Medicinal Products; Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
ICH Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
To Manufacturers of FDA-Regulated Drug/Biological/Device Products, Bovine Spongiform Encephalopathy (BSE)	May 9, 1996	Do	Do
Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leucocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	May 16, 1996	Do	Do
Guidance for Industry—The Content and Format for Pediatric Use Supplements	May 23, 1996	Do	Do
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair of Reconstruction	May 24, 1996	Do	Do
Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products	May 29, 1996	Do	Do
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1, 1996	FDA Personnel	Do
To Manufacturers: Implementation of Testing for Hepatitis C Virus RNA by Manufacturers: Implementation of Testing for Hepatitis C Virus RNA by Polymerase Chain Reaction (PCR) of Intramuscular Immune Globulin Preparations	June 13, 1996	FDA Regulated Industry	Do
ICH Final Guidelines on Stablity Testing of Biotechnological/Biological Products	July 10, 1996		
ICH Guideline on Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
Recommendations for the Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Virus Type I (HTLV–I)	July 19, 1996	Do	Do
To Manufacturers: HIV–1 Group O	July 31, 1996	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use	August 15, 1996	Do	Do
ICH Revised Guidance: Single Dose Acute Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
ICH Draft Guideline on Data Elements for Transmission of Individual Case Reports	October 1, 1996	Do	Do
To All Plasma Derivative Manufacturers and to ABRA: Warning Statement for Plasma Derivative Product Labeling	October 7, 1996	Do	Do
Advertising and Promotion; Guidance; Notice	October 8, 1996	Do	Do
To Biologic Product Manufacturers: Revised Procedures for Internal Labeling Review Number Assignment	December 3, 1996	Do	Do
Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection	December 11, 1996	Do	Do
PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications	December 22, 1996	Do	Do
Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products	January 1997	Do	Do
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	FDA Personnel	Do
PTC in the Manufacturing and Testing of Monoclonal Antibody Products for Human Use	February 28, 1997	Do	Do
Proposed Approach to Regulation of Cellular and Tissue-Based Products	February 27, 1997	Do	Do
Tables 1 and 2 From Proposed Approach to Regulation of Cellular and Tissue-Based Products	March 4, 1997	Do	Do
Preclearance of Promotional Labeling; Clarification	March 5, 1997	Do	Do
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies	April 1997	Do	Do
ICH Draft Guideline on Dose Selection for Carcinogenicity Studies for Pharmaceuticals: Addendum on the Limit Dose	April 2, 1997	Do	Do
ICH Draft Guideline on the Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	May 2, 1997	Do	Do
ICH Draft Guideline on Impurities: Residual Solvents	May 2, 1997 (Correction May 19, 1997)	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Guideline on Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
ICH Draft Guideline on Statistical Principles for Clinical Trials, Part III	May 9, 1997	Do	Do
ICH Good Clinical Practice: Consolidated Guideline, Part II	May 9, 1997	Do	Do
ICH Guideline for the Photostability Testing of New Drug Substances and Products, Part II	May 16, 1997	Do	Do
ICH Guideline on Impurities in New Drug Products, Part IV	May 19, 1997	Do	Do
ICH Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs, Part VI	May 19, 1997	Do	Do
ICH Guideline on the Validation of Analytical Procedures: Methodology, Part V	May 19, 1997	Do	Do
To Plasma Fractionators—CBER's View on Product Recalls Conducted by the Plasma Fractionation Industry	May 29, 1997	Do	Do
ICH Draft Guideline on General Considerations for Clinical Trials	May 30, 1997	Do	Do
Guide to Inspections of Source Plasma Establishments (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs)	June 1, 1997	FDA Personnel	Do
Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability	June 18, 1997	FDA Regulated Industry	Do
Guidance for Industry—Changes to an Approved Application: Biological Products	July 1997	Do	Do
Guidance for Industry—Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 1997	Do	Do
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 1997	Do	Do
Guidance for Industry—Donor Screening for Antibodies to HTLV–II	August 1997	Do	Do
Guidance for Industry—Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	August 1997	Do	Do
Draft Guidance for Industry Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers	September 1997	Do	Do
Guidance for Industry—The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use	September 1997	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Notification Process for Transfusion Related Fatalities and Donation Related Deaths (revised telephone number)	October 7, 1997	Do	Do
Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries	October 15, 1997	Do	Do
ICH Guidance on Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
ICH Guidance on Genotoxicity: A Standard Battery for Genotoxicity Testing for Pharmaceuticals	November 21, 1997	Do	Do
ICH Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	Do	Do
Guidance for FDA and Industry: Direct Final Rule Procedures	November 21, 1997	FDA Personnel and Regulated Industry	Do
Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMS)	December 1997	FDA Regulated Industry	Do
Guidance for Industry: Industry-Supported Scientific and Educational Activities	December 3, 1997	Do	Do
ICH Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do
To Biologic Product Manufacturers—Withdrawal of Human Blood-Derived Materials Because Donors Diagnosed With, or at Increased Risk for, CJD	December 11, 1997	Do	Do
To Allergenic Extract Manufacturers—Standardized Grass Pollen Extracts	December 23, 1997	Do	Do
ICH Guidance on Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998		
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	Do	Do
Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products	January 1998	Do	Do
ICH Guidance on Testing for Carcinogenicity of Pharmaceuticals	February 28, 1998		
Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients	March 1998	Do	Do
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products	May 1998	Do	Do
Guidance for Industry: Classifying Resubmissions in Response to Action Letters	May 1998	Do	Do
Guidance for Industry: Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis and Impact on Dosing and Labeling	May 1998	Do	Do
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 1998	Do	Do
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products	June 1998	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	June 1998	Do	Do
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing	June 1998	Do	Do
ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	June 9, 1998	Do	Do
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Do	Do
Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 1998	Do	Do
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	July 1998	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV	September 1998	Do	Do
Draft Guidance for Industry: Submitting Debarment Certification Statements	September 1998	Do	Do
Guidance for Industry: How to Complete the Vaccine Adverse Reporting System Form (VAERS–1)	September 1998	Do	Do
Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review	September 1998	Do	Do
ICH Guidance on Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Guidance for Industry: On Advisory Committees: Implementing Section 120 of the Food and Drug Administration Act of 1997	October 1998	Do	Do
Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 1998	Do	Do
To Viral Vaccine IND Sponsors—Use of PCR-Based Reverse Transcriptase Assay	December 18, 1998	Do	Do
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	Do	Do
Draft Guidance for Industry: Content and Format of Geriatric Labeling	December 1998	Do	Do
Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling	January 1999	Do	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product	January 1999	Do	Do
Guidance on Amended Procedures for Advisory Panel Meetings	January 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations	January 1999	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products	February 1999	Do	Do
Guidance for Industry: Population Pharmacokinetics	February 1999	Do	Do
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 1999	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products	February 1999	Do	Do
Draft Guidance for Industry: INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry, Manufacturing and Controls Content and Format	February 1999	Do	Do
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials	March 1999	Do	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product	March 1999	Do	Do
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans	April 1999	Do	Do
Guidance for Industry on the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	April 1999	Do	Do
Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h ''Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use''	May 1999	Do	Do
Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products	May 1999	Do	Do
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	May 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation	May 1999	Do	Do
Draft Guidance for Industry: Establishing Pregnancy Registries	June 1999	Do	Do
Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data	June 1999	FDA Personnel	Do
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)	June 1999	FDA Regulated Industry	Do
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 1999	Do	Do
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do	Do
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	August 1999	Do	Do
Guidance for Industry: Consumer-Directed Broadcast Advertisements	August 1999	Do	Do
Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do	Do
Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 1999	Do	Do
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors	September 1999	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	September 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
International Conference on Harmonisation Draft Guidance; Choice of Control Group in Clinical Trials	September 24, 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)]—Revised	November 1999	Do	Do
Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products	November 1999	Do	Do
Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis and Recommendations for Dosing and Labeling	November 1999	Do	Do
Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma	November 1999	Do	Do
Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling	November 1999	Do	Do
International Conference on Harmonsation of Technical Requirements for Registration of Pharmaceuticals for Human Use M4: Common Technical Document	November 8, 1999	Do	Do
Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2	December 1999	Do	Do
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts	December 1999	Do	Do
Draft Guidance for Industry: Special Protocol Assessment	December 1999	Do	Do
Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture	January 2000	Do	Do
Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	February 2000	FDA Personnel	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information	February 2000	FDA Regulated Industry	Do
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 2000	Do	Do
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do	Do
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	February 2000	Do	Do
Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	March 2000	Do	Do
International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products	April 21, 2000	Do	Do
Draft Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics	May 2000	Do	Do
Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components	June 2000	Do	Do
Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria	June 2000	Do	Do
Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request	June 2000	Do	Do
Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use With Cadaveric Blood Specimens (Level 2)	June 2000	Do	Do
Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment	June 2000	Do	Do
Draft Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From an Outside Supplier	June 2000	Do	Do
Draft Guidance for Industry: Developing Medical Imaging Drugs and Biological Products	June 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guidance; Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (March 17, 2000)	June 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Revised Guidance on Impurities in New Drug Products	July 19, 2000	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
International Conference on Harmonisation (ICH) Draft Revised Guidance on Impurities in New Drug Substances	July 20, 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guideline: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use	July 20, 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guideline on Safety Pharmacology Studies for Human Pharmaceuticals	August 2000	Do	Do
Draft Guidance for Industry: Analytical Procedures and Methods Validation—Chemistry, Manufacturing, and Controls Documentation	August 2000	Do	Do
Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications	August 2000	Do	Do
Guidance for Industry: Q & A Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	October 2000	Do	Do
Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors	October 2000	Do	Do
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	October 2000	Do	Do
Draft Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications	November 2000	Do	Do
Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts	November 2000	Do	Do
Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices (Level 2)	November 2000	Do	Do
Draft Guidance for Industry: Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a))	November 2000	Do	Do
International Conference on Harmonisation (ICH) Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population	December 2000	Do	Do
Draft Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis	December 2000	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees	December 2000	Do	Do
International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do	Do
PHS Guideline on Infectious Disease Issues in Xenotransplantation	January 19, 2001	Do	Do
Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion	January 2001	Do	Do
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	January 2001	Do	Do
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling	January 2001	Do	Do
Draft Guidance for Industry: Source Animal, Product, Preclinical and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans	February 2001	Do	Do
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods—Technical Correction February 2001	February 2001	Do	Do
Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research	February 2001	Do	Do
Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines	March 2001	Do	Do
Guidance for Industry: Acceptance of Foreign Clinical Studies	March 2001	Do	Do
Guidance for Industry: Financial Disclosure by Clinical Investigators	March 2001	Do	Do
Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 2001	Do	Do
Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	April 2001	Do	Do
Draft Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements	April 2001	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	April 2001	Do	Do
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports	May 2001	Do	Do
Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials	May 2001	Do	Do
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information	May 2001	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Accelerated Approval Products—Submission of Promotional Materials—Draft	March 26, 1999	Advertising Draft	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling—Draft	March 12, 1999	Do	Do
Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Management Companies—Draft	January 5, 1998	Do	Do
Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements—Draft	April 23, 2001	Do	Do
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Do
Consumer-Directed Broadcast Advertisements	August 9, 1999	Do	Do
Industry-Supported Scientific and Educational Activities	December 3, 1997	Do	Do
Antifungal (Topical)—Draft	February 24, 1990	Biopharmaceutic Draft	Do
Antifungal (Vaginal)—Draft	February 24, 1990	Do	Do
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action—Draft	June 2, 1999	Do	Do
Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence—Draft	March 9, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Food-Effect Bioavailability and Bioequivalence Studies—Draft	December 30, 1997	Do	Do
In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Studies—Draft	December 10, 1997	Do	Do
Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies—Draft	June 18, 1998	Do	Do
Bioanalytical Method Validation	May 23, 2001	Biopharmaceutic	Do
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations	October 27, 2000	Do	Do
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do	Do
Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do	Do
Corticosteroids, Detmatologic (Topical) In Vivo	June 2, 1995	Do	Do
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	August 25, 1997	Do	Do
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	September 26, 1997	Do	Do
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	March 8, 2001	Do	Do
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do
Phenytoin/Phenytion Sodium (Capsules, Tablets, Suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do	Do
Potassium Chloride (Slow-Release Tablets and Capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 6, 1994	Do	Do
Statistical Approaches to Establishing Bioequivalence	February 2, 2001	Do	Do
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System	August 31, 2000	Do	Do
Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation—Draft	August 30, 2000	Chemistry Draft	Do
Botanical Drug Products—Draft	August 11, 2000	Do	Do
INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry, Manufacturing, and Controls Content and Format—Draft	April 20, 1999	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation—Draft	November 19, 1998	Do	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing—Draft	June 24, 1999	Do	Do
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Draft	June 2, 1999	Do	Do
Stability Testing of Drug Substances and Drug Products—Draft	June 8, 1998	Do	Do
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications—Draft	November 1, 1991	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
SUPAC–SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum—Draft	January 5, 1999	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Tracking of NDA and NDA Reformulations for Solid, Oral, Immediate Release Drug Products—Draft	April 12, 1989	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
BACPAC1: Intermediates in Drug Substance Synthesis: Bulk Actives Post-approval Changes: Chemistry, Manufacturing, and Controls Documentation	February 16, 2001	Chemistry	Do
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 24, 1997	Do	Do
Changes to an Approved NDA or ANDA	November 23, 1999	Do	Do
Changes to an Approved NDA or ANDA: Questions and Answers	January 22, 2001	Do	Do
Container Closure Systems for Packaging Human Drugs and Biologics	July 7, 1999	Do	Do
Development of New Stereoisomeric Drugs	May 1, 1992	Do	Do
Drug Master Files	September 1, 1989	Do	Do
Drug Master Files for Bulk Antibiotic Drug Substances	November 29, 1999	Do	Do
Environmental Assessment of Human Drugs and Biologics Applications	July 27, 1998	Do	Do
Format and Content for the CMC Section of an Annual Report	September 1, 1994	Do	Do
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application	February 1, 1987	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Format and Content of the Microbiology Section of an Application	February 1, 1987	Do	Do
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information	May 25, 2001	Do	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 29, 2001	Do	Do
NDAs: Impurities in Drug Substances	February 25, 2000	Do	Do
PAC–ALTS: Postapproval Changes—Analytical Testing Laboratory Sites	April 28, 1998	Do	Do
Reviewer Guidance: Validation of Chromatographic Methods	November 1, 1994	Do	Do
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1, 1994	Do	Do
Submission of Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products	November 1, 1994	Do	Do
Submitting Documentation for the Manufacturing of and Controls for Drug Products	February 1, 1987	Do	Do
Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Submitting Samples and Analytical Data for Methods Validation	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances	February 1, 1987	Do	Do
SUPAC IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation	November 30, 1995	Do	Do
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum	February 26, 1999	Do	Do
SUPAC–IR: Questions and Answers	February 18, 1997	Do	Do
SUPAC–MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	October 6, 1997	Do	Do
SUPAC–SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation	June 13, 1997	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy	December 20, 2000	Do	Do
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Clinical Antimicrobial Draft	Do
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment—Draft	October 18, 1999	Do	Do
Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements—Draft	September 1, 1999	Do	Do
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Developing Antimicrobial Drugs—General Considerations for Clinical Trials—Draft	July 22, 1998	Do	Do
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products—Draft	February 17, 1997	Do	Do
Lyme Disease; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Uncomplicated Gonorrhea—Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Vulvovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Clinical Antimicrobial	Do
Clinical Evaluation of Anti-Infective Drugs (Systemic)	September 1, 1977	Do	Do
Preclinical Development of Antiviral Drugs	November 1, 1990	Do	Do
Abuse Liability Assessment—Draft	July 1, 1990	Clinical Medical Draft	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Allergic Rhinitis: Clinical Development Programs for Drug Products—Draft	June 21, 2000	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Cancer Drug and Biological Products—Clinical Data in Marketing Applications—Draft	November 9, 2000	Do	Do
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment—Draft	June 28, 2000	Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)—Draft	July 15, 1999	Do	Do
Clinical Evaluation of Anti-Anginal Drugs—Draft	January 1, 1989	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Evaluation of Anti-Arrhythmic Drugs—Draft	July 1, 1985	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Evaluation of Antihypertensive Drugs—Draft	May 1, 1988	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure—Draft	December 1, 1987	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)—Draft	January 7, 1991	Do	Do
Clinical Evaluation of Lipid-Altering Agents In Adults and Children—Draft	September 1, 1990	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Evaluation of Motility-Modifying Drugs—Draft	Date not available	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Evaluation of Weight-Control Drugs—Draft	September 24, 1996	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Developing Medical Imaging Drugs and Biologics—Revised—Draft	July 31, 2000	Do	Do
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders—Draft	February 12, 1992	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Development of Parathyroid Hormones for the Prevention and Treatment of Osteoporosis—Draft	June 14, 2000	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Establishing Pregnancy Registries—Draft	June 4, 1999	Do	Do
Evaluation of Human Pregnancy Outcome Data—Draft	June 4, 1999	Do	Do
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment—Draft	May 19, 2000	Do	Do
Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent Requirements for Emergency Research—Draft	March 30, 2000	Do	Do
OTC Treatment of Herpes Labialis With Antiviral Agents—Draft	March 8, 2000	Do	Do
Pediatric Oncology Studies in Response to a Written Request—Draft	June 21, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines—Draft	March 12, 2001	Do	Do
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis—Draft	April 1, 1994	Do	Do
Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals—Draft	September 1, 1991	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Recommendations for Complying With the Pediatric Rule—Draft	December 4, 2000	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
System Inflammatory Response Syndrome (SIRS) (1st draft)—Draft	July 1993	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Acceptance of Foreign Clinical Studies	March 13, 2001	Clinical Medical	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 17, 1999	Do	Do
Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do	Do
Clinical Evaluation of Analgesic Drugs	December 1, 1992	Do	Do
Clinical Evaluation of Antacid Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (Adults and Children)	April 1, 1988	Do	Do
Clinical Evaluation of Antianxiety Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidepressant Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidiarrheal Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antiepileptic Drugs (Adults and Children)	January 1, 1981	Do	Do
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	March 20, 1995	Do	Do
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	September 1, 1977	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clinical Evaluation of General Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Hypnotic Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Laxative Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Local Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Psychoactive Drugs in Infants and Children	July 1, 1979	Do	Do
Clinical Evaluation of Radiopharmaceutical Drugs	October 1, 1981	Do	Do
Content and Format for Pediatric Use Supplements	May 24, 1996	Do	Do
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	November 20, 1995	Do	Do
Development of Vaginal Contraceptive Drugs (NDA)	April 19, 1995	Do	Do
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	February 2, 1999	Do	Do
FDA Requirements for Approval of Drugs to Treat Non-Small Lung Cancer	January 29, 1991	Do	Do
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	June 20, 1989	Do	Do
Format and Content of the Clinical and Statistical Sections of an Application	July 1, 1988	Do	Do
Format and Content of the Summary for New Drug and Antibiotic Applications	February 1, 1987	Do	Do
Formatting, Assembling and Submitting New Drug and Antibiotic Applications	February 1, 1987	Do	Do
General Considerations for the Clinical Evaluation of Drugs	December 1, 1978	Do	Do
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	September 1, 1977	Do	Do
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	March 8, 2001	Do	Do
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	April 13, 1988	Do	Do
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer	April 19, 1988	Do	Do
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products; Clarification of What to Report	August 27, 1997	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Postmarketing Reporting of Adverse Drug Experiences	March 1, 1992	Do	Do
Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders	September 4, 1992	Do	Do
Preparation of Investigational New Drug Products (Human and Animal)	November 1, 1992	Do	Do
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	May 15, 1998	Do	Do
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs	July 22, 1993	Do	Do
Study of Drugs Likely To Be Used in the Elderly	November 1, 1989	Do	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 13, 1999	Do	Do
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products—Draft	November 30, 1998	Clinical Pharmacology Draft	Do
Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling—Draft	December 7, 1999	Do	Do
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro	April 7, 1997	Clinical Pharmacology	Do
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	February 1, 1987	Do	Do
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 24, 1999	Do	Do
Pharmacokinetics and Pharmacodynamics in Patients With Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	May 15, 1998	Do	Do
Population Pharmacokinetics	February 10, 1999	Do	Do
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24)—Draft	March 30, 2000	Compliance Draft	Do
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production—Draft	September 30, 1998	Do	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients—Draft	April 17, 1998	Do	Do
Repacking of Solid Oral Dosage Form Drug Products—Draft	February 1, 1992	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
A Review of FDA's Implementation of the Drug Export Amendments of 1986		Compliance	Do
Compressed Medical Gases	December 1, 1989	Do	Do
Computerized Systems Used in Clinical Trials	May 10, 1999	Do	Do
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron	June 27, 1997	Do	Do
General Principles of Process Validation	May 1, 1987	Do	Do
Good Laboratory Practice Regulations Questions and Answers		Do	Do
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities	April 6, 2001	Do	Do
Monitoring of Clinical Investigations	January 1, 1988	Do	Do
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	May 1, 1984	Do	Do
Possible Dioxin/PCB Contamination of Drug and Biological Products	August 23, 1999	Do	Do
Sterile Drug Products Produced by Aseptic Processing	May 1, 1987	Do	Do
Street Drug Alternatives	April 3, 2000	Do	Do
Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1, 1987	Do	Do
Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports—Draft	May 4, 2001	Electronic Submission Draft	Do
Providing Regulatory Submissions in Electronic Format: Prescription Drug Advertising and Promotional Labeling—Draft	January 31, 2001	Do	Do
Preparing Data for Electronic Submissions in ANDAs	September 23, 1999	Electronic Submission	Do
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Do	Do
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do	Do
ANDAs; Blend Uniformity Analysis—Draft	August 26, 1999	Generic Drug Draft	Do
ANDAs; Impurities in Drug Products—Draft	January 5, 1999	Do	Do
Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products—With Specific Information for ANDAs for Fludeoxyglucose F18 Injection—Draft	April 18, 1997	Do	Do
Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs—Draft	December 12, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ANDAs: Impurities in Drug Substances	December 3, 1999	Generic Drugs	Do
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	Do	Do
Letter Announcing That the OGD Will Now Accept the ICH Long-Term Storage Conditions as Well as the Stability Studies Conducted in the Past	August 18, 1995	Do	Do
Letter Describing Efforts by CDER and ORA to Clarify the Responsibilities of CDER Chemistry Review Scientists and ORA Field Investigators in the New and Abbreviated Drug Approval Process in Order to Reduce Duplication or Redundancy in the Process	October 14, 1994	Do	Do
Letter on Incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations From OGD Policy	April 8, 1994	Do	Do
Letter on the Provision of New Information Pertaining to New Bioequivalence Guidelines and Refuse-to-File Letters	July 1, 1992	Do	Do
Letter on the Provision of New Procedures and Policies Affecting the Generic Drug Review Process	March 15, 1989	Do	Do
Letter on the Request for Cooperation of Regulated Industry to Improve the Efficiency and Effectiveness of the Generic Drug Review Process, by Assuring the Completeness and Accuracy of Required Information and Data Submissions	November 8, 1991	Do	Do
Letter on the Response to 12/20/84 Letter From the Pharmaceutical Manufacturers Association About the Drug Price Competition and Patent Term Restoration Act	March 26, 1985	Do	Do
Letter to all ANDA and AADA Applicants About the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to Refuse-to-File Incomplete Submissions as Required by the New Law	January 15, 1993	Do	Do
Letter to Regulated Industry Notifying Interested Parties About Important Detailed Information Regarding Labeling, Scale-up, Packaging, Minor/major Amendment Criteria, and Bioequivalence Requirements	August 4, 1993	Do	Do
Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications (Revised)	May 1, 2000	Do	Do
Organization of an ANDA	March 2, 1999	Do	Do
Revising ANDA Labeling Following Revision of the RLD Labeling	April 25, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 3, 2000	Do	Do
Variations in Drug Products That May Be Included ANDA	January 27, 1999	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review—Draft	November 22, 1996	Good Review Practices Draft	Do
Pharmacology/Toxicology Review Format	May 10, 2001	Good Review Practices	Do
Q1A(R)—Stability Testing of New Drug Substances and Products—Draft	April 21, 2000	ICH Draft—Quality	Do
Q3A(R)—Impurities in New Drug Substances—Draft	July 20, 2000	Do	Do
Q3B(R)—Impurities in New Drug Products—Draft	July 19, 2000	Do	Do
Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances—Draft	November 25, 1997	Do	Do
Q7A—Good Manufacturing Practice for Active Pharmaceutical Ingredients—Draft	August 1, 2000	Do	Do
S7—Safety Pharmacology Studies for Human Pharmaceuticals—Draft	August 7, 2000	ICH Draft—Safety	Do
E12 A—Principles for Clinical Evaluation of New Antihypertensive Drugs—Draft	August 9, 2000	ICH Draft—Efficacy	Do
M4—Common Technical Document—Draft	August 24, 2000	ICH Draft—Joint Safety/Efficacy (Multidisciplinary)	Do
Q1A—Stability Testing of New Drug Substances and Products	September 22, 1994	ICH—Quality	Do
QIB—Photostability Testing of New Drug Substances and Products	May 16, 1997	Do	Do
QIC—Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
Q2A—Text on Validation of Analytical Procedures	March 1, 1995	Do	Do
Q2B—Validation of Analytical Procedures: Methodology	May 19, 1997	Do	Do
Q3A—Impurities in New Drug Substances	January 4, 1996	Do	Do
Q3B(R)— Impurities in New Drug Products	July 19, 2000	Do	Do
Q3C—Impurities: Residual Solvents	December 24, 1997	Do	Do
Q5A—Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Q5B—Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	February 23, 1996	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Q5C—Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products	July 10, 1996	Do	Do
Q5D—Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do	Do
Q6B—Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
S1A—The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	ICH—Safety	Do
S1B—Testing for Carcinogenicity in Pharmaceuticals	February 23, 1998	Do	Do
S1C—Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 1, 1995	Do	Do
S1C(R)—Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do
S2A—Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
S2B—Genotoxicity: Standard Battery Testing	November 21, 1997	Do	Do
S3A—Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	March 1, 1995	Do	Do
S3B—Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	March 1, 1995	Do	Do
S4A—Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
S5A—Detection of Toxicity to Reproduction for Medicinal Products	September 22, 1994	Do	Do
S5B—Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
S6—Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
S7A—Safety Pharmacology Studies for Human Pharmaceuticals	July 13, 2001	Do	Do
EIA—The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	March 1, 1995	ICH—Efficacy	Do
E2A—Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
E2B—Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Do	Do
E2C—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do	Do
E3—Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
E4—Dose-Response Information to Support Drug Registration	November 9, 1994	Do	Do
E5—Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
E6—Good Clinical Practice: Consolidated Guideline	May 9, 1997	Do	Do
E7—Studies in Support of Special Populations: Geriatrics	August 2, 1994	Do	Do
E8—General Considerations for Clinical Trials	December 24, 1997	Do	Do
E9—Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
E10—International Conference on Harmonisation: Choice of Control Group and Related Issues in Clinical Trials	May 14, 2001	Do	Do
E11—Clinical Investigation of Medicinal Products in the Pediatric Population	December 15, 2000	Do	Do
M3—Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	ICH—Joint Safety/Efficacy (Multidisciplinary)	Do
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	July 15, 1996	Industry Letters	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Certification Requirements for Debarred Individuals in Drug Applications	June 1, 1990	Do	Do
Continuation of a Series of Letters Communicating Interim and Informal Generic Drug Policy and Guidance. Availability of Policy and Procedure Guides, and Further Operational Changes to the Generic Drug Review Program	March 2, 1998	Do	Http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Fifth of a Series of Letters Providing Informal Notice About the Act, Discussing the Statutory Mechanism by Which ANDA Applicants May Make Modifications in Approved Drugs Where Clinical Data Is Required	April 10, 1987	Do	Do
Fourth of a Series of Letters Providing Informal Notice to Affected Parties About Policy Developments and Interpretations Regarding the Act. Three-Year Exclusivity Provisions of Title 1	October 31, 1986	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Implementation of the Drug Price Competition and Patent Term Restoration Act; Preliminary Guidance	October 11, 1984	Do	Do
Implementation Plan USP Injection Nomenclature	October 2, 1995	Do	Do
Instructions for Filing Supplements Under the Provisions of SUPAC–IR	April 11, 1996	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Seventh of a Series of Letters About the Act Providing Guidance on the ''180-Day Exclusivity'' Provision of Section 505(j)(4)(B)(iv) of the Act	July 29, 1988	Do	Http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Sixth of a Series of Informal Notice Letters About the Act Discussing 3- and 5-year Exclusivity Provisions of Section 505(c)(3)(D) and (j)(4)(D) of the Act	April 28, 1988	Do	Do
Streamlining Initiative	December 24, 1996	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Supplement to 10/11/84 Letter About Policies, Procedures and Implementation of the Act (Q & A Format)	November 16, 1984	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Third of a Series of Letters Regarding the Implementation of the Act	May 1, 1985	Do	Do
Y2K Letter From Dr. Janet Woodcock	October 19, 1998	Do	Do
Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients—Draft	July 10, 2000	Labeling Draft	Do
Content and Format for Geriatric Labeling—Draft	January 21, 1999	Do	Do
Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics—Draft	June 21, 2000	Do	Do
Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling—Draft	January 8, 1999	Do	Do
Noncontraceptive Estrogen Class Labeling—Draft	September 27, 1999	Do	Do
Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)—Draft	July 16, 1998	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications—Draft	October 26, 2000	Do	Do
Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling—Draft	January 28, 1999	Do	Do
Acetaminophen and Codeine Phosphate Tablets/Capsules	December 1, 1993	Labeling	Do
Acetaminophen and Codeine Phosphate Oral Solution/Suspension	December 1, 1993	Do	Do
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Do
Alprazolam Tablets USP	August 1, 1996	Do	Do
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	September 1, 1997	Do	Do
Amlodipine Besylate Tablets	September 1, 1997	Do	Do
Astemizole Tablets	September 1, 1997	Do	Do
Atenolol Tablets USP	August 1, 1997	Do	Do
Barbiturate, Single Entity-Class Labeling	March 1, 1981	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Butalbital, Acetaminophen and Caffeine Capsules/Tablets USP	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Butalbital, Acetaminophen, Caffeine and Hydocodone Bitartrate Tablets	September 21, 1997	Do	Do
Butorphanol Tartrate Injection USP	October 1, 1992	Do	Do
Captopril and Hydrochlorothiazide Tablets USP	April 1, 1995	Do	Do
Captopril Tablets	February 1, 1995	Do	Do
Carbidopa and Levodopa Tablets USP	February 1, 1992	Do	Do
Chlordiazepoxide Hydrochloride Capsules	January 1, 1988	Do	Do
Cimetidine Hydrochloride Injection	September 1, 1995	Do	Do
Cimetidine Tablets	September 1, 1995	Do	Do
Cisapride Oral Suspension	September 1, 1997	Do	Do
Cisapride Tablets	September 1, 1997	Do	Do
Clindamycin Phosphate Injection USP	September 1, 1998	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Combination Oral Contraceptives—Physician and Patient Labeling	January 1, 1994	Do	Do
Cyproheptadine Hydrochloride Tablets/Syrup	December 1, 1986	Do	Do
Diclofenac Sodium Delayed-Release Tablets	January 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Diltiazem Hydrochloride Extended-Release Capsules	September 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	April 1, 1995	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	November 2, 1998	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Ergoloid Mesylates Tablets	January 1, 1988	Do	Do
Fludeoxyglucose F18 Injection	January 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Flurbiprofen Tablets USP	January 1, 1994	Do	Do
Fluvoxamine Maleate Tablets	September 1, 1997	Do	Do
Gentamicin Sulfate Ophthalmic Ointment and Solution USP	April 1, 1992	Do	Do
Heparin Sodium Injection USP	March 1, 1991	Do	Do
Hydrocodone Bitartrate and Acetaminophen Tablets USP	April 1, 1994	Do	Do
Hydroxyzine Hydrochloride Injection	December 1, 1989	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Hypoglycemic Oral Agents Federal Register	April 1, 1984	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Indomethacin Capsules USP	September 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Informal Labeling Guidance Texts for Estrogen Drug Products Patient Labeling	August 1, 1992	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Informal Labeling Guidance Texts for Estrogen Drug Products: Professional Labeling	August 1, 1992	Do	Do
Isoetharine Inhalation Solution	March 1, 1989	Do	Do
Itraconazole Capsules, USP	September 1, 1998	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Leucovorin Calcium for Injection	July 1, 1996	Do	Do
Leucovorin Calcium Tablets, USP	July 1, 1996	Do	Do
Local Anesthetics Class Labeling	September 1, 1982	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Meclofenamate Sodium Capsules	July 1, 1992	Do	Do
Medroxyprogesterone Acetate Tablets, USP	September 1, 1998	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Metaproterenol Sulfate Inhalation Solution USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Syrup USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Tablets	May 1, 1992	Do	Do
Metoclopramide Tablets USP/Oral Solution	February 1, 1995	Do	Do
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Naproxen Sodium Tablets, USP	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Naproxen Tablets, USP	September 1, 1997	Do	Do
Niacin Tablets	July 1, 1982	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Paclitaxel Injection	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Phendimetrazine Tartrate Capsules/T Nets, and Extended-Release Capsules	February 1, 1991	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Phentermine Hydrochloride Capsules/Tablets	August 1, 1988	Do	Do
Promethazine Hydrochloride Tablets	March 1, 1990	Do	Do
Propantheline Bromide Tablets	August 1, 1988	Do	Do
Pyridoxine Hydrochloride Injection	June 1, 1984	Do	Do
Quinidine Sulfate Tablets/Capsules USP	October 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Ranitidine Tablets USP	November 1, 1993	Do	Do
Risperidone Oral Solution	September 1, 1997	Do	Do
Risperidone Tablets	September 1, 1997	Do	Do
Sulfacetainide Sodium and Prednisolone Acetate Ophthalmic Suspension and Ointment	January 1, 1995	Do	Do
Sulfacetamide Sodium Ophthalmic Solution/Ointment	August 1, 1992	Do	Do
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension	August 1, 1993	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Theophylline Immediate-Release Dosage Forms	February 1, 1995	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Theophylline Intravenous Dosage Forms	September 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Thiamine Hydrochloride Injection	February 1, 1988	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Tobramycin Sulfate Injection USP	May 1, 1993	Do	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
Venlafaxine Hydrochloride Tablets	October 1, 1997	Do	Do
Verapamil Hydrochloride Tablets	October 1, 1991	Do	Do
Vitamin A Capsules	February 1, 1992	Do	Do
Zolpidem Tartrate Tablets	September 1, 1997	Do	Do
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	April 1, 1996	Microbiology	Do
Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals—Draft	December 19, 2000	OTC Draft	Do
Labeling OTC Human Drug Products: Updating Labeling in ANDAs—Draft	February 22, 2001	Do	Do
OTC Actual Use Studies—Draft	July 22, 1994	Do	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
OTC Nicotine Substitutes—Draft	March 1, 1994	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)		OTC	http://www.fda.gov/cder/guidance/index.htm Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573
General Guidelines for OTC Combination Products		Do	Do
Labeling OCT Human Drug Products Using a Column Format	December 19, 2000	Do	Do
Upgrading Category III Antiperspirants to Category 1 (43 FR 46728–46731)		Do	Do
Carcinogenicity Study Protocol Submissions—Draft	November 7, 2000	Pharmacology/Toxicology Draft	Do
Immunotoxicology Evaluation of Investigational New Drugs—Draft	May 11, 2001	Do	Do
Photosafety Testing—Draft	January 10, 2000	Do	Do
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals—Draft	May 8, 2001	Do	Do
Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	October 4, 2000	Pharmacology/Toxicology	Do
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application	February 1, 1987	Do	Do
Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives	October 16, 1996	Do	Do
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	February 1, 1989	Do	Do
Single Dose Acute Toxicity Testing Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
Applications Covered by Section 505(b)(2)—Draft	December 8, 1999	Procedural Draft	Do
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products—Draft	March 10, 2000	Do	Do
Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000—Draft	December 22, 1999	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—Draft	May 15, 2001	Do	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank—Draft	March 29, 2000	Do	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan—Draft	July 9, 2001	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act—Draft	August 17, 1999	Do	Do
PET Drug Applications—Content and Format for NDAs and ANDAs—Draft	March 10, 2000	Do	Do
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines—Draft	March 12, 2001	Do	Do
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies—Draft	January 4, 2001	Do	Do
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997—Draft	April 4, 2001	Do	Do
Special Protocol Assessment—Draft	February 9, 2000	Do	Do
Submitting Debarment Certification Statements—Draft	October 2, 1998	Do	Do
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	July 14, 1998	Procedural	Do
Advisory Committees: Implementing Section 120 of the Food and Drug Modernization Act of 1997	November 2, 1998	Do	Do
Court Decisions, ANDA Approvals, and 130-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	Do	Do
Disclosure of Materials Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000	November 30, 1999	Do	Do
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	November 23, 1998	Do	Do
Fast Track Drug Development Programs: Designation, Development, and Application Review	November 18, 1998	Do	Do
Financial Disclosure by Clinical Investigators	March 20, 2001	Do	Do
Formal Dispute Resolution: Appeals Above the Division Level	March 7, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Formal Meetings With Sponsors and Applicants for PDUFA Products	March 7, 2000	Do	Do
Implementation of Section 120 of the FDA Modernization Act of 1997—Advisory Committees	November 20, 1998	Do	Do
Implementation of Section 126 of the FDA Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 21, 1998	Do	Do
Levothyroxine Sodium Products—Enforcement of August 14, 2001, Compliance Date and Submission of New Applications	July 13, 2001	Do	Do
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs	April 9, 1998	Do	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act—Revised	October 1, 1999	Do	Do
Reduction of Civil Money Penalties for Small Business Entities	March 20, 2001	Do	Do
Refusal to File	July 12, 1993	Do	Do
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	June 15, 1998	Do	Do
Standards for the Prompt Review of Efficacy Supplements Including Priority Efficacy Supplements	May 15, 1998	Do	Do
Women and Minorities Guidance Requirements	July 20, 1998	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 17, 1999	User Fee Draft	Do
Submitting Separate Marketing Applications and Definitions of Clinical Data for Purposes of Assessing User Fees—Draft	February 22, 2001	Do	Do
Waivers of and Reductions in User Fees (Attachment G)—Draft	July 16, 1993	Do	Do
Applicability of User Fees to: (1) Applications Withdrawn Before Filing Decision, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F)	July 12, 1993	User Fee	Do
Application, Product, and Establishment Fees: Common Issues and Their Resolution (Attachment D)	December 16, 1994	Do	Do
Classifying Resubmissions in Response to Action Letters	May 14, 1998	Do	Do
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act	August 25, 1999	Do	Do
Formal Meetings With Sponsors and Applicants for PDUFA Products	March 7, 2000	Do	Do
Submitting and Reviewing Complete Responses to Clinical Holds (Revised)	October 26, 2000	Do	Do

WITHDRAWALS

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal
Dissemination and Reprints of Certain Published Original Data (No Replacement)	October 8, 1996	Advertising	February 16, 2000
Funded Dissemination of Reference Texts (No Replacement)	October 8, 1996	Advertising	February 16, 2000
Buspirone Hydrochloride Tablets In Vivo Bioequivalence (No Replacement)	May 14, 1998	Biopharmaceutics	November 30, 2000
Cimetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Diclofenac Sodium (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing (No Replacement)	October 6, 1994	Biopharmaceutics	November 30, 2000
Glipizide In Vivo Bioequivalence and In Vivo Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Glyburide In Vivo Bioequivalence and In Vivo Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Oral Extended (Controlled) Release Dosage Forms In Vivo Bioequivalence and In Vitro Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design (No Replacement)	July 1, 1992	Biopharmaceutics	November 30, 2000
Clinical Evaluation of Drugs to Prevent Dental Caries (No Replacement)	November 1, 1978	Clinical Medical	May 18, 2000
Clinical Evaluation of Drugs to Prevent, Control, and/or Treat Periodontal Disease (No Replacement)	November 1, 1978	Clinical Medical	May 18, 2000
OTC Treatment of Hypercholesterolemia (No Replacement)	October 27, 1997	OTC	August 3, 2000
Levothyroxine Sodium: Questions and Answers (Replaced by Levothyroxine Sodium Products Enforcement of August 14, 2001, Compliance Date and Submission of New Applications issued on July 13, 2001)	March 8, 2001	Procedural	July 13, 2001

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
The FDA Export Reform and Enhancement Act of 1996/ Export Certification Package Including ''Instructions for Requests for Certificate to Foreign Governments''	February 7, 2000	Office of Compliance (OC)	Division of Small Manufacturers Assistance; 1–800–638–2041 or 301–827–0111 or (FAX) Facts-on-Demand (FOD) at 1–800–899–0381 or Internet at http://www.fda.gov/ cdrh/ ggpmain.html	865
Commercial Distribution/Exhibit Letter	April 10, 1992	OC	Do	246
Color Additive Status List (Inspection Operations Manual)	February 1, 1989	OC	Do	268
FDA Guide for Validation of Biological Indicator Incubation Time	January 1, 1986	OC	Do	283

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	OC	Do	286
Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236)	September 1, 1989	OC	Do	295
Color Additive Petitions (p. 11–19 of PMA Manual)	June 1, 1987	OC	Do	296
Guidance for Preparation of PMA Manufacturing Information	August 1, 1992	OC	Do	448
Civil Money Penalty Policy; Guidance for FDA Staff	June 8, 1999	OC	Do	1124
General Principles of Software Validation; Draft Guidance	June 9, 1997	OC	Do	938
Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub. No. 95–4246)	March 1, 1995	OC	Do	10
Cover Letter/Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cable	March 9, 1998	OC	Do	1197
Guidance on Medical Device Tracking [FDAMA]; Guidance for Industry and FDA Staff	January 24, 2000	OC	Do	169
Compliance Program Guidance Manual: Inspection of Medical Devices; Draft	August 12, 1999	OC	Do	1702
Procedures for Laboratory Compliance Testing of Television Receivers—Part of TV Packet	May 1, 1986	OC	Do	945
Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [510(k)] [CPG 7124.19]	September 24, 1987	OC	Do	181
Letter to Medical Device Manufacturer on Pentium Processors	February 14, 1995	OC	Do	456
Implementation of the Biomaterials Access Assurance Act of 1998	April 2, 2001	OC	Do	1324
Guideline for the Monitoring of Clinical Investigations	January 1, 1988	OC	Do	428
Regulating In Vitro Diagnostic Device (IVD) Studies; Guidance for FDA Staff	December 17, 1999	OC/Division of Bioresearch Monitoring (DBM)	Do	1132
Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects	March 19, 1999	OC/DBM	Do	2229
Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables	November 15, 1999	OC/Division of Enforcement (DOE) I	Do	1129
Guidance on Quality System Regulation Information for Various Premarket Submissions; Draft	August 3, 1999	OC/DOEII	Do	1140
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; Guidance for Industry—Draft	July 26, 2000	OC/DOEII	Do	1141
Manufacturers/Assemblers of Diagnostic X-Ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	OC/DOEI	Do	116
Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and their Major Components	January 1, 1982	OC/DOEI	Do	257

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Exemption From Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	OC/DOEI	Do	343
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	OC/DOEI	Do	545
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89–8221)	March 1, 1989	OC/DOEI	Do	758
CPG 7133.19: Retention of Microwave Oven Test Record/Cover Letter: 08/24, 1981 Retention of Records Required by 21 CFR [Part] 1002	March 1, 1995	OC/DOEI	Do	880
Guideline for the Manufacture of In Vitro Diagnostic Products	January 10, 1994	OC/DOEI	Do	918
A Guide for the Submission of Abbreviated Radiation Safety Reports on Cephalometric X-Ray Devices: Defined as Dental Units With an Attachment for Mandible Work That Holds a Cassette and Beam Limiting Device	March 1, 1996	OC/DOEI	Do	977
A Guide for the Submission of an Abbreviated Radiation Safety Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	March 1, 1996	OC/DOEI	Do	978
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X-Ray Systems	March 1, 1996	OC/DOEI	Do	979
Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment; Guidance for FDA Staff	March 15, 2000	OC/DOEI	Do	1133
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA	April 2, 2001	OC/DOEI	Do	2619
Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	OC/DOEI&III	Do	235
Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)—E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems	August 1, 1995	OC/DOEI&III	Do	236
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	OC/DOEI&III	Do	239
Reporting Guide for Laser Light Shows and Displays (21 CFR [Part] 1002) (FDA 88–8140)	September 1, 1995	OC/DOEI&III	Do	251
Guide for Filing Annual Reports for X-Ray Components and Systems	July 1, 1980	OC/DOEI&III	Do	253
Reporting and Compliance Guide for Television Products Including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance	October 1, 1995	OC/DOEI&III	Do	260
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (Replaces FDA 82–8127)	September 1, 1995	OC/DOEI&III	Do	264

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	OC/DOEI&III	Do	399
Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	OC/DOEI&III	Do	697
Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products	August 1, 1995	OC/DOEI&III	Do	951
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	OC/DOEI&III	Do	960
Letter—Manufacturers, Distributors and Importers of Condom Products	February 23, 1994	OC/DOEII	Do	52
Letter—Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	February 13, 1989	OC/DOEII	Do	53
Letter—Condom Manufacturers and Distributors	April 5, 1994	OC/DOEII	Do	56
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	OC/DOEII	Do	101
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	OC/DOEII	Do	277
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	OC/DOEII	Do	278
Condoms: Inspection and Sampling at Domestic Manufacturers and of All Repackers; Sampling From All Importers (Damaska Memo to Field on 4/8, 1987)	April 8, 1987	OC/DOEII	Do	293
Dental Handpiece Sterilization (Dear Doctor Letter)	September 28, 1992	OC/DOEII	Do	589
Latex Labeling Letter (Johnson)	March 18, 1993	OC/DOEII	Do	831
Pesticide Regulation Notice 94–4: Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides With Medical Device Use Claims Under the Memorandum of Understanding Between EPA and FDA	June 30, 1994	OC/DOEII	Do	851
Letter to Industry, Powered Wheelchair Manufacturers From RM Johnson	May 10, 1993	OC/DOEII	Do	869
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	OC/DOEII	Do	901
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	OC/DOEII	Do	933
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	OC/DOEII	Do	1019
Letter to: Manufacturers and Users of Lasers for Refractive Surgery [Excimer]	October 10, 1996	OC/DOEII	Do	1093
Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy	August 23, 1996	OC/DOEII	Do	1122
Surveillance and Detention Without Physical Examination of Condoms; Guidance for Industry; Draft	August 14, 2000	OC/DOEII	Do	1139
All U.S. Condom Manufacturers, Importers and Repackagers	April 7, 1987	OC/DOEII	Do	2510

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	OC/DOEII	Do	2507
Laser Light Show Safety—Who's Responsible? (FDA 86–8262)	May 1, 1986	OC/DOEIII	Do	13
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub. No. 83–8220)	January 1, 1982	OC/DOEIII	Do	70
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	May 28, 1981	OC/DOEIII	Do	231
Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	OC/DOEIII	Do	237
Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	OC/DOEIII	Do	240
Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	OC/DOEIII	Do	241
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	October 1, 1987	OC/DOEIII	Do	243
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	OC/DOEIII	Do	247
Guide for Preparing Product Reports for Ultrasonic Therapy Products (Physical Therapy Only)	August 1, 1996	OC/DOEIII	Do	249
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	September 1, 1980	OC/DOEIII	Do	254
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	OC/DOEIII	Do	261
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (Replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do	262
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps (Replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do	263
Quality Control Guide for Sunlamp Products (FDA 88–8234)	March 1, 1988	OC/DOEIII	Do	270
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	September 1, 1984	OC/DOEIII	Do	271
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR [Part] 1002)	September 1, 1995	OC/DOEIII	Do	279
Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	August 21, 1986	OC/DOEIII	Do	342
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR [Part] 1002)	September 1, 1995	OC/DOEIII	Do	348
Quality Control Practices for Compliance With the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	OC/DOEIII	Do	349

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Keeping Up With the Microwave Revolution (FDA Pub. No. 91–4160)	March 1, 1990	OC/DOEIII	Do	356
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	OC/DOEIII	Do	507
Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	March 28, 1980	OC/DOEIII	Do	646
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	OC/DOEIII	Do	675
Import: Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	OC/DOEIII	Do	756
Unsafe Patient Lead Wires and Cables	September 3, 1993	OC/DOEIII	Do	889
Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device [Form FDA 3147]	July 1, 1998	OC/DOEIII	Do	903
Letter to Trade Association: Reuse of Single-Use or Disposable Medical Devices	December 27, 1995	OC/DOEIII	Do	961
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	OC/DOEIII	Do	994
Keeping Medical Devices Safe From Electromagnetic Interference	July 1, 1995	OC/DOEIII	Do	1081
Medical Devices and EMI: The FDA Perspective	January 1, 1995	OC/DOEIII	Do	1082
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations		OC/DOEIII	Do	1086
Safety of Electrically Powered Products: Letter to Medical Device and Electronic Product Manufacturers From Lillian Gill and BHB Correction Memo	September 18, 1996	OC/DOEIII	Do	1087
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff	August 14, 2000	OC/DOEIII	Do	1168
Labeling for Electronic Anti-Theft Systems; Guidance for Industry; Final	August 15, 2000	OC/DOEIII	Do	1170
Wireless Medical Telemetry Risks and Recommendations, Guidance for Industry; Final	September 27, 2000	OC/DOEIII	Do	1173
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	OC/DOEIII	Do	1343
Policy on Lamp Compatibility (Sunlamps)	September 2, 1986	OC/DOEIII	Do	2343
Guidance for Industry on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval	August 5, 1999	OC/Division of Program Operations (DPO)	Do	1269
Guidance on IDE Policies and Procedures [FDAMA]; Final	January 20, 1998	Office of Device Evaluation (ODE)	Do	882
Color Additives for Medical Devices	November 15, 1995	ODE	Do	575
Preamendment Class III Devices	March 11, 1992	ODE	Do	584
Viable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution	Date not available	ODE	Do	595
Guidance for Submitting Reclassification Petition	June 1, 1989	ODE	Do	609

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Electromagnetic Compatibility for Medical Devices: Issues and Solutions; Memorandum	June 13, 1995	ODE	Do	639
SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices [510(k)] Manual Insert	April 17, 1992	ODE	Do	655
''Real-Time'' Review Program for Premarket Approval Application (PMA) Supplements	April 22, 1997	ODE	Do	673
Classified Convenience Kits	April 30, 1993	ODE	Do	789
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH [FDAMA]; Final	February 19, 1998	ODE	Do	795
Suggested Content for Original IDE Application Cover Letter—Version 4	February 27, 1996	ODE	Do	797
Device Specific Guidance Documents (List)	May 11, 1993	ODE	Do	815
PMA Shell Development and Modular Review; Guidances for the Medical Device Industry; Final	November 6, 1998	ODE	Do	835
Determination of Intended Use for 510(k) Devices—Guidance for Industry and CDRH Staff [FDAMA]; Final	January 30, 1998	ODE	Do	857
Premarket Notification [510(k)] Status Request Form, Revised	March 14, 1997	ODE	Do	858
CDRH's 510(k)/IDE/PMA Refuse to Accept/Accept/File Policies	June 30, 1993	ODE	Do	859
Indications for Use Statement	February 6, 1996	ODE	Do	879
The New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final	March 20, 1998	ODE	Do	905
Preamendments Class III Strategy; SXAlpert	April 19, 1994	ODE	Do	611
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer From Susan Alpert, Ph.D., M.D.	May 26, 1994	ODE	Do	883
ODE Executive Secretary Guidance Manual	August 7, 1987	ODE	Do	1338
Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Guidance for Industry; Draft	August 6, 1998	ODE	Do	102
CDRH Submissions Coversheet [PMA/PDP/510k/IDE]	May 8, 1998	ODE	Do	147
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	ODE	Do	159
Limulus Amebocyte Lysate; Reduction of Samples for Testing	October 23, 1987	ODE	Do	178
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance	April 1, 1996	ODE	Do	198
New Section 513(f)(2)—Evaluation of Automatic Class III Designation; Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	ODE	Do	199

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	ODE	Do	225
Suggestions for Submitting a Premarket Approval (PMA) Application	April 1, 1993	ODE	Do	228
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	September 9, 1999	ODE	Do	1252
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	ODE	Do	267
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products (From John C. Petricciani, M.D.)	June 1, 1984	ODE	Do	269
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff [FDAMA]	February 19, 1998	ODE	Do	310
Format for IDE Progress Reports	June 1, 1996	ODE	Do	311
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—For Use by CDRH and Industry [FDAMA]; Final	February 19, 1998	ODE	Do	322
Industry Representatives on Scientific Panels	March 27, 1987	ODE	Do	329
PMA Review Schedule [P87–1]	March 31, 1988	ODE	Do	333
Necessary Information for Diagnostic Ultrasound 510(k) (Draft)	November 24, 1987	ODE	Do	335
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for FDA and Reviewers and Industry; Final	May 29, 1998	ODE	Do	337
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	ODE	Do	338
510(k) Quality Review Program (Blue Book Memo) (I96–1)	March 29, 1996	ODE	Do	344
FDA Policy for the Regulation of Computer Products (Draft)	November 13, 1989	ODE	Do	351
Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	ODE	Do	352
4-of-A-Kind PMAs	October 1, 1991	ODE	Do	371
Supplements to Approved Applications for Class III Medical Devices: Use Published Literature, Use of Previously Submitted Materials, and Priority Review [FDAMA]; Guidance for Industry; Final	May 20, 1998	ODE	Do	380
Substantial Equivalence (SE) Decision Making Documentation ATTACHED: ''SE'' Decision Making Process (Detailed), i.e., the Decision Making Tree	January 1, 1990	ODE	Do	390
Shelf Life of Medical Devices	March 1, 1991	ODE	Do	415
Guideline on General Principles of Process Validation	May 1, 1987	ODE	Do	425
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	ODE	Do	426

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	ODE	Do	427
General/Specific Intended Use [FDAMA]; Draft Guidance for Industry	November 4, 1998	ODE	Do	499
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages [Blue Book Memo #P98–1]; Final	October 10, 1997	ODE	Do	563
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources and T93–28 dated 6/25, 1993, Device ''Fast Track'' Plan Announcement (Include with 926–930)	June 30, 1993	ODE	Do	931
New Model Medical Device Development Process; Guidance for Industry; Final	July 21, 1998	ODE	Do	1101
Guidance on the Use of Standards in Substantial Equivalence Determinations; Final	March 12, 2000	ODE	Do	1131
Guidance for Industry and for FDA Reviewers; Interpretive Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997	August 9, 2000	ODE	Do	1135
Evidence Models for the Least Burdensome Means to Market; Guidance for Industry and FDA Reviewers; Draft	September 1, 1999	ODE	Do	1154
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	September 3, 1996	ODE	Do	1198
Deciding When to Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry	November 30, 2000	ODE	Do	1073
Guidance on Amended Procedures for Advisory Panel Meetings	July 22, 2000	ODE	Do	413
Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Final	November 16, 1998	ODE	Do	2206
Frequently Asked Questions on the New 510(k) Paradigm; Guidance for Industry; Final	October 22, 1998	ODE	Do	2230
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry	May 3, 2001	ODE	Do	1332
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	ODE Division of Reproductive, Abdominal, and Radiological Devices (DRARD)	Do	97
Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology	November 1, 1994	ODE/DRARD	Do	98
Convenience Kits Interim Regulatory Guidance (Include 874)	May 20, 1997	ODE/510K	Do	562

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Announcement: Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Categorization of Investigational Devices #D95–2 (Blue Book Memo)	September 15, 1995	ODE/BlueBook	Do	106
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90–2 (Blue Book Memo)	October 19, 1990	ODE/BlueBook	Do	30
Consolidated Review of Submissions for Lasers and Accessories #G90–1 (Blue Book Memo)	October 19, 1990	ODE/BlueBook	Do	31
Review of Final Draft Medical Device Labeling #P91–4 (Blue Book Memo)	August 29, 1991	ODE/BlueBook	Do	34
Review of 510(k)s for Computer Controlled Medical Devices #K91–1 (Blue Book Memo)	August 29, 1991	ODE/BlueBook	Do	35
Use of International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'' (Replaces #G87–1 #8294) (Blue Book Memo)	May 1, 1995	ODE/BlueBook	Do	164
ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures #G87–2 (Blue Book Memo)	May 15, 1987	ODE/BlueBook	Do	276
Panel Review of ''Me-Too'' Devices #P86–6 (Blue Book Memo)	July 1, 1986	ODE/BlueBook	Do	280
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86–3 (Blue Book Memo)	June 30, 1986	ODE/BlueBook	Do	289
PMA Filing Decisions #P90–2 (Blue Book Memo)	May 18, 1990	ODE/BlueBook	Do	297
PMAs—Early Review and Preparation of Summaries of Safety and Effectiveness #P86–1 (Blue Book Memo)	January 27, 1986	ODE/BlueBook	Do	302
Criteria for Panel Review of PMA Supplements #P86–3 (Blue Book Memo)	January 30, 1986	ODE/BlueBook	Do	304
Review and Approval of PMAs of Licensees #P86–4 (Blue Book Memo)	October 22, 1990	ODE/BlueBook	Do	305
Panel Report and Recommendations on PMA Approvals #P86–5 (Blue Book Memo)	April 18, 1986	ODE/BlueBook	Do	306
510(k) Sign-Off Procedures #K94–2 (Blue Book Memo)	June 3, 1994	ODE/BlueBook	Do	308
Review of Laser Submissions #G88–1 (Blue Book Memo)	April 15, 1988	ODE/BlueBook	Do	330
Delegation of IDE Actions #D88–1 (Blue Book Memo)	April 26, 1988	ODE/BlueBook	Do	331
Premarket Notification—Consistency of Reviews #K89–1 (Blue Book Memo)	February 28, 1989	ODE/BlueBook	Do	339
Telephone Communications Between ODE Staff and Manufacturers #I93–1 (Blue Book Memo)	January 29, 1993	ODE/BlueBook	Do	360
510(k) Sterility Review Guidance—and Revision of 11/18/1994 #K90–1 (Blue Book Memo)	February 12, 1990	ODE/BlueBook	Do	361
Review of IDEs for Feasibility Studies #D89–1 (Blue Book Memo)	May 17, 1989	ODE/BlueBook	Do	362

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Toxicology Risk Assessment Committee #G89–1 (Blue Book Memo)	August 9, 1989	ODE/BlueBook	Do	363
Assignment of Review Documents #I90–2 (Blue Book Memo)	August 24, 1990	ODE/BlueBook	Do	366
Meetings With the Regulated Industry #I89–3 (Blue Book Memo)	November 20, 1989	ODE/BlueBook	Do	367
Policy Development and Review Procedures #I90–1 (Blue Book Memo)	February 15, 1990	ODE/BlueBook	Do	368
PMA Supplements: ODE Letter to Manufacturers; Identifies Situations Which May Require the Submission of a PMA Supplement (When PMA Supplements Are Required) #P90–1 (Blue Book Memo)	April 24, 1990	ODE/BlueBook	Do	387
510(k) Refuse to Accept Procedures #K94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	401
PMA Refuse to File Procedures #P94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	402
Premarket Approval Application (PMA) Closure #P94–2 (Blue Book Memo)	July 8, 1994	ODE/BlueBook	Do	403
PMA/510(k) Triage Review Procedures #G94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	404
Goals and Initiatives for the IDE Program #D95–1 (Blue Book Memo)	July 12, 1995	ODE/BlueBook	Do	405
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (Blue Book Memo #K95–1)	November 21, 1995	ODE/BlueBook	Do	406
IDE Refuse to Accept Procedures #D94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	410
Device Labeling Guidance #G91–1 (Blue Book Memo)	March 8, 1991	ODE/BlueBook	Do	414
Clinical Utility and Premarket Approval #P91–1 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	443
Panel Review of Premarket Approval Applications #P91–2 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	444
PMA Compliance Program #P91–3 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	445
Document Review Processing #I91–1 (Blue Book Memo)	February 12, 1992	ODE/BlueBook	Do	446
Integrity of Data and Information Submitted to ODE #I91–2 (Blue Book Memo)	May 29, 1991	ODE/BlueBook	Do	447
Nondisclosure of Financially Sensitive Information #I92–1 (Blue Book Memo)	March 5, 1992	ODE/BlueBook	Do	587
Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #G96–3))	August 9, 1996	ODE/BlueBook	Do	806
Continued Access to Investigational Devices During PMA Preparation and Review (Blue Book Memo) (D96–1)	July 15, 1996	ODE/BlueBook	Do	872

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
510(k) Additional Information Procedures #K93–1 (Blue Book Memo)	July 23, 1993	ODE/BlueBook	Do	886
Overdue IDE Annual Progress Report Procedures #D93–1 (Blue Book Memo)	July 23, 1993	ODE/BlueBook	Do	887
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93–1 (Blue Book Memo)	December 23, 1993	ODE/BlueBook	Do	920
Deciding When to Submit a 510(k) for a Change to an Exisiting Device; (Blue Book Memo #K97–1)	January 10, 1997	ODE/BlueBook	Do	1935
Interagency Agreement Between FDA and HCFA; #D95–2, Attachment A	September 15, 1995	ODE/BlueBook	Do	2106
Executive Secretaries Guidance Manual #G87–3	August 7, 1987	ODE/BlueBook	Do	2326
Criteria for Categorization of Investigational Devices (HCFA); #D95–2, Attachment B	September 15, 1995	ODE/BlueBook	Do	3106
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy—(Updated Checklist March 14, 1995)	June 30, 1993	ODE/BlueBook	Do	3859
HCFA Reimbursement Categorization Determinations for FDA-Approved IDEs	October 31, 1995	ODE/BlueBook	Do	4106
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	ODE/BlueBook	Do	4859
Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance; Draft Guidance—Not for Implementation	November 14, 2000	ODE Division of Clinical Laboratory Devices (DCLD)	Do	152
Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	August 31, 1995	ODE/DCLD	Do	1191
Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing; Draft	December 21, 1999	ODE/DCLD	Do	1359
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies Using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)	February 1, 1994	ODE/DCLD	Do	51
Review Criteria for Blood Culture Systems	August 12, 1991	ODE/DCLD	Do	82
Points to Consider for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance	September 26, 1994	ODE/DCLD	Do	95
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	ODE/DCLD	Do	122
Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies; Draft	August 31, 1995	ODE/DCLD	Do	1191
Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry	February 21, 1997	ODE/DCLD	Do	165

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Assessing the Safety/Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Points to Consider Regarding Labeling and Premarket Submissions; Draft	October 1, 1988	ODE/DCLD	Do	272
Guidance for Submission of Immunohistochemistry Applications to the FDA; Final	June 3, 1998	ODE/DCLD	Do	364
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	ODE/DCLD	Do	417
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	July 15, 1994	ODE/DCLD	Do	459
Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies; Draft	September 26, 1991	ODE/	Do	475
Points to Consider for Hematology Quality Control Materials	September 30, 1997	ODE/DCLD	Do	512
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	August 1, 1992	ODE/DCLD	Do	527
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter Dated March 14, 1996	February 1, 1996	ODE/DCLD	Do	553
Review Criteria for Devices Intended for the Detection of Hepatitis B ''e'' Antigen and Antibody to HBe	December 30, 1991	ODE/DCLD	Do	554
Guidance Criteria for Cyclosporine PMAs	January 24, 1992	ODE/DCLD	Do	564
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter Pylori	September 17, 1992	ODE/DCLD	Do	588
Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	September 27, 1995	ODE/DCLD	Do	592
Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) With Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bi; Draft	September 10, 1992	ODE/DCLD	Do	603
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	February 14, 1996	ODE/DCLD	Do	604
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	ODE/DCLD	Do	605
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	May 31, 1990	ODE/DCLD	Do	629
Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs; Draft	September 30, 1991	ODE/DCLD	Do	658
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	ODE/DCLD	Do	770

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance Document for 510(k) Submission of Fecal Occult Blood Tests; Draft	July 29, 1992	ODE/DCLD	Do	772
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	ODE/DCLD	Do	778
Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices; Draft	September 1, 1992	ODE/DCLD	Do	785
Review Criteria for the Assessment of Allergen-Specific Immunoglobulin E (IGE) In Vitro Diagnostic Devices Using Immunological Test Methodologies	March 2, 1993	ODE/DCLD	Do	800
Review Criteria for the Assessment of Anti-Nuclear Antibodies (ANA) In Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD) and Enzyme Linked Immunosorbant Assay (ELISA).	September 1, 1992	ODE/DCLD	Do	848
Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms; Draft	June 14, 1993	ODE/DCLD	Do	861
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)]	July 6, 1993	ODE/DCLD	Do	862
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	ODE/DCLD	Do	950
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA	September 19, 1996	ODE/DCLD	Do	957
Points to Consider for Cervical Cytology Devices	July 25, 1994	ODE/DCLD	Do	968
Review Criteria for In Vitro Diagnostic Devices That Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	February 15, 1996	ODE/DCLD	Do	980
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1102
In Vitro Diagnostic Chloride Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1103
In Vitro Diagnostic Creatinine Test System; Guidance for Industry; Final	July 2, 1998	ODE/DCLD	Do	1104
In Vitro Diagnostic Glucose Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1105
In Vitro Diagnostic Potassium Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1107
In Vitro Diagnostic Sodium Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1109
In Vitro Diagnostic Urea Nitrogen Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1110
Guidance for Administrative Procedures for CLIA Categorization; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance; Draft	August 14, 2000	ODE/DCLD	Do	1143

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications	March 1, 2001	ODE/DCLD	Do	1147
Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s	July 22, 2000	ODE/DCLD	Do	1171
Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s	July 22, 2000	ODE/DCLD	Do	1172
Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices; Draft	March 8, 2000	ODE/DCLD	Do	631
In Vitro Diagnostic C-Reactive Protein Immunological Test System; Guidance for Industry; Final	July 20, 1998	ODE/DCLD	Do	1246
Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Guidance for Industry: Final	February 22, 1999	ODE/DCLD	Do	1247
Guidance on Labeling for Laboratory Tests; Guidance for Industry; Draft	June 24, 1999	ODE/DCLD	Do	1352
Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease; Draft	October 8, 1999	ODE/DCLD	Do	1353
Class II Special Control Guidance Document for Anti-Saccharomyces Cerevisiae (S. Cerevisiae) Antibody (ASCA) Premarket Notifications; Final	August 23, 2000	ODE/DCLD	Do	1183
Guidance for Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final; Guidance for Industry and FDA	November 1, 2000	ODE/DCLD	Do	1184
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	October 30, 1996	ODE/DCLD	Do	1631
Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications; Guidance for Industry; Draft	November 14, 2000	ODE/DCLD	Do	2209
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Guidance for Industry	February 3, 1999	ODE/DCLD	Do	2231
Document for Special Controls for Erythropoietin Assay Premarket Notifications [510(k)s]; Guidance for Industry; Final	April 28, 1999	ODE/DCLD	Do	2241
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Guidance for Industry and FDA Reviewers/Staff; Final	April 27, 1999	ODE/DCLD	Do	2242
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers	November 30, 2000	ODE/DCLD	Do	1072
Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions	June 28, 2000	ODE Division of Cardiovascular and Respiratory Devices (DCRD)	Do	1161
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final	November 1, 2000	ODE/DCRD	Do	372

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Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers	November 8, 2000	ODE/DCRD	Do	1199
Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final	November 1, 2000	ODE/DCRD	Do	1357
Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff	January 31, 2001	ODE/DCRD	Do	1358
1–Consolidated Annual Report for a Device Product Line (1–CARD); Pilot for Preparation of Annual Reports for Pacemaker Premarket Approval Applications	July 6, 2000	ODE/DCRD	Do	1167
Excerpts Related to EMI From November 1993 Anesthesiology and Respiratory Devices Branch (Including Electromagnetic Compatibility Standard for Medical Devices; 10/1/79)	November 1, 1993	ODE/DCRD	Do	638
Guidance for Infant/Child Apnea Monitor 510(k) Submissions	September 22, 2000	ODE/DCRD	Do	1178
Guidance for Industry and for FDA Reviewers: Recommended Clinical Study Design for Ventricular Tachycardia Ablation	May 7, 1999	ODE/DCRD	Do	2244
Guidance for Industry: Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Draft	August 25, 1999	ODE/DCRD	Do	266
Guidance for Cardiovascular Intravascular Filter 510(k) Submission; Final	November 26, 1999	ODE/DCRD	Do	24
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Electrode—Version 1.0	February 11, 1997	ODE/DCRD	Do	25
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Lead Switching Adapter—Version 1.0	February 11, 1997	ODE/DCRD	Do	26
Guidance Document Device: Electrocardiograph (ECG) Surface Electrode Tester—Version 1.0	February 11, 1997	ODE/DCRD	Do	27
Draft Guidance Outline—Points to Consider for Clinical Studies for Vasovasostomy Devices	November 30, 1993	ODE/DCRD	Do	100
Medical Device Labeling—Suggested Format and Content; Draft Document	April 25, 1997	ODE/DCRD	Do	119
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	ODE/DCRD	Do	123
Policy for Expiration Dating (DCRD RB92–G)	October 30, 1992	ODE/DCRD	Do	137
Human Heart Valve Allografts; Draft	June 21, 1991	ODE/DCRD	Do	224
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final	February 16, 2000	ODE/DCRD	Do	1632
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final	February 21, 2000	ODE/DCRD	Do	1622
Balloon Valvuloplasty Guidance for the Submission of an IDE Application and a PMA Application	January 1, 1989	ODE/DCRD	Do	370
Replacement Heart Valve Guidance; Draft	October 14, 1994	ODE/DCRD	Do	375

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Implantable Pacemaker Testing Guidance	January 12, 1990	ODE/DCRD	Do	383
Letter/Guidance: Vascular Graft Manufacturer, Developer, or Representative	May 11, 1990	ODE/DCRD	Do	391
Reviewer Guidance for Ventilators; Draft	July 1, 1995	ODE/DCRD	Do	500
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	ODE/DCRD	Do	515
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	ODE/DCRD	Do	522
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	ODE/DCRD	Do	533
Letter: Notice to Manufacturers of Bone Mineral Densitometers	September 25, 1997	ODE/DCRD	Do	552
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Draft	September 30, 1997	ODE/DCRD	Do	560
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters	January 24, 1992	ODE/DCRD	Do	567
Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age	May 1, 1990	ODE/DCRD	Do	577
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	ODE/DCRD	Do	582
Draft Version: Electrode Recording Catheter Preliminary Guidance (Data to Be Sumitted to the FDA in Support of Premarket Notifications [510(k)s])	March 1, 1995	ODE/DCRD	Do	602
Cardiac Ablation Preliminary Guidance (Data to Be Submitted to the FDA in Support Investigation Device Exemption Application; Draft	March 1, 1995	ODE/DCRD	Do	619
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	ODE/DCRD	Do	621
Guidelines for Evaluation of Non-Drug IUDs	September 28, 1976	ODE/DCRD	Do	641
Simplified 510(k) procedures for certain radiology devices: 12/21, 1993, letter from L Yin, ODE/ODE/DRARD, to NEMA	December 21, 1993	ODE/DCRD	Do	708
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	ODE/DCRD	Do	768
Heated Humidifier Review Guidance	August 30, 1991	ODE/DCRD	Do	780
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	October 1, 1993	ODE/DCRD	Do	784
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	February 1, 1990	ODE/DCRD	Do	788
Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube With Valve	April 1, 1990	ODE/DCRD	Do	791
Guidance for Magnetic Resonance Diagnostic Devices—Criteria for Significant Risk Investigations	September 29, 1997	ODE/DCRD	Do	793

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Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	ODE/DCRD	Do	809
Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	ODE/DCRD	Do	810
Draft Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	May 30, 1997	ODE/DCRD	Do	842
Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents; Draft	May 1, 1995	ODE/DCRD	Do	846
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	ODE/DCRD	Do	850
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	ODE/DCRD	Do	866
Battery Guidance	July 12, 1993	ODE/DCRD	Do	873
Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses; Draft	August 1, 1993	ODE/DCRD	Do	885
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	ODE/DCRD	Do	892
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	ODE/DCRD	Do	899
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k)—Includes 00192	March 27, 1996	ODE/DCRD	Do	907
Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	ODE/DCRD	Do	953
Intravascular Brachytherapy—Guidance for Data to be Submitted to the Food and Drug Administration in Support of Investigational Device Exemption (IDE) Applications; Draft	May 24, 1996	ODE/DCRD	Do	955
Percutaneous Transluminal Coronary Angioplasty Package Insert Template; Draft	February 7, 1995	ODE/DCRD	Do	959
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	ODE/DCRD	Do	964
Guidance for Implantable Cardioverter-Defibrillators; Draft	June 24, 1996	ODE/DCRD	Do	965
Carotid Stent—Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications	October 26, 1996	ODE/DCRD	Do	974
Emergency Resuscitator Guidance; Draft	April 14, 1993	ODE/DCRD	Do	985
Review Guidelines for Oxygen Generators and Oxygen Equipment; Draft Document	April 14, 1993	ODE/DCRD	Do	986
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	ODE/DCRD	Do	991
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	ODE/DCRD	Do	992

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Reviewer Guidance on Face Masks and Shield for CPR; Draft	March 16, 1994	ODE/DCRD	Do	996
General Guidance Document: Non-Invasive Pulse Oximeter	September 7, 1992	ODE/DCRD	Do	997
Guidance for Peak Flow Meters for Over-the-Counter Sale	June 23, 1992	ODE/DCRD	Do	998
510(K) Submission Requirements for Peak Flow Meters; Draft	January 13, 1994	ODE/DCRD	Do	999
Guidance for Industry and FDA; Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	February 21, 2000	ODE/DCRD	Do	1126
Guidance Document for Premarket Notification Submission for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer; Final	January 24, 2000	ODE/DCRD	Do	1157
Latex Condoms for Men—Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	July 23, 1998	ODE/DCRD	Do	1250
Guidance for Industry—Uniform Contraceptive Labeling; Final	July 23, 1998	ODE/DCRD	Do	1251
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final	January 17, 2000	ODE/DCRD	Do	1361
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final	January 16, 2000	ODE/DCRD	Do	177
Federal Register Notice; Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k); Draft; Availability	September 10, 1998	ODE/DCRD	Do	1620
Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)	August 1, 1995	ODE/DCRD	Do	1907
Guidance for Industry and CDRH Reviewers—Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems; Final	August 7, 1998	ODE/DCRD	Do	2202
Noise Claims in Hearing Aid Labeling; Final	October 21, 1998	ODE/DCRD	Do	2210
Guidance for Industry—Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement); Final	November 5, 1998	ODE/DCRD	Do	2232
Guidance for Industry—Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); Final	November 5, 1998	ODE/DCRD	Do	2233
Guidance for Industry—Harmonic Imaging With/Without Contrast—Premarket Notification; Final	November 16, 1998	ODE/DCRD	Do	2234
Guidance for Industry—Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final	November 30, 1998	ODE/DCRD	Do	2235
Guidance for Industry—Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final	November 20, 1998	ODE/DCRD	Do	2238
Guidance for Industry—Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance; Version 1; Final	November 19, 1998	ODE/DCRD	Do	2239

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for Industry—Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Final	December 3, 1998	ODE/DCRD	Do	2240
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final	February 5, 1998	ODE/DCRD	Do	2243
Guidance for the Submission of 510(k)'s for Solid State X-Ray Imaging Devices; Final	August 6, 1999	ODE/DCRD	Do	644
Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices	July 30, 2000	ODE/DCRD	Do	1138
Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft	November 16, 1999	ODE Division of Dental, Infection Control and General Hospital Devices (DDIGD)	Do	1355
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft	February 8, 2000	ODE/DDIGD	Do	1156
Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA	March 2, 2001	ODE/DDIGD	Do	891
Guidance on the Content and Format of Premarket Notification 510(k) Submissions of Washers and Washer-Disinfectors	June 2, 1998	ODE/DDIGD	Do	4
Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final	April 21, 1999	ODE/DDIGD	Do	86
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for Prosthetic Attachment	May 16, 1989	ODE/DDIGD	Do	353
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	ODE/DDIGD	Do	392
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles	April 1, 1993	ODE/DDIGD	Do	450
Guidance Document on Dental Handpieces	July 1, 1995	ODE/DDIGD	Do	556
Guidance on the Content and Format of Premarket Notification 510(k) Submissions for Liquid Chemical Germicides	December 6, 1996	ODE/DDIGD	Do	576
Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes	April 1, 1993	ODE/DDIGD	Do	821
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers	March 1, 1993	ODE/DDIGD	Do	822
Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps	March 1, 1993	ODE/DDIGD	Do	823
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	ODE/DDIGD	Do	824
Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	March 1, 1993	ODE/DDIGD	Do	833

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	August 1, 1993	ODE/DDIGD	Do	881
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	ODE/DDIGD	Do	888
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	October 1, 1993	ODE/DDIGD	Do	895
Draft Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention Features (Antistick)	March 1, 1995	ODE/DDIGD	Do	934
Guidance for Industry and FDA Reviewers/Staff—Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Latex Products [Draize Testing]	January 13, 1999	ODE/DDIGD	Do	944
Information Necessary for Premarket Notification Submissions for Screw-Type Endossesous Implants	December 9, 1996	ODE/DDIGD	Do	948
Draft Guidance Document for the Preparation of Premarket Notification [510(k)'s] for Dental Alloys	March 3, 1997	ODE/DDIGD	Do	984
Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints	December 1, 1995	ODE/DDIGD	Do	993
Guidance on Premarket Notifications for Intravascular Administration Sets; Guidance for Industry and FDA Review Staff; Final	October 12, 2000	ODE/DDIGD	Do	1189
Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	September 19, 1995	ODE/DDIGD	Do	1833
Groups Capable of Testing for Latex Skin Sensitization (Addendum to #944)	July 28, 1997	ODE/DDIGD	Do	1944
Guidance for Industry and FDA Reviewers; Neonatal and Neonatal Transport Incubators—Premarket Notifications; Final	September 18, 1998	ODE/DDIGD	Do	2201
Dental Impression Materials—Premarket Notification; Final	August 17, 1998	ODE/DDIGD	Do	2203
Dental Cements Premarket Notification; Final	August 18, 1998	ODE/DDIGD	Do	2204
OTC Denture Cushions, Pads, Reliners, Repair Kits and Partially Fabricated Denture Kits; Final	August 18, 1998	ODE/DDIGD	Do	2205
Guidance for the Preparation of a Premarket Notification [510(k)] for Direct Filling Dental Composites	November 27, 1998	ODE/DDIGD	Do	642
Guidance and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants; Final	January 3, 2000	ODE/DDIGD	Do	397
Class II Special Control Guidance Document: Pharmacy Compounding Devices; Final Guidance for Industry and FDA	March 12, 2001	ODE/DDIGD	Do	1326
Guidance for Industry: Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Final	April 28, 1998	ODE Division of General, Restorative and Neurological Devices (DGRND)	Do	6

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	ODE/DGRND	Do	33
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	ODE/DGRND	Do	47
Letter: Core Study for Silicone Breast Implants	January 11, 1996	ODE/DGRND	Do	107
Protocol for Dermal Toxicity Testing for Devices in Contact With Skin (Draft)	January 1, 1985	ODE/DGRND	Do	124
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRND	Do	143
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 28, 1995	ODE/DGRND	Do	180
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	ODE/DGRND	Do	187
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	ODE/DGRND	Do	207
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	ODE/DGRND	Do	208
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	ODE/DGRND	Do	209
Draft Version Cranial Perforator Guidance	July 13, 1994	ODE/DGRND	Do	212
Draft Version Neuro Endoscope Guidance	July 7, 1994	ODE/DGRND	Do	214
Galvanic Skin Response Measurement Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRND	Do	215
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	February 18, 1993	ODE/DGRND	Do	233
Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered Muscle Stimulator 510(k)s; Final	June 9, 1999	ODE/DGRND	Do	2246
Guidance for Industry—Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Final	August 30, 1999	ODE/DGRND	Do	54
Guide for TENS 510(k) Content (Draft)	August 1, 1994	ODE/DGRND	Do	300
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment	July 26, 1995	ODE/DGRND	Do	307
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes	July 26, 1995	ODE/DGRND	Do	325
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Exercise Equipment	July 26, 1995	ODE/DGRND	Do	326
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	ODE/DGRND	Do	346

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems	January 10, 1995	ODE/DGRND	Do	355
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	ODE/DGRND	Do	386
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	ODE/DGRND	Do	453
Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft	March 18, 1998	ODE/DGRND	Do	487
Copy of October 9, 1992, Letter and Original Suture Labeling Guidance (Reformatted 12/17/1997)	October 9, 1992	ODE/DGRND	Do	502
Alternate Suture Labeling Resulting From the January 11, 1993, Meeting With HIMA (Reformatted 12/17/1997)	January 11, 1993	ODE/DGRND	Do	503
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	February 1, 1997	ODE/DGRND	Do	593
Draft Version—Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	ODE/DGRND	Do	627
Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	ODE/DGRND	Do	640
ORDB 510(k) Sterility Review Guidance	July 3, 1997	ODE/DGRND	Do	659
Draft Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD)	August 30, 1994	ODE/DGRND	Do	667
Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement, Request for Comments by December 10, 1993	November 1, 1993	ODE/DGRND	Do	668
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds	July 26, 1995	ODE/DGRND	Do	689
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths	July 26, 1995	ODE/DGRND	Do	729
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	July 26, 1995	ODE/DGRND	Do	735
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems	July 26, 1995	ODE/DGRND	Do	762
Electroencephalograph Devices Guidance for 510(k) Content; Draft	November 3, 1997	ODE/DGRND	Do	767
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators	July 26, 1995	ODE/DGRND	Do	818
Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement (Replaces 8623 and 8093)	April 28, 1994	ODE/DGRND	Do	827

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Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	July 26, 1995	ODE/DGRND	Do	828
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	ODE/DGRND	Do	829
Draft Guidance for the Preparation of Premarket Notifications [510(k)]s for Cemented, Semi-Constrained Total Knee Prostheses	April 1, 1993	ODE/DGRND	Do	830
Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices—The Basic Elements	July 16, 1997	ODE/DGRND	Do	832
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	ODE/DGRND	Do	904
Draft Guidance for Arthroscopes and Accessory 510(k)s	May 1, 1994	ODE/DGRND	Do	909
Guidance Document for Testing Biodegradable Polymer Implant Devices; Draft	April 20, 1996	ODE/DGRND	Do	914
Guidance Document for Testing Bone Anchor Devices; Draft	April 20, 1996	ODE/DGRND	Do	915
Guidance Document for Testing Non-Articulating, ''Mechanically Locked'', Modular Implant Components; Draft	May 1, 1995	ODE/DGRND	Do	916
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	ODE/DGRND	Do	956
Draft Guidance for Testing MR Interaction With Aneurysm Clips	May 22, 1996	ODE/DGRND	Do	958
Guidance for Industry—Guidance Document for Dura Substitute Devices; Final	August 13, 1999	ODE/DGRND	Do	1152
Guidance Document for Surgical Lamp 510Ks; Final	July 13, 1998	ODE/DGRND	Do	1244
Guidance for Industry—Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses; Draft	October 5, 1999	ODE/DGRND	Do	1354
Guidance Document for the Preparation of IDEs for Spinal Systems; Final	January 13, 2000	ODE/DGRND	Do	2250
Draft Guidance for the Preparation of an IDE Submission for a Interactive Wound and Burn Dressing	April 4, 1995	ODE/DGRND	Do	1817
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance—Guidance Document for Powered Suction Pump 510(k)s	October 30, 1998	ODE/DGRND	Do	2207
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final	March 2, 1999	ODE/DGRND	Do	2247
Class II Special Controls Guidance Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis; Final	October 31, 2000	ODE/DGRND	Do	1193
Guidance for Dermabrasion Devices; Final	March 2, 1999	ODE/DGRND	Do	2248
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing [510(k)]	May 31, 1995	ODE/DGRND	Do	2817

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Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Draft	December 16, 1999	ODE/DGRND	Do	1356
Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief; Guidance for Industry; Draft	September 6, 2000	ODE/DGRND	Do	1179
Guidance for Surgical Suture 510(k)s; Guidance for Industry; Final	August 10, 2000	ODE/DGRND	Do	1180
Guidance for Neurological Embolization Devices; Guidance for Industry; Final	November 1, 2000	ODE/DGRND	Do	1151
Guidance for Spinal System 510(k)s	September 27, 2000	ODE/DGRND	Do	636
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs	May 29, 1997	ODE Division of Ophthalmic and Ear, Nose, and Throat Devices (DOED)	Do	55
Announcement: Information for Manufacturers and Users of Lasers for Refractive Surgery [Excimer]	September 22, 1997	ODE/DOED	Do	93
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Mask—Draft	January 16, 1998	ODE/DOED	Do	94
New FDA Recommendations and Results of Contact Lens Study (7-Day Letter)	May 30, 1989	ODE/DOED	Do	265
Draft Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 1, 1997	ODE/DOED	Do	674
Important Information About Rophae Intraocular Lenses	August 20, 1992	ODE/DOED	Do	811
Draft Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses and 6/28, 1994, Corrections to Pages 18 and 20	May 12, 1994	ODE/DOED	Do	896
Retinoscope Guidance; Final	July 8, 1998	ODE/DOED	Do	1240
Guidance for Industry—Ophthalmoscope Guidance (Direct and Indirect)	July 8, 1998	ODE/DOED	Do	1241
Slit Lamp Guidance; Final	July 13, 1998	ODE/DOED	Do	1242
Guidance for Industry and FDA Staff—Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval (PMA) Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Final	August 11, 1998	ODE/DOED	Do	1249
Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft	August 4, 1999	ODE/DOED	Do	1350
Guidance on 510(k) Submissions for Keratoprostheses; Final	March 3, 1999	ODE/DOED	Do	1351
Amendment 1: Draft Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	ODE/DOED	Do	1896
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [Excimer]	October 10, 1996	ODE/DOED	Do	2093
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification [510(k)]	January 31, 1997	ODE/DOED	Do	2196

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Guidance Document for Nonprescription Sunglasses; Final	October 9, 1998	ODE/DOED	Do	2208
Aqueous Shunts—510(k) Submissions; Final	November 16, 1998	ODE/DOED	Do	2236
Discussion Points for Expansion of the ''Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers'' Draft Document	September 5, 1997	ODE/DOED	Do	7093
Intraocular Lens (IOL) Guidance Document; Draft	October 14, 1999	ODE/DOED	Do	834
Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications	August 1, 2000	ODE/DOED	Do	1145
Guidance on Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final	April 10, 2000	ODE/DOED	Do	1134
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final	March 12, 2000	ODE/DOED	Do	954
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch—Draft	April 13, 1994	ODE Division of Reproductive, Abdominal, and Radiological Devices (DRARD)	Do	398
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	ODE/DRARD	Do	96
Draft—510(k) Checklist for Conditioned Response Enuresis Alarms	November 23, 1994	ODE/DRARD	Do	99
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	ODE/DRARD	Do	161
Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology	March 17, 1995	ODE/DRARD	Do	162
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	ODE/DRARD	Do	166
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	ODE/DRARD	Do	189
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	ODE/DRARD	Do	190
Guidance (''Guidelines'') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	May 1, 1978	ODE/DRARD	Do	232
Guidance (''Guidelines'') for Evaluation of Fetal Clip Electrode	March 8, 1977	ODE/DRARD	Do	244
Guidance (''Guidelines'') for Evaluation of Tubal Occlusion Devices	November 22, 1977	ODE/DRARD	Do	245
Guidance (''Guidelines'') for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	ODE/DRARD	Do	248
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	ODE/DRARD	Do	298

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Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application For A Cochlear Implant in Children Ages 2 Through to 17 Years	May 1, 1990	ODE/DRARD	Do	327
Guidance for Industry—Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	November 14, 1998	ODE/DRARD	Do	340
Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	April 4, 1990	ODE/DRARD	Do	384
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 18, 1991	ODE/DRARD	Do	418
Guidance for the Content of Premarket Notifications for Conventional and Permeability Hemodialyzers; Final	August 7, 1998	ODE/DRARD	Do	421
Guidance for the Content of Premarket Notifications for Urethral Stents	February 10, 1993	ODE/DRARD	Do	431
Testing Guidance for Male Condoms Made From New Material (Non-Latex)	June 29, 1995	ODE/DRARD	Do	455
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	ODE/DRARD	Do	482
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	ODE/DRARD	Do	490
Guidance for Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport, and Storage of Organs for Transplantation; Final Guidance for Industry and FDA Reviewers	January 16, 2001	ODE/DRARD	Do	1164
Guidance for the Submission of Premarket Notifications for Medical Image Management Devices; Guidance for Industry; Final	July 27, 2000	ODE/DRARD	Do	416
Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final	August 9, 2000	ODE/DRARD	Do	1226
Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources; Guidance for Industry; Final	August 2, 2000	ODE/DRARD	Do	1177
Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA	February 16, 2001	ODE/DRARD	Do	983
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers	March 9, 2001	ODE/DRARD	Do	820
Class II Special Controls Guidance Document for Clitoral Engorgement Devices; Guidance for Industry and FDA Reviewers	July 3, 2000	ODE/DRARD	Do	1144
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE); Final	March 14, 1996	ODE/DRARD	Do	547
Draft Guidance for the Clinical Investigation of Urethral Stents	November 2, 1995	ODE/DRARD	Do	573

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Tympanostomy Tubes Submission Guidance for a 510(k) Premarket Notification; Final	January 14, 1998	ODE/DRARD	Do	930
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff	February 28, 2001	ODE Program Operations Staff (POS)	Do	310
PMA/510(k) Expedited Review #G98–4 (Blue Book Memo)	March 20, 1998	ODE/POS	Do	7
PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff [FDAMA]; Final	March 20, 1998	ODE/POS	Do	108
Deciding When to Submit a 510(k) for a Change to an Existing Device	January 10, 1997	ODE/POS	Do	935
A Suggested Approach to Resolving Least Burdensome Issues	September 11, 2000	ODE/POS	Do	1188
Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final; Guidance for Industry and FDA Staff	November 2, 2000	ODE/POS	Do	1195
FDA Modernization Act of 1997 Guidance for the Device Industry on Implementation of Highest Priority Provisions [FDAMA]	February 6, 1998	Office of Health and Industry Programs (OHIP)	Do	434
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies	August 13, 1998	OHIP	Do	1071
Compliance Guidance—The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections	May 5, 1999	OHIP Division of Mammography Quality and Radiation Programs (DMQRP)	Do	6400
Guidance for Submission of Request for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Acts, 42 U.S.C. 263(b)/4/8, 1998	March 26, 1998	OHIP/DMQRP	Do	69
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)/4/8, 1998	March 26, 1998	OHIP/DMQRP	Do	83
Compliance Guidance; The Mammography Quality Standards Act Final Regulations Document #4; Draft	September 13, 2000	OHIP/DMQRP	Do	1159
The Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #2; Final Guidance for Industry and FDA (Incorporated into PGHS)	January 24, 2001	OHIP/DMQRP	Do	1317
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3 (Incorporated into PGHS)	December 8, 1999	OHIP/DMQRP	Do	1496
Guidance: The Mammography Quality Standards Act Final Regulations Document #1 (Incorporated into PGHS)	March 4, 1999	OHIP/DMQRP	Do	1499
Policy and Standard Operating Procedures When Mammography Facilities in States That Have Accreditation Bodies Intend to Change Accreditation Bodies	April 15, 1998	OHIP/DMQRP	Do	1186

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. Section 263(b)	May 4, 1999	OHIP/DMQRP	Do	2217
Continuing Education Credit for Reading/Writing Articles/Papers and Presenting Courses/Lectures (Incorporated into PGHS)	March 17, 1998	OHIP/DMQRP	Do	66206
Guidance for Industry—Requalification for Interpreting Physician's Continuing Experience Requirement (Incorporated into PGHS)	May 28, 1998	OHIP/DMQRP	Do	66301
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly (Incorporated into PGHS)	March 23, 1999	OHIP/DMQRP	Do	2256
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation (Incorporated into PGHS)	December 7, 1999	OHIP/DMQRP	Do	1194
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 (Incorporated into PGHS)	February 25, 2000	OHIP/DMQRP	Do	1498
Compliance Guidance—Mammography Facility Survey, Equipment Evaluation and Medical Physicist Qualification Requirements Under MQSA; Final	November 6, 2000	OHIP/DMQRP	Do	6409
Medical Glove Guidance Manual Draft FDA 99–4257	August 12, 1999	OHIP Division of Small Manufacturers Assistance (DSMA)	Do	852
Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892	July 1, 1997	OHIP/DSMA	Do	12
An Introduction to Medical Device Regulations (FDA 92–4222)	January 1, 1992	OHIP/DSMA	Do	18
Regulatory Requirements for Devices for the Handicapped (FDA 87–4221)	August 1, 1987	OHIP/DSMA	Do	22
Impact Resistant Lenses: Questions and Answers (FDA 87–4002)	September 1, 1987	OHIP/DSMA	Do	23
Comparison Chart: 1996 Quality System Reg vs. 1978 Good Manufacturing Practices Reg vs. ANSI/ISO/ASQC Q9001 and ISO/DI 13485:1996 (Include 126)	November 29, 1996	OHIP/DSMA	Do	133
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution	February 19, 1998	OHIP/DSMA	Do	396
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158) [Available on Disk]	August 1, 1995	OHIP/DSMA	Do	469
Labeling—Regulatory Requirements for Medical Devices (FDA 89–4203)	September 1, 1989	OHIP/DSMA	Do	470
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (FDA 97–4224) [Available on Disk]	January 1, 1997	OHIP/DSMA	Do	471
Investigational Device Exemptions [IDE] Manual (FDA 96–4159) DSMA [Available on Disk]	June 1, 1996	OHIP/DSMA	Do	472

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Regulation of Medical Devices; Background Information for International Officials (Entire Document Available on Disk)	April 14, 1999	OHIP/DSMA	Do	610
Medical Device Reporting for Manufacturers [Available on Disk]	March 1, 1997	OHIP/DSMA	Do	987
Premarket Approval (PMA) Manual	January 1, 1998	OHIP/DSMA	Do	1051
Overview of FDA Modernization Act of 1997 Medical Device Provisions [FDAMA]	February 19, 1998	OHIP/DSMA	Do	1174
Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview and Procedure; Medical Device Annex, Version 7, June 29, 2000; Draft	June 29, 2000	OHIP/DSMA	Do	1175
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties	February 2, 2001	OHIP/DSMA	Do	1160
CDRH Manual for the Good Guidance Practices (GGP) Regulations; Final Guidance for FDA Staff	February 9, 2001	OHIP Division of Device User Programs and Systems Analysis (DUPSA)	Do	1323
Human Factors Principles for Medical Device Labeling	September 1, 1993	OHIP/DUPSA	Do	227
Human Factors Points to Consider for IDE Devices	January 17, 1997	OHIP/DUPSA	Do	839
Write It Right	August 1, 1993	OHIP/DUPSA	Do	897
Medical Device Reporting for User Facilities	April 1, 1996	OHIP/DUPSA	Do	989
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1, 1996	OHIP/DUPSA	Do	995
Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management; Guidance for Industry and FDA Premarket and Design Control Reviewers	July 18, 2000	OHIP/DUPSA	Do	1497
Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	April 19, 2001	OHIP/DUPSA	Do	1128
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)		Office of Surveillance and Biometrics (OSB) Division of Biostatistics (DB)	Do	78
PMA Review Statistical Checklist	(no date available)	OSB/DB	Do	84
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (Also Includes as Appendix the Article Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions	June 1, 1984	OSB/DB	Do	537
MDR Guidance Document: Remedial Action Exemption—E1996001; Final	July 30, 1996	OSB/DSS	Do	188
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Originial Equipment Manufacturer for Single Use	April 24, 2001	OSB/DSS	Do	1334
MDR Guidance Document No. 1–IOL–E1996004; Final	August 7, 1996	OSB/DSS	Do	216
MDR Guidance Document No. 3—Needlestick and Blood Exposure—E1996003; Final	August 9, 1996	OSB/DSS	Do	250

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Common Problems: Baseline Reports and Medwatch Form 3500A	January 1, 1997	OSB/DSS	Do	379
MDR Reporting Guidance for Breast Implants—E1996002; Final	August 7, 1996	OSB/DSS	Do	452
Medical Device Reporting: An Overview; Final	April 1, 1996	OSB/DSS	Do	509
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH)(MDR); Final	December 15, 1995	OSB/DSS	Do	853
MEDWATCH FDA Form 3500A for Use by User Facilities, Distributors and Manufacturers for Mandatory Reporting (MDR); Final	June 1, 1993	OSB/DSS	Do	854
Variance From Manufacturer Report Number Format [MDR Letter]; Final	July 16, 1996	OSB/DSS	Do	1059
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report [MDR]; Final	March 31, 1997	OSB/DSS	Do	1061
MDR Internet List Server (listserv) Instruction Sheet; Final	August 29, 1996	OSB/DSS	Do	1094
Medical Device Reporting-Alternative Summary Reporting (ASR) Program; Guidance for Industry	October 19, 2000	OSB/DSS	Do	315
Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (MDR); Final	June 9, 1999	OSB/DSS	Do	1853
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	OSB Issues Management Staff (IMS)	Do	206
Guidance on Criteria and Approaches for Postmarket Surveillance	November 2, 1998	OSB/IMS	Do	9
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies [FDAMA]; Final	February 19, 1998	OSB/IMS	Do	316
Guidance on Procedures for Review of Postmarket Surveillance Submissions [FDAMA]; Final	February 19, 1998	OSB/IMS	Do	317
Guidance for Industry and FDA Staff—SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols [FDAMA]; Final	November 2, 1998	OSB/IMS	Do	318
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	March 30, 1994	OSB/IMS	Do	374
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	February 2, 2000	OSB/IMS	Do	946
Guidance on Frequently Asked Questions on Recognition of Consensus Standards [FDAMA]	December 21, 1998	Office of Science and Technology (OST)	Do	109
Guidance on the Recognition and Use of Consensus Standards/Appendix A [FDAMA]	February 19, 1998	OST	Do	321
A Primer on Medical Device Interactions With Magnetic Resonance Imaging Systems; Draft	February 7, 1997	OST	Do	952
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition	August 6, 1999	OST	Do	616

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problems	May 15, 1998	OST	Do	2000
Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing	May 6, 1999	OST Division of Life Sciences (DLS)	Do	635

WITHDRAWALS

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, Draft Guidance—Not for Implementation (Replaced by Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff 8/14/00)	February 8, 2000	OC	August 8, 2000	801029
Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Guidance for Industry (Replaced by Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA 4/2/01)	October 18, 1999	OC/DOEI	March 30, 2001	802619
Final Design Control Report and Guidance (No Replacement)	June 1, 1998	OC/DOEIII	July 24, 2000	800949
Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule (No Replacement)	July 1, 1995	OC/OT	April 24, 2000	800303
Guidance on Amended Procedures for Advisory Panel Meetings [FDAMA]; Final (Replaced by Guidance on Amended Procedures for Advisory Panel Meetings, 7/22/00)	January 26, 1999	ODE	August 4, 2000	800413
Review Criteria for Assessment of Antimicrobial Susceptibility Devices (Replaced by Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices, 3/8/00)	May 31, 1991	ODE/DCLD	June 16, 2000	800631
Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used by the Consumer; Guidance for Industry; Draft (Replaced by Over-the-Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications; Guidance for Industry; Draft 11/14/00)	December 30, 1998	ODE/DCLD	October 30, 2000	802209
Guidance Document for Vascular Prostheses 510(k) Submission; Final (Replaced by Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final 11/1/00)	November 1, 2000	ODE/DCRD	January 16, 2000	801357
Guidance to Manufacturers on the Development of Required Postapproval Epidemiological Study Protocols for Testicular Implants (No Replacement)	Date not available	ODE/DCRD	June 15, 2000	800202
510(k) Reviewer Guidelines—Tracheostomy Tubes 868.5800 (No Replacement)	Date not available	ODE/DCRD	June 15, 2000	800550

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for the Comment and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices (Replaced by Guidance for the Submission of Premarket Notifications for Medical Image Management Devices; Guidance for Industry; Final 7/27/00)	August 1, 1993	ODE/DCRD	August 8, 2000	800416
Guidance for Industry—Guidance for the Content of Premarket Notifications [510(k)s] for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi (Replaced by Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final 8/9/00)	February 8, 1999	ODE/DCRD	August 10, 2000	801226
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II (No Replacement)	February 1, 1989	ODE/DCRD	August 30, 2000	800583
Reviewer's Guidance for Oxygen Concentrator (No Replacement)	August 30, 1991	ODE/DCRD	August 30, 2000	800781
Guidance Document for Vascular Prostheses 510(k) Submission; Final (Replaced by Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final 11/1/00)	November 26, 1999	ODE/DCRD	November 16, 2000	801357
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final (Replaced by Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final 11/1/00)	January 14, 2000	ODE/DCRD	January 21, 2000	800372
Draft Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi (Replaced by Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final 8/9/00)	February 5, 1992	ODE/DCRD	January 10, 2001	800864
Guidance for Annuloplasty Rings 510(k) Submissions; Final (Replaced by Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff 1/31/01)	November 26, 1999	ODE/DCRD	February 12, 2001	801358
Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications (Replaced by Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers, 3/9/01)	July 30, 1999	ODE/DCRD	March 2001	800820
Status Update—Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems (Replaced by Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA 2/16/01)	February 4, 1999	ODE/DCRD	February 27, 2001	800983
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants (includes Addendum of 3/9, 1994) (No Replacement)	October 1, 1993	ODE/DDIGD	August 10, 2000	800902
Guidance for the Preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers (No Replacement)	April 1, 1991	ODE/DDIGD	September 1, 2000	800028

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for Spinal System 510(k); Final (Replaced by Guidance for Spinal System 510(k)s 9/27/00)	May 7, 1999	ODE/DGRND	October 2, 2000	800636
Guidance for Industry—Guidance Document for Neurological Embolization Devices; Final (Replaced by Guidance for Neurological Embolization Devices; Guidance for Industry; Final 11/1/00)	August 13, 1999	ODE/DGRND	November 7, 2000	801151
Ophthalmic Device Triage (No Replacement)	March 19, 1998	ODE/DOED	June 20, 2000	800160
Announcement by Dr Alpert at 7/26, 1996, Ophthalmic Panel Meeting Concerning Manufacturers and Users of Lasers for Refractive Surgery [Excimer] (No Replacement)	August 26, 1996	ODE/DOED	July 17, 2000	803093
Owners Certification of Lasers as PMA Approved Devices [Excimer] (No Replacement)	September 26, 1996	ODE/DOED	July 17, 2000	804093
Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA (Replaced by Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA; Final 11/6/00)	May 5, 1999	OHIP/DMORP	April 8, 2000	806409
A Pocket Guide to Device GMP Inspections—Inspections of Medical Device Manufacturers and GMP Regulation Requirements (No Replacement)	November 1, 1991	OHIP/DSMA	June 28, 2000	800508
Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997—June 2000; Draft (Replaced by Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties 2/2/01)	June 12, 2000	OHIP/DSMA	February 2, 2001	801160
Guidance for Industry—Device Use Safety: Incorporating Human Factors in Risk Management (No Replacement)	August 3, 1999	OHIP/DUPSA	July 20, 2000	801497
Guidance on Medical Device Patient Labeling; Final Guidance for Industry (Replaced by Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers 4/19/01)	March 3, 2000	OHIP/DUPSA	April 9, 2001	801128
MDR Documents Access Information for National Technical Information Service (NTIS) (No Replacement)	May 10, 1996	OSB	June 28, 2000	803799
Proposed Draft Guidance to Sponsors Regarding Required Postmarket Surveillance Studies of Plasma-Sprayed Porous-Coated Hip Prostheses (Archived by OSB—Replaced by Guidance Testing Metallic Plasma Sprayed Orthopedic Implants, 2/2/00)	October 7, 1994	OSB/DPS	June 16, 2000	800323
Letter to Manufacturers: Summary Reporting Approval for Adverse Events; Final (Replaced by Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry 10/19/00)	July 31, 1997	OSB/DSS	October 30, 2000	800315
Draft Thermal Endometrial Ablation Devices (Submission Guidance for an IDE) (Replaced by Thermal Endometrial Ablation Devices (Submission Guidance for an IDE); Final 3/14/96))	March 14, 1996	ODE/DCRD	March 1996	800547
Guidance for Review of Cases of Possible Suspension or Revocation of Mammography Facility Certificates Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)/4/8, 1998 (No Replacement)	March 26, 1998	OHIP/DMORP	May 23, 2001	800080

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA , Draft (replaced by Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA; Final 11/6/00	May 5, 1999	OHIP/DMORP	November 8, 2000	806409

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Compliance Policy Guides Manual	1998	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, NTIS Order No. PB96–920500
Compliance Programs Guidance Manual	1995	FDA Regulated Industries	Do (NTIS Order No. PB95–915499
FDA Recall Policy	1995	FDA Regulated Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204
Investigators' Operations Manual	May 1996	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB–95–913399)
Regulatory Procedures Manual	August 1995	FDA Regulated Industries	Do (NTIS Order No. PB95–265534)
Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration ''Blue Book''	1997	FDA Regulated Industries	Superintendent of Documents, Government Printing Office, Washington, DC 20402
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, (NTIS Order No. PB96–920500)
Pesticides Analytical Manual	1996	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB94–911899)
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed	September 16, 1993	Food and Animal Feed Industries	Office of Plant and Dairy Foods and Beverages, Food and Drug Administration (HFS–306), 200 C St. SW., Washington, DC 20204, 202–205–4681
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic Industry	Food and Drug Administration, Office of Colors and Cosmetics (HFS–105), 200 C St. SW., Washington, DC 20204, 202–205–4493
Statement of Policy: Foods Derived From New Plant Varieties: Notice	May 29, 1992	Developers of New Plant Food Varieties	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
A Food Labeling Guide	May 1997	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Model Small Business Food Labeling Exemption Notice	1998	Food Industry	Do
Food Labeling: Questions and Answers	August 1994	Food Industry	Do

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Food Labeling: Questions and Answers: Volume II	February 1996	Food Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20420, 202–512–1800
Fair Packaging and Labeling Act Manual	June 1978	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650, (NTIS Order No. PB–83–222117)
Bacteriological Analytical Manual 7th Edition	1992	FDA Regulated Industries	AOAC International, 481 N. Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, 301–924–7077
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1985	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Evaluation of Milk Laboratories	1995	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Methods of Making Sanitation Ratings of Milk Supplies	1999	States	Do
Dry Milk Ordinance	1995	States	Do
Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers	1999	Dairy Industry	Do
Frozen Dessert Processing Guidelines	1989	Dairy Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Pasteurized Milk Ordinance	1999	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Guidelines for Determining Metric Equivalents of Household Measures	October 1, 1993	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration (HFS–800), 200 C St. SW., Washington, DC 20204, 202–205–4561
List of Food Defect Action Levels (DALs)	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Action Levels for Poisonous or Deleterious Substances in Human Food and Feed (Also Found in CPGs)	1995	Food and Animal Feed Industries	Do
FDA Food Code	1999	States	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650
Seafood List	1993	Seafood Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20402, 202–512–1800
Manual of Operations National Shellfish Sanitation	1992	States	Office of Seafood (HFS–407), Shellfish Sanitation Branch, 200 C St. SW., Washington, DC 20204, 202–418–3150

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Fish and Fisheries Product Hazards and Control Guide	1996	Seafood Industry	Do
Guidance for Submitting Requests Under 21 CFR 170.39, Threshold of Regulation for Substances Used in Food Articles	1996	Food Packaging Industry	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Guidelines for the Preparation of Petition Submissions	1996	Food Ingredient or Packaging Industry	Do
Guideline for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or Contact Lens Industry	Do
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs or Cosmetics Use	February 1993	Color Additives Industry	Do
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Food Packaging Industry	Do
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	Food Packaging Industry	Do
Recommendations for Chemistry Data for Indirect Food Additive Petitions	June 1995	Food Packaging Industry	Do
Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions	January 1993	Food Enzyme Industry	Do
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet	September 1995	Food and Food Ingredient Industry	Do
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I)	1982	Petitioners for Food or Color Additives	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 2216, (NT IS Order No. PR–83–170696
Environmental Assessment Technical Handbook	March 1987	Petitioners for Food or Color Additives	Do (NTIS Order No. PB87175345–AS, A–01)
Color Additive Petitions Information and Guidance	1996	Petitioners for Color Additives	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Toxological Testing of Food Additives	1983	Petitioners for Food or Color Additives	Do
List of Products for Each Product Category	October 8, 1992	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561
Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers	June 10, 1996	Food Industry	Do
Guidance on Labeling of Foods That Need Refrigeration by Consumers	February 24, 1997	Food Industry	Do
Guidelines Concerning Notification and Testing of Infant Formula	1985	Infant Formula Manufacturers	Do

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Guidelines for the Evaluation of Safety and Suitability of New Infant Formulas for Feeding Preterm Infants	1988	Infant Formula Manufacturers	Do
Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants	1988	Infant Formula Manufacturers	Do
Guidelines for the Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants With Allergic Diseases	1990	Infant Formula Manufacturers	Do
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children and Pregnant Women With Metabolic Disorders	1987	Infant Formula Manufacturers	Do
Guidance Document for Arsenic (Trace Elements in Seafood)	January 1993	States	Office of Seafood, Food and Drug Administration (HFS–400), 200 C St. SW., Washington, DC 20204, 202–418–3150, Internet: FDA Home Page Http://vm.cfsan.fda.gov/list.html
Guidance Document for Cadmium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Chromium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Lead (Trace Elements in Seafood)	August 1993	States	Do
Guidance Document for Nickel (Trace Elements in Seafood)	January 1993	States	Do
Guidance on Consultation Procedures for Foods Derived From New Plant Varieties	October 1997	Regulated Industry	Office of Premarket Approval (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100, Internet: FDA Home Page Http://vm.cfsan.fda.gov
FDA's Policy for Foods Developed by Biotechnology	1995	Food Industry	Do
Bovine Spongiform Encephalopathy (BSE) in Products for Human Use	1997	Food Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175, Internet: FDA Home Page Http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm
Interim Guidance on the Voluntary Labeling of Milk and Milk Products That Have Not Been Treated With Recombinant Bovine Somatropin	February 1994	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168
Shellfish Sanitation Model Ordinance	1995	States	Shellfish Program Implementation Branch, Division of Cooperative Programs, Office of Field Programs (HFS–628), 200 C St. SW., Washington, DC 20204, 202–205–8137
Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables (Available in English, Spanish, Portuguese, and French)	1998	Farmers and Food Packers	Food Safety Initiative (HFS–32), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, or jsaltsman@bangate.fda.gov

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging; Small Entity Compliance Guide	1997	Dietary Supplement Manufacturers: Small Entities	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–450), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Partial List of Enzyme Preparations That Are Used in Foods	1998	FDA Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998	FDA Regulated Industry	Do
Fish and Fishery Products Hazards and Controls Guide, 2d Edition	January 1998	FDA Regulated Industry	Office of Seafood (HFS–400), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
HACCP Regulations for Fish and Fishery Products: Questions and Answers	1998	FDA Regulated Industry	Do
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	1998	FDA Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–150), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
FDA Nutrition Labeling Manual, A Guide for Developing and Using Data Bases	March 1998	FDA Regulated Industry	Do
HACCP Regulation for Fish and Fishery Products: Questions and Answers, Issue Three, Revised January 1999	January 1999	Seafood Processors	Office of Seafood (HFS–400), Center for Food Safety and Nutrition, 200 C St. SW., Washington, DC 20204, Ellen Nesheim, 202–418–3150
Foods—Adulteration Involving Hard or Sharp Foreign Objects (CPG)	February 1999	FDA Field Offices	Office of Plant and Dairy Foods and Beverages (HFS–300), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Food Additive Petition Expedited Review	January 1999	Guidance for Industry and Center for Food Safety and Applied Nutrition Staff	Robert L. Martin (HFS–215), OPA/CFSAN/FDA, 200 C St. SW., Washington, DC 20204, 202–418–3074, premarkt@cfsan.fda.gov or http://vm.cfsan.fda.gov/≤dms/opa-expe.html
Use of Antibiotic Resistance Marker Genes in Transgenic Plants	September 1998	Guidance for Industry	Nega Beru (HFS–206), OPA/CFSAN/FDA, 200 C St. SW., Washington, DC 20204, 202–418–3097, premarkt@cfsan.fda.gov or http://vm.cfsan.fda.gov//≤dms/opa-armg.html
Guidance: Channels of Trade Policy for Commodities With Methyl Parathion Residues	December 2000	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition (HFS–300), FDA, 200 C St. SW., Washington, DC 20204, http://vm.cfsan.fda.gov/'dms
Draft Guidance: Fumonisin Levels in Human Foods and Animal Feeds	June 2000	Regulated Industry	Do
Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide	January 1999	Small Business Entities	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999)	December 1999	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Antimicrobial Food Additives	July 1999	Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–418–3100
Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations	November 1999	Regulated Industry	Do
Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations	November 1999	Regulated Industry	Do
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking	October 1999	Small Business Entities	Division of Market Studies (HFS–726), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC 20204, 202–401–4590
Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide	September 1998	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561
Reducing Microbial Food Safety Hazards for Sprouted Seeds	October 1999	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production	October 1999	Regulated Industry	Do
Seafood HACCP Transition Policy	December 1999	Regulated Industry	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–3150
FDA Recommendations for Sampling and Testing Yellow Corn Shipments for Cry9C Protein Residues	January 19, 2001	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Draft Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering	January 2001	Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–418–3100
Bacteriological Analytical Manual	2001	Regulated Industry	Do
Importation of PMO Defined Dairy Products	April 11, 2000	Dairy Industry	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Draft Guidance: Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin	June 2000	Juice Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Draft Guidance for Industry on Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products	November 2000	Seafood Industry	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–3150

WITHDRAWALS

Name of Document	Date of Issuance/ Date Withdrawn	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases (Replaced by 1998 update with the same title.)	1993/June 2001	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration (HFS–800), 200 C St. SW., Washington, DC 20204, 202–205–4561
Fabrication of Single Service Containers and Closures for Milk and Milk Products (Incorporated into Pasteurized Milk Ordinance as an appendix.)	1995/June 2001	States	Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175

VI. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR VETERINARY MEDICINE (CVM)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Equine (VICH GL15)—Draft	September 2000	Animal Drug Industry	Internet via: http://www.fda.gov/cvm Communications Staff (HFV–12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301–827–4582, FAX 301–594–1831
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Porcine (VICH GL16)—Draft	September 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Canine (VICH GL19)—Draft	September 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Feline (VICH GL20)—Draft	December 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Poultry (VICH GL21)—Draft	December 2000	Do	Do
Guidance for Industry: Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies (VICH GL22)—Draft	December 2000	Do	Do
Guidance for Industry: Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies (VICH GL23)—Draft	December 2000	Do	Do
Guidance for Industry: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs)(VICH GL24)—Draft	December 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: General Recommendations (VICH GL7)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Bovines (VICH GL12)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Ovines (VICH GL13)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Caprines (VICH GL14)—Final	March 2000	Do	Do

VI. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR VETERINARY MEDICINE (CVM)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs)—Phase I (VICH GL6)—Final	March 2000	Do	Do
Guidance for Industry: Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products (VICH GL17)—Final	March 2000	Do	Do
Guidance for Industry: Good Clinical Practices (VICH GL9)—Final	May 2000	Do	Do
Guidance for Industry: Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (VICH GL18)—Final	May 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter (NFDAs)	February 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes	February 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation	February 2000	Do	Do
How to Use E-Mail to Submit Information to the Center for Veterinary Medicine—Final	February 2000	Do	Do
Dioxin in Anti-Caking Agents Used in Animal Feed and Feed Ingredients	Revised April 2000	Do	Do
Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds—Draft	June 2000	Do	Do
The Use of Published Literature in Support of New Animal Drug Approval	November 2000	Do	Do
Guidance for Industry: Bioequivalence Guidance	Revised October 2000	Do	Do
Guidance for Industry #124: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering—Draft	January 2001	Do	Do
Guidance for Industry #126: BACPAC I: Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation, February 2001	February 2001	Do	Do
Guidance for Industry #120: Veterinary Feed Directive Regulation	March 2001	Do	Do
Guidance for Industry #121: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims	March 2001	Do	Do

VI. Guidance Documents Issued by the Center for Veterinary Medicine (CVM)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry and Reviewers: How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug—Draft	March 2001	Do	Do

VII. Guidance Documents Issued by the Office of Policy (OP)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry; Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Regulated Industry	Internet via www.fda.gov/opacom/fedregister/frexport.html or 63 FR 32219, June 12, 1998, or Office of Policy, 301–827–3360
Direct Final Rule Guidance	November 21, 1997	FDA Personnel	Internet via www.fda.gov/opacom/morechoices/industry/guidance.htm or 62 FR 62467, November 21, 1997, or Office of Policy, 301–827–3480
International Harmonization; Policy on Standards	October 1995	FDA Personnel and Regulated Industry	60 FR 53078, October 11, 1995, or Office of Policy, 301–827–3360

Withdrawals

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date Withdrawn
FDA's Development, Issuance and Use of Guidance Documents	February 27, 1997	FDA Personnel and Regulated Industry	September 19, 2000
Small Entities Compliance Guide On: Regulations To Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)	February 1997	Regulated Industry	March 31, 2000
Children and Tobacco—Frequently Asked Questions About the New Regulations (Draft)	July 1997	Regulated Industry	March 31, 2000
Children and Tobacco—A Retailers Guide to the New Federal Regulations	October 1997	Regulated Industry	March 31, 2000
Children and Tobacco—A Guide to the New Federal Regulations	October 1997	Regulated Industry	March 31, 2000

VIII. Guidance Documents Issued by the Office of Regulatory Affairs (ORA)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Compliance Policy Guide Manual—Compliance Policy Guidance for FDA Staff (Replaces Compliance Policy Guide—January 1996)	August 2000	FDA Staff	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 or Internet at: www.fda.gov/ora/cpgm/default.html
Compliance Policy Guide, New Sec. 615.115 Extra-Label Use of Medicated Feeds for Minor Species	April 2001	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Compliance Policy Guide, New Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens	April 2001	Do	Do
Compliance Policy Guide, Reformat Sec. 220.100 Interstate Shipment of Biological Products for Use in Medical Emergencies	March 2001	Do	Do
Compliance Policy Guide, Reformat Sec. 270.100 Final Container Labels—Allergenic Extracts Containing Glycerin; Reporting Changes	March 2001	Do	Do
Compliance Policy Guide, Draft Sec. 230.150, Blood Donor Incentives	December 2000	Do	Do
Compliance Policy Guide, Draft Distributor Medical Reporting	August 28, 1997	FDA Staff Personnel and Regulated Industry	Do Internet at: www.fda.gov/ora/compliance—;ref/cpg—;mdr3.txt
Compliance Policy Guide Sec. 7150.09 Fraud, Statements of Material Facts, Bribery, and Illegal Gratuities	July 1991	FDA Staff and Regulated Industry	Do Internet at: www.fda.gov/ora/compliance—;ref/aip—;page.html
Medical Device Warning Letter Pilot	March 8, 1999	FDA Staff and Regulated Industry	Do Internet at: www.fda.gov/ohrms/Dockets/98fr/030899e.pdf
Glossary of Computerized System and Software Development Terminology	August 1995	Do	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127352) or via Internet: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guidelines for Entry Review of Radiation-Emitting Electronic Devices	March 12, 1999	FDA Staff	Division of Import Operations and Policy (HFC–170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1218
Laboratory Procedures Manual	June 1994	Do	Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, or Internet at: www.fda.gov/ora/science—;ref/lpm/lpmtc.html
Laboratory Procedures Manual Chapter X, New: Method Validation Samples	May 1999	Do	Do
Memorandum: ORA Investigational Strategy on Gamma-Butyrolactone (GBL) and Related Products	May 15, 2000	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Not Available on the Internet
Investigations Operations Manual	January 2001	Do	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB2001–913399 and Internet at www.fda.gov/ora/inspect—;ref/iom/default.htm)
Medical Devices: Draft Guidance entitled ''Guidance for FDA Staff on Civil Money Penalty Policy''	Released for Comment June 8, 1999	FDA Staff	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420, or Internet at: http://www.fda.gov/ohrms/dockets/98fr/060899e.pdf

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Regulatory Procedures Manual Update/ New Subchapter 5 Civil Money Penalty Reduction Policy for Small Entities	April 19, 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual New RPM Subchapter: Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual: Update, New Subchapter Application Integrity Policy	March 1998	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual: Update/ Revision Subchapter/Priority Enforcement Strategy for Problem Importers	April 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Notice of Sampling	April 1998	FDA Staff	Do
Regulatory Procedures Manual: Update New Subchapter/Granting and Denying Transportation and Exportation (T&E) Entries	May 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Seizure	June 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch6.html
Regulatory Procedures Manual: Update/ Revision Subchapter/Supervisory Charges	June 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/new2/ch9chgs.html
Regulatory Procedures Manual: New Subchapter: Civil Penalties—Electronic Product Radiation Control	July 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/ch6civpen.html
Regulatory Procedures Manual: Update/ Revision, Chapter 4, Subchapter/ Warning Letters	March 21, 2000	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch4.html
Regulatory Procedures Manual New Chapter 9, Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs in Cases Involving Imported Food	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch9civmonpen.html
Regulatory Procedures Manual New Chapter 9, Secured Storage	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch9securedstorage.html
Guide to Inspections of Bulk Pharmaceutical Chemicals	May 1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB96–127154) or via Internet at: www.fda.gov/ora/inspect)—;ref/igs/iglist.html
Guide to Inspections of Pharmaceutical Quality Control Laboratories	July 1993	Do	Do (NTIS Order No. PB96–127279) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do	Do (NTIS Order No. PB96–127287) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do	Do (NTIS Order No. PB96–127246) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do	Do (NTIS Order No. PB96–127253) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of High Purity Water Systems	July 1993	Do	Do (NTIS Order No. PB96–127261) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Dosage Form Drug Manufacturers—CGMPs	October 1993	Do	Do (NTIS Order No. PB96–127212) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Vaccination	January 1994	Do	Do (NTIS Order No. PB96–127345) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Topical Drug Products	July 1994	Do	Do (NTIS Order No. PB96–127394) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do	Do (NTIS Order No. PB96–127295) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do	Do (NTIS Order No. PB96–127147) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do	Do (NTIS Order No. PB96–127378) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do	Do (NTIS Order No. PB96–127386) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do	Do (NTIS Order No. PB96–127329) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. 1	May 1995	Do	Do (NTIS Order No. PB97–127220) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. 11	September 1996	Do	Do (NTIS Order No. PB97–196133) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 1—Administrative Procedures/Scheduled Processes	November 1996	Do	Do (NTIS Order No. PB97–196141) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do	Do (NTIS Order No. PB96–127238) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 2—Processes/ Procedures	April 1997	Do	Do (NTIS Order No. PB97–196158) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 3—Container Closurers	July 2001	FDA Staff	Do (NTIS Order No. PB00–133795)
Guide to Inspections of Blood Banks	September 1994	Do	Do (NTIS Order No. PB96–127303) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Source Plasma Establishments	December 1994	Do	Do (NTIS Order No. PB96–127360) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1996	Do	Do (NTIS Order No. PB96–199476) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Biotechnology Inspections Guide	November 1991	Do	Do (NTIS Order No. PB96–127402) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Computerized Systems in Drug Processing	February 1983	Do	Do (NTIS Order No. PB96–127337) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Foreign Medical Device Manufacturers	September 1995	Do	Do (NTIS Order No. PB96–127311) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Foreign Pharmaceutical Manufacturers	May 1996	Do	Do (NTIS Order No. PB96–199468) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Mammography Quality Standards Act (MQSA) Auditors Guide	January 1998	Do	Do (NTIS Order No. PB98–127178) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems	December 1997	Do	Do (NTIS Order No. PB98–127152) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Acidified Food Manufacturers	May 1998	Do	http://www.fda.gov/ora/inspect—;ref/igs/acidfgde.htm
Guide to Inspection of Aseptic Processing and Packaging for the Food Industry	February 2001	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1240
Guide to Inspections of Grain Product Manufacturers	March 1998	Do	(NTIS Order No. PB–98–137128) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Bioresearch Monitoring Inspections of In Vitro Devices	February 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Trace Back of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	April 2001	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igf/foodcomp.html
Guide to International Inspections and Travel, Revision (Formerly, FDA/ORA International Inspection Manual and Travel Guide)	July 1999	Do	Do Revision not available on Internet

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Quality Systems	August 1999	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/qsit/QSITGUIDE.PDF
Guide to Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients	April 2001	Do	Do Internet at: http://www.fda.gov/ora/inspect—;ref/igs/iglist.html
Computerized Systems Used in Clinical Trials	April 1999	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/ffinalact.html
Compliance Program 7348.001: Bioresearch Monitoring, Human Drugs, In Vivo Bioequivalence	October 1, 1999	D0	Do Internet at: www.fda.gov/ora/compliance—;ref/Bimo/7348—;001/default.html
Good Laboratory Practice Program (Nonclinical Laboratories) 7348.808A; EPA Data Audit Inspections	October 1, 1991	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Guideline for the Monitoring of Clinical Investigators	January 1988	FDA Regulated Industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Small Business Guide to FDA (FDA 96–1092)	January 1, 1996	Do	Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2905 Internet at: www.fda.gov/ora/indust—;assit/default.htm
Compliance Program 7348.808 Bioresearch Monitoring: Good Laboratory Practices (Nonclinical)	Revised August 17, 1998	FDA Staff	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/default.html
Compliance Program 7348.809 Bioresearch Monitoring: Institutional Review Board	August 18, 1994	Do	Do
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	Revised October 30, 1998	Do	Do
Good Laboratory Practice Regulations Management Briefings	August 1979	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/default.html
Draft: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	March 31, 2000	FDA Regulated Industry	Do

Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–26650 Filed 10–23–01; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Wednesday,
October 24, 2001

Part III

Department of Housing and Urban Development

24 CFR Parts 200 and 203

Single Family Mortgage Insurance; Section 203(k) Consultant Placement and Removal Procedures; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 200 and 203

[Docket No. FR–4592–P–01]

RIN 2502–AH51

Single Family Mortgage Insurance; Section 203(k) Consultant Placement and Removal Procedures

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish placement and removal procedures for HUD's list of qualified consultants under the Section 203(k) Rehabilitation Loan Insurance program. The 203(k) Program is the Federal Housing Administration's (FHA's) primary program for the rehabilitation and repair of single family properties. A 203(k) lender may select a qualified independent consultant, who is an expert in the field of home inspection, cost estimating, and construction, to perform various tasks required for the rehabilitation of the property. Presently, there are no regulatory procedures for placing a consultant on, nor for removing a poorly performing consultant from, the list. HUD believes that the establishment of these placement and removal procedures will better protect 203(k) borrowers and lenders and safeguard FHA insurance funds.

DATES: *Comments Due Date:* December 24, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, Room 9266, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–8000; telephone (202) 708–2121 (this is not a toll-free number). Hearing -or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background—The Section 203(k) Rehabilitation Loan Insurance Program

Section 203(k) of the National Housing Act (12 U.S.C. 1709(k)) authorizes HUD to insure loans for the purchase and/or rehabilitation and repair of residential properties. The 203(k) Program is HUD's primary program for the rehabilitation and repair of single family properties. Section 203(k) loan insurance enables homebuyers and homeowners to finance both the purchase (or refinance) of a house and the cost of its rehabilitation through a single mortgage. The regulations implementing the 203(k) Program are located in 24 CFR 203.50 and 24 CFR 203.440 through 203.449. The program is administered by HUD's Office of Single Family Housing-Federal Housing Administration (FHA).

The 203(k) Program fills a unique and important role for homebuyers. In the conventional loan market, a homebuyer who purchases a home that is in need of repair or modernization usually has to follow a complicated and costly process. The homebuyer must obtain financing to purchase the dwelling, additional financing for the rehabilitation work, and a permanent mortgage after rehabilitation is completed to pay off the interim loans. The interim acquisition and improvement loans often have relatively high interest rates and short repayment terms. The 203(k) Program was designed to address this situation. Under this program, a homebuyer may obtain a single loan, at a long-term fixed (or variable) rate, to finance both the acquisition and rehabilitation of the property.

The extent of the rehabilitation covered by 203(k) loan insurance may range from relatively minor (though exceeding $5,000 in cost) to virtual reconstruction. For example, a home that has been demolished, or will be razed as part of rehabilitation, is eligible, provided that some of the existing foundation system remains in place. Section 203(k) loan insurance can also finance the rehabilitation of the residential portion of a property that has non-residential uses. In addition to typical home rehabilitation projects, the 203(k) Program can be used to convert a property of any size to a one-to four-unit dwelling.

HUD requires that properties financed under this program meet certain basic health, safety, energy efficiency and structural standards. All improvements undertaken with loan insurance under the 203(k) Program must comply with the HUD minimum property standards and all local codes and ordinances.

II. 203(k) Consultants

One of the most time consuming and difficult parts of the 203(k) loan process is for the borrower to properly prepare the required cost estimate, work write-up, and architectural exhibits. A borrower using the 203(k) Program may choose to have a qualified independent consultant, who is an expert in the field of home inspection, cost estimating, and construction, perform these tasks. The use of a consultant by the borrower is not required. However, many borrowers elect to use consultants to expedite processing of their 203(k) loans.

Although the borrower determines whether to use a consultant, the lender is solely responsible for selecting the 203(k) consultant and for determining the scope of the work to be performed by the consultant. The consultant must enter into a written agreement with the lender that completely explains what services the consultant will perform for the lender. Consultant fees are set in accordance with HUD's established fee schedule. The lender may require that the borrower enter into a written agreement obligating the borrower to pay for any or all of the consultant fees, whether or not the property is rehabilitated. The fee charged by the consultant may be included in the mortgage as a part of the cost of rehabilitation.

In some cases, the lender may also request a consultant to conduct a preliminary feasibility analysis. The purpose of this analysis is to determine the extent of the rehabilitation work required, a rough cost estimate of the work, and the expected market value of the property after completion of the work. The analysis may be conducted before or after submission of the sales contract to the seller.

The consultant may perform the required draw inspections for the release of funds during the construction period. The lender may also have the consultant conduct the plan review to ensure that the architectural exhibits are acceptable and comply with all applicable program requirements. HUD notes that the plan review is a mandatory step in the processing of the 203(k) loan. There is no requirement that the consultant conduct the plan review. However, if a consultant is not used to perform this function, the borrower must hire an independent plan reviewer.

HUD, through its four Homeownership Centers (HOCs), maintains lists of qualified consultants

on the applicable HOC internet website. Only those consultants included on a HOC's list of qualified consultants may be employed by the lender as a consultant under the 203(k) Program. Currently, to apply for placement on the list of qualified consultants, a consultant must submit his or her qualifications to the appropriate HOC and demonstrate knowledge of 203(k) Program requirements.

III. This Proposed Rule—Placement and Removal of 203(k) Consultants

A. Placement Procedures

This proposed rule would establish the placement and removal procedures for 203(k) consultants in subpart F to part 200 of the FHA regulations (entitled ''Placement and Removal Procedures for Participation in FHA Programs''). Part 200 (entitled ''Introduction to FHA Programs'') prescribes requirements that apply to several of the FHA programs. The 203(k) consultant placement procedures would be located in a new § 200.191.

The proposed rule would provide that, to apply for placement on the list, a consultant must submit an application (or materials) in a form prescribed by HUD. To be eligible for placement on the list:

1. The consultant must demonstrate to HUD that it has a minimum of three years' experience as a remodeling contractor, general contractor or home inspector. A state license as a state certified engineer or architect may be submitted in lieu of the documentation of the three years' experience.

2. If located in a state that requires the licensing of home inspectors, the consultant would be required to submit proof of such licensing.

3. The consultant must submit a narrative description of the consultant's ability to perform home inspections, prepare architectural drawings, use proper methods of cost estimating and complete draw inspections.

4. The consultant must certify that it has read and fully understands the requirements of the HUD handbook on the 203(k) Program (4240.4), and all Mortgagee Letters and other instructions issued by HUD relating to the 203(k) Program. Copies of HUD Handbook 4240.4 and the HUD Mortgagee Letters concerning the 203(k) Program may be obtained by accessing the HUD internet Web site at *http://www.hud.gov.*

5. The consultant must not be listed on the General Service Administration's Suspension and Debarment List, HUD's Limited Denial of Participation List, or HUD's Credit Alert Interactive Voice Response System.

HUD also intends to develop a formal comprehensive examination on the 203(k) Program, which consultants would be required to pass before placement on the list. Consultants included on the list on the date this examination is enacted would have until 6 months following this date to pass the comprehensive test. Failure of the 203(k) consultant to pass the examination by the deadline date would constitute cause for removal from the list.

The inclusion of a consultant on the list means only that the consultant has met the qualifications and conditions prescribed by the Secretary for placement on the list of consultants qualified for the 203(k) Program. The inclusion of a consultant on the list does not create or imply a warranty or endorsement by HUD of the consultant, nor does it represent a warranty of any work performed by the consultant.

B. Removal Procedures

This proposed rule would also establish regulatory standards for the removal of a poorly performing consultant from the list. HUD has determined that regulatory removal procedures are necessary to better protect 203(k) lenders and safeguard FHA insurance funds. The proposed removal procedures are largely modeled on the existing and successful procedures for the removal of appraisers from the FHA Appraiser Roster (see the final rule published on April 3, 2000 (66 FR 17974)).

These procedures would supplement HUD's existing debarment, suspension and limited denial of participation remedies. The proposed removal procedure would provide a less lengthy process, and would fully protect the due process rights of consultants. The removal procedures would be located in new § 200.192 of subpart F.

The proposed rule provides that HUD may remove a consultant for any cause that HUD determines to be detrimental to HUD or its programs. Cause for removal includes, but is not limited to:

1. Poor performance on a HUD quality control field review;

2. Failure to comply with applicable regulations or other written instructions or standards issued by HUD;

3. Failure to comply with applicable Civil Rights requirements;

4. Being debarred or suspended, or subject to a limited denial of participation;

5. Misrepresentation or fraudulent statements;

6. Failure to retain standing as a state licensed architect or state-licensed engineer (unless the consultant can demonstrate the required three years' experience as a home inspector or remodeling contractor); or

7. Serving, or having served, as the rehabilitation consultant for properties securing 203(k) mortgages of which a significant percentage are in foreclosure, default or claim status.

8. Failure to respond within a reasonable time to HUD inquiries or requests for documentation.

The removal procedure proposed by this rule would require HUD to give a consultant written notice of a proposed decision to remove the consultant from the list. This notice would state the reasons for, and the duration of, the proposed removal. The consultant would be given not less than 20 days from the date of the removal notice to submit a written response appealing the proposed removal. The consultant would also have the right to submit a written request for a conference along with the written response. This procedure would not be applicable, however, if the consultant has been debarred or suspended or subject to a limited denial of participation.

A HUD official, designated by the Secretary, would review the consultant's appeal and send the consultant a final decision either affirming, modifying, or cancelling the removal from the list. The HUD official designated by the Secretary to review the consultant's appeal would not be someone involved in HUD's initial removal decision. HUD would respond with a decision within 30 days of receiving the appeal or, if the consultant has requested a conference, within 30 days after the completion of the conference. HUD may extend the 30-day period by providing written notice to the consultant.

If the consultant does not submit a timely written response, the removal would become effective 20 days after the date of HUD's initial removal notice (or after a longer period provided in the notice). If the consultant submits a written response, and the removal decision is affirmed or modified, the removal would become effective on the date of HUD's notice affirming or modifying its initial removal decision.

The proposed addition of § 200.192 would not prohibit HUD from debarring, suspending, issuing a limited denial of participation, seeking a false claims action, or taking such other action against a consultant as provided for in 24 CFR part 24 (entitled ''Government Debarment and Suspension and Governmentwide Requirements for Drug-Free Workplace (Grants)''), or from seeking any other remedy against a

consultant available to HUD by statute or otherwise.

A consultant who has been removed from the list may apply for placement on the list after the period for the consultant's removal from the list has expired.

C. Small Business Concerns Related to the Removal of Consultants

With respect to removing a consultant from the list, or taking other appropriate enforcement action against a consultant, HUD is cognizant that section 222 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) (referred to as ''SBREFA'') requires the Small Business and Agriculture Regulatory Enforcement Ombudsman to ''work with each agency with regulatory authority over small businesses to ensure that small business concerns that receive or are subject to an audit, on-site inspection, compliance assistance effort or other enforcement related communication or contact by agency personnel are provided with a means to comment on the enforcement activity conducted by this personnel.'' To implement this statutory provision, the Small Business Administration has requested that agencies include the following language on agency publications and notices that are provided to small businesses concerns at the time the enforcement action is undertaken. The language is as follows:

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 enforcement actions of [insert agency name], call 1–888–REG–FAIR (1–888–734–3247).

As HUD stated in its notice describing HUD's actions on the implementation of SBREFA, which was published on May 21, 1998 (63 FR 28214), HUD intends to work with the Small Business Administration to provide small entities with information on the Fairness Boards and National Ombudsman program, at the time enforcement actions are taken, to ensure that small entities have the full means to comment on the enforcement activity conducted by HUD.

IV. Findings and Certifications

Public Reporting Burden

The information collection requirements contained in this proposed rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and are pending OMB approval. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

The burden of the information collections in this proposed rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Section reference	Number of parties	Number of responses per respondent	Estimated average time for requirement (in hours)	Estimated annual burden (in hours)
200.191 (Consultant Application Package)	2,500	1	4	10,000
200.191(b)(6) (Consultant Proficiency Exam)	2,500	1	36	90,000

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this proposal. Under the provisions of 5 CFR part 1320, OMB is required to make a decision concerning this collection of information between 30 and 60 days after today's publication date. Therefore, a comment on the information collection requirements is best assured of having its full effect if OMB receives the comment within 30 days of today's publication. This time frame does not affect the deadline for comments to the agency on the proposed rule, however. Comments must refer to the proposal by name and docket number (FR–4592) and must be sent to:

Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503;

and

Ethelene Washington, Reports Liaison Officer, Office of the Assistant Secretary for Housing-Federal Housing Commissioner, Department of Housing and Urban Development, 451—7th Street, SW., Room 9114, Washington, DC 20410.

Regulatory Planning and Review

The Office of Management and Budget (OMB) reviewed this rule under Executive Order 12866, *Regulatory Planning and Review*. OMB determined that this rule is a ''significant regulatory action'' as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to this rule as a result of that review are identified in the docket file, which is available for public inspection in the office of the Department's Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410–0500.

Environmental Impact

This proposed rule would establish placement and removal procedures for HUD's list of qualified 203(k) rehabilitation loan consultants. The proposed rule would not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Therefore, in

accordance with 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

Regulatory Flexibility Act

The Secretary has reviewed this proposed rule before publication, and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this proposed rule would not have a significant economic impact on a substantial number of small entities. The reasons for HUD's determination are as follows.

The proposed rule would establish the procedure by which a consultant, who has violated FHA single family mortgage insurance program requirements, may be removed from HUD's list of qualified 203(k) consultants. Accordingly, to the extent that this proposed rule would impact small entities it will be as a result of actions taken by small entities themselves—that is, violation of single family program regulations and requirements.

Further, the proposed rule would provide several procedural safeguards designed to minimize any potential impact on small entities. For example, the rule grants consultants, selected for removal from the list, the opportunity to provide a written response and to request a conference regarding a proposed removal. The rule also specifies that the official designated by HUD to review an appeal may not be the same HUD official involved in the initial removal decision. In addition, the proposed examination requirements would be ''phased-in'' for consultants on the list, and not take effect until six months after the effective date of promulgation. This delayed effective date will provide consultants on the list with additional time to meet the new requirements.

Notwithstanding HUD's determination that this rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This proposed rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance Number for the Section 203(k) Rehabilitation Loan Insurance program is 14.108.

List of Subjects

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Lead poisoning, Loan programs—housing and community development, Minimum property standards, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 203

Hawaiian Natives, Home improvement, Indians—lands, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

Accordingly, for the reasons described in the preamble, HUD proposes to amend 24 CFR parts 200 and 203 as follows:

PART 200—INTRODUCTION TO FHA PROGRAMS

1. The authority citation for 24 CFR part 200 is revised to read as follows:

Authority: 12 U.S.C. 1702–1715z–21; 42 U.S.C. 3535(d).

2. In subpart F as proposed to be added at 66 FR 48082, add a new undesignated centerheading and §§ 200.190 through 200.193 to read as follows:

Subpart F—Placement and Removal Procedures for Participation in FHA Programs

Sec.

Section 203(k) Rehabilitation Loan Consultants

200.190 HUD list of qualified 203(k) consultants.
200.191 Placement of 203(k) consultant.
200.192 Removal of 203(k) consultant.
200.193 Responsibilities of 203(k) consultants on the list.

Section 203(k) Rehabilitation Loan Consultants

§ 200.190 HUD list of qualified 203(k) consultants.

(a) *Qualified consultant list.* HUD maintains a list of qualified consultants for use in the rehabilitation loan insurance program authorized by section 203(k) of the National Housing Act (12 U.S.C. 1709(k)) (referred to as the ''203(k) Program'').

(b) *Consultant functions.* Only a consultant included on the list may be selected by the lender to conduct any consultant function under the 203(k) Program (see § 203.50(l) of this chapter).

(c) *Disclaimer.* The inclusion of a consultant on the list means only that the consultant has met the qualifications and conditions prescribed by the Secretary for placement on the list of consultants qualified for the 203(k) Program. The inclusion of a consultant on the list does not create or imply a warranty or endorsement by HUD of the consultant, nor does it represent a warranty of any work performed by the consultant.

§ 200.191 Placement of 203(k) consultant.

(a) *Application.* To be considered for placement on the list, a consultant must apply to HUD using an application (or materials) in a form prescribed by HUD.

(b) *Eligibility.* To be eligible for placement on the list:

(1) The consultant must demonstrate to HUD that it either:

(i) Has at least three years' experience as a remodeling contractor, general contractor or home inspector; or

(ii) Is a state-licensed architect or state-licensed engineer;

(2) If located in a state that requires the licensing of home inspectors, the consultant must submit proof of such licensing;

(3) The consultant must submit a narrative description of the consultant's ability to perform home inspections, prepare architectural drawings, use proper methods of cost estimating and complete draw inspections;

(4) The consultant must certify that it has read and fully understands the

requirements of the HUD handbook on the 203(k) Program (4240.4) and all HUD Mortgagee Letters (*see http://www.hudclips.org*) and other instructions relating to the 203(k) Program;

(5) The consultant must not be listed on:

(i) The General Service Administration's Suspension and Debarment List;

(ii) HUD's Limited Denial of Participation List; or

(iii) HUD's Credit Alert Interactive Voice Response System;

(6) The consultant must have passed a comprehensive examination on the 203(k) Program, if HUD has developed such an exam.

(c) *Delayed effective date of examination requirement for consultants currently on the list.* Consultants who are included on the list on the date when the requirement for the examination described in paragraph (b)(6) of this section becomes effective have until 6 months following this date to pass the comprehensive exam. Failure to pass the examination by the deadline date constitutes cause for removal under § 200.192.

§ 200.192 Removal of 203(k) consultant.

(a) *Cause for removal.* HUD may remove a consultant from the list for any cause that HUD determines to be detrimental to HUD or its programs. Cause for removal includes, but is not limited to:

(1) Poor performance on a HUD quality control field review;

(2) Failure to comply with applicable regulations or other written instructions or standards issued by HUD;

(3) Failure to comply with applicable Civil Rights requirements;

(4) Being debarred or suspended, or subject to a limited denial of participation;

(5) Misrepresentation or fraudulent statements;

(6) Failure to retain standing as a state licensed architect or state-licensed engineer (unless the consultant can demonstrate the required three years experience as a home inspector or remodeling contractor);

(7) Serving, or having served, as the rehabilitation consultant for properties securing 203(k) mortgages of which a significant percentage are in foreclosure, default or claim status; or

(8) Failure to respond within a reasonable time to HUD inquiries or requests for documentation.

(b) *Procedure for removal.* A consultant that is debarred or suspended, or subject to a limited denial of participation will be automatically removed from the list. In all other cases, the following procedure for removal will be followed:

(1) HUD will give the consultant written notice of the proposed removal. The notice will state the reasons for, and the duration of, the proposed removal.

(2) The consultant will have 20 days from the date of the notice (or longer, if provided in the notice) to submit a written response appealing the proposed removal and to request a conference. A request for a conference must be in writing and must be submitted along with the written response.

(3) A HUD official will review the appeal and send a response either affirming, modifying, or cancelling the removal. The HUD official will not be someone who was involved in HUD's initial removal decision. HUD will respond with a decision within 30 days of receiving the appeal or, if the consultant has requested a conference, within 30 days after the completion of the conference. HUD may extend the 30-day period by providing written notice to the consultant.

(4) If the consultant does not submit a timely written response, the removal will be effective 20 days after the date of HUD's initial removal notice (or after a longer period provided in the notice). If a written response is submitted, and the removal decision is affirmed or modified, the removal will be effective on the date of HUD's notice affirming or modifying the initial removal decision.

(c) *Placement on the list after removal.* A consultant that has been removed from the list may apply for placement on the list (in accordance with § 200.191) after the period of the consultant's removal from the list has expired. An application will be rejected if the period for the consultant's removal from the list has not expired.

(d) *Other action.* Nothing in this section prohibits HUD from taking such other action against a consultant, as provided in 24 CFR part 24, or from seeking any other remedy against a consultant available to HUD by statute or otherwise.

§ 200.193 Responsibilities of 203(k) consultants on the list.

All consultants included on the list are responsible for:

(a) Obtaining and reading the HUD handbook on the 203(k) Program (4240.4) and any updates to the handbook.

(b) Complying with the HUD handbook on the 203(k) Program (4240.4), and any updates to the handbook, when performing any consultant function under the 203(k) Program.

(c) Obtaining and reading all Mortgagee Letters and other instructions issued by HUD relating to the 203(k) Program.

(d) Complying with all Mortgagee Letters and other instructions issued by HUD relating to the 203(k) Program, when undertaking any consultant function under the 203(k) Program.

(e) Complying with HUD's request for documentation relating to any 203(k) project on which the consultant has worked.

(f) Complying with HUD's monitoring requirements relating to the 203(k) Program.

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

3. The authority citation for 24 CFR part 203 continues to read as follows:

Authority: 12 U.S.C. 1709, 1710, 1715b, and 1715u; 42 U.S.C. 3535(d).

4. Add § 203.50(l) to read as follows:

§ 203.50 Eligibility of rehabilitation loans.

* * * * *

(l) *Rehabilitation loan consultants.* HUD maintains a list of qualified consultants, in accordance with §§ 200.190–200.193 of this chapter. The lender may select a consultant on the list to perform one or more of the following tasks:

(1) Conduct a preliminary feasibility analysis before or after the submission of a sales contract;

(2) Prepare the cost estimate, work write-up, and architectural exhibits required for the rehabilitation of the property;

(3) Conduct a plan review; and

(4) Conduct the draw inspections for the release of funds during the construction phase of the project.

Dated: July 12, 2001.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 01–26709 Filed 10–23–01; 8:45 am]

BILLING CODE 4210–27–P

Federal Register

Wednesday,
October 24, 2001

Part IV

Federal Communications Commission

Change in Filing Procedures; Notices

FEDERAL COMMUNICATIONS COMMISSION

[DA 01–2430]

Change in Filing Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces new procedures for all persons wishing to hand-deliver documents at the filing counter of the Federal Communications Commission's (the Commission) Secretary. The new procedures are due to precautionary measures.

DATES: The new procedures were effective on October 17, 2001.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Magalie Roman Salas, Secretary, FCC, (202) 418–0300.

SUPPLEMENTARY INFORMATION: This is a notice for all persons wishing to hand-deliver documents at the filing counter of the Commission's Secretary, located at 445 12th Street, SW., Washington, DC. As a precautionary measure, effective immediately and until further notice, the following procedures are in place:

- The staff at the Secretary's filing counter will not accept documents enclosed in envelopes.
- Any filer or messenger carrying such documents into the Commission's building will be asked to leave the building and dispose of the envelope in a receptacle that will be placed outside the building. Once this is done, the filer or messenger will be allowed to proceed to the filing counter.
- Originals and copies of each official filing must continue to be addressed to the Commission's Secretary and held together with rubber bands or fasteners. As usual, ''stamp and return'' copies will be provided as long as they clearly accompany each individual filing.
- Documents intended to be received by specific staff persons within Bureaus and Offices must be clearly labeled on the first page of the document or with a cover sheet indicating the destination. As appropriate, originals and copies must be held together with rubber bands or fasteners.
- Filings requesting confidential treatment under the Commission's rules must also be filed without envelopes. As long as the request for confidential treatment is clearly indicated on the first page of the filing, the staff at the filing counter will enclose the filing in a Commission envelope labeled ''confidential'' to signal that the filing contains material that is subject to a request for confidential treatment.
- The Office of the Secretary will work with specific Bureaus and Offices, as appropriate, to handle bulk filings in accordance with the precautionary measures described.

As the Commission continues to balance its efforts to be accessible to its customers with the need for heightened security measures, the Commission encourages its customers to make full use of the Commission's electronic filing systems to facilitate the filing of documents.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–26823 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 01–2451]

Clarification on Changes in Filing Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document clarifies two other notices that were published elsewhere in this issue as a result of numerous inquires that the Federal Communications Commission (the Commission) received concerning changes in the filing procedures.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Magalie Roman Salas, Secretary, FCC, (202) 418–0300.

SUPPLEMENTARY INFORMATION: This notice is issued as a result of inquiries that the Commission has received today about the Public Notices issued yesterday announcing changes in filing procedures (DA 01–2430; DA 01–2436).

The Commission clarifies that:

- No hand-delivered or messenger-delivered filings will be accepted today or tomorrow, October 18 and 19, at either 445 12th Street, SW., Washington, DC, or at Capitol Heights, MD. Hand-delivered or messenger-delivered filings will be accepted only at our Capitol Heights, MD, facility beginning Monday, October 22, 2001.
- The due date for any filings due at the Commission on October 18 and October 19, 2001 has been extended to Monday, October 22, 2001. This extension applies to both paper and electronic filings. This determination is consistent with past extensions of time that have been granted due to the Commission's early closing for inclement weather or other extraordinary situations.
- The procedures for filings stated in DA 01–2430, released October 17, 2001, remain in effect. Only the filing location has changed. These procedures stated, among other things, that filings enclosed in envelopes will not be accepted. Therefore, all hand-delivered or messenger-delivered filings at the Capitol Heights, MD, location will not be accepted for filing if they are enclosed in an envelope.
- We remind all parties that the Commission's unique agency zip code ''20554'' cannot be used for documents delivered by entities such as Federal Express or any other express mail service. In these circumstances, you must use the zip code ''20024'' as follows:

Federal Communications Commission, 445 12th Street, SW., Washington, DC 20024.

Filings and other documents sent by United States Postal Service should use the ''20554'' zip code.

The Commission continues to encourage its customers to make full use of the Commission's electronic filing systems to facilitate the filing of documents.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–26822 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 01–2436]

Changes in Filing Location for Paper Documents

AGENCY: Federal Communications Commission

ACTION: Notice.

SUMMARY: This document announces that the Federal Communications Commission (the Commission) will no longer accept hand-delivered or messenger-delivered paper filings at its headquarters location, 445—12th Street, SW., Washington, DC 20554.

DATES: The due date for any filings due at the Commission Thursday, October 18, 2001, or Friday, October 19, 2001, is hereby extended to Monday, October 22, 2001.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Magalie Roman Salas, Secretary, FCC, (202) 418–0300.

SUPPLEMENTARY INFORMATION: On Monday, October 22, 2001, the Commission will resume accepting hand-delivered or messenger-delivered paper filings only at our Capitol Heights facility located at 9300 East Hampton Drive, Capitol Heights, MD 20743. To accommodate this change in location, the time deadline for filing at the Capitol Heights facility is extended hereafter to 9 p.m. Eastern Time. Filings received at the Capitol Heights facility will be date-stamped. Filings made pursuant to 47 CFR 1.13(a) should also be made at the Capitol Heights facility where they will be date and time stamped. Subpoenas directed to the Commission or its employees in their official capacities will be received only at the Capitol Heights facility. The Commission is currently looking for an alternative site in Washington, DC, to accept delivery of filings on a more permanent basis. The public will be notified of that location as quickly as possible.

We encourage our customers to make full use of the Commission's electronic filings systems to facilitate the filing of documents.

Filings and other documents sent to the Commission by United States Postal Service or overnight delivery services should continue to be addressed to the Commission at 445—12th Street, SW., Washington, DC 20554. The Commission itself will divert those deliveries to the Capitol Heights facility.

This notice supersedes any Commission rules permitting the hand filing of documents at the Commission's headquarters.

The Commission finds it necessary at this time to make these changes to its procedures to protect the health and safety of its employees and therefore finds good cause to make them effective as expeditiously as possible in accordance with this notice.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–26824 Filed 10–23–01; 8:45 am]

BILLING CODE 6712–01–P

Federal Register

Wednesday,
October 24, 2001

Part V

The President

Executive Order 13232—Further Amendment to Executive Order 10789, as Amended, To Authorize the Department of Health and Human Services To Exercise Certain Contracting Authority in Connection With National Defense Functions

Federal Register
Vol. 66, No. 206
Wednesday, October 24, 2001

Presidential Documents

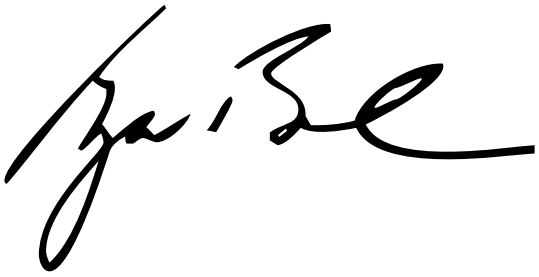
Title 3—

The President

Executive Order 13232 of October 20, 2001

Further Amendment to Executive Order 10789, as Amended, To Authorize the Department of Health and Human Services To Exercise Certain Contracting Authority in Connection With National Defense Functions

By the authority vested in me as President by the Constitution and the laws of the United States of America, including 50 U.S.C. 1431–35, and in order to authorize the Department of Health and Human Services to exercise certain contracting authority in connection with national defense functions, it is hereby ordered that Executive Order 10789 of November 14, 1958, as amended, is further amended by inserting the words ''Department of Health and Human Services'' in the list of departments and agencies in section 21 of that order after the words ''Department of Commerce.''



THE WHITE HOUSE,
October 20, 2001.

[FR Doc. 01–26990
Filed 10–23–01; 11:17 am]
Billing code 3195–01–P

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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H.J. Res. 69/P.L. 107–53

Making further continuing appropriations for the fiscal year 2002, and for other purposes. (Oct. 22, 2001; 115 Stat. 269)

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