

(2) If a crack is indicated but is not visible externally, repeat a visual detailed inspection using 10X magnification at intervals not to exceed 500 landings.

(3) If a crack is visible and is less than .10 inch long, measured from the edge of the countersink, modify in accordance with inspection using 10X magnification at intervals not to exceed 100 landings.

(4) If a crack is visible and is more than .10 inch long measured from the edge of the countersink, modify in accordance with Boeing Service Bulletin 747-53-2253, dated December 14, 1984, or later FAA approved revisions, prior to the next pressurized flight. Inspections in accordance with paragraph B, below, are to continue after modification.

B. For airplanes that have been modified in accordance with Boeing Service Bulletin 747-53-2253, dated December 14, 1984, or later FAA approved revisions: within the next 2,500 landings after the effective date of this AD or prior to the accumulation of 10,000 landings after the modification, whichever is later, and thereafter at intervals not to exceed 5,000 landings, use high frequency eddy-current procedures to inspect for cracking at the fuselage skin lap splice between body stations 340 and 400, of aft as far as the crew door, at stringers S6-L and S6-R, in accordance with Boeing Service Bulletin 747-53-2253, dated December 14, 1984, or later FAA approved revisions. If a crack is found, repair in accordance with an FAA approved method and continue to inspect.

C. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

E. Upon the request of an operator, an FAA Principal Maintenance Inspector subject to prior approval of the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region, may adjust the inspection times specified in this AD, if the request contains substantiating data to justify the change for that operator.

F. Flight cycles during which the cabin pressure differential does not exceed 1.5 psi do not need to be counted when determining the number of landings on an airplane for the inspection requirements of this AD.

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. These documents also may be examined at FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective September 26, 1985.

Issued in Seattle, Washington, on August 12, 1985.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 85-19665 Filed 8-16-85; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 82-CEF-1-AD; Amendment 39-4360]

Airworthiness Directives; Mitsubishi Heavy Industries, Ltd. (MHI) MU-2B, -10, -15, -20, -25, -26, -30, -35, and -36 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction of final rule.

SUMMARY: This action corrects Airworthiness Directive (AD) 82-08-02, Amendment 39-4360 (47 FR 15569), applicable to Mitsubishi Heavy Industries, Ltd. (MHI) MU-2B, -10, -15, -20, -25, -26, -30, -35, and -36 airplanes. This correction is necessary because the identification of the basic model, MU-2B, was inadvertently omitted from the applicability statement when the AD was published in the Federal Register.

EFFECTIVE DATE: August 21, 1985.

FOR FURTHER INFORMATION CONTACT:

Mr. Jerry Sullivan, Aerospace Engineer, Airframe Section, ANM-172W, Western Aircraft Certification Office, Northwest Mountain Region, FAA, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009-2007; Telephone (213) 536-6166.

SUPPLEMENTARY INFORMATION:

Subsequent to the issuance of AD 82-08-02, Amendment 39-4360 (47 FR 15569), applicable to MHI MU-2B, -10, -15, -20, -25, -26, -30, -35, and -36 airplanes, the FAA found that the identification of the basic model, MU-2B, was inadvertently omitted from the applicability statement when the AD was published in the Federal Register. This omission has raised questions as to the applicability of the subject AD. The serial numbers listed in the applicability statement are correct and do include the MU-2B as intended. Since the issuance of AD 82-08-02 the Honolulu Aircraft Certification Office has been closed. Accordingly, Paragraph C is also changed to reflect the current FAA organization. Therefore, action is taken herein to make these corrections. Since this action is clarifying in nature, notice and procedure hereon are unnecessary and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

List of Subjects in 14 CFR Part 39

Air Transportation, Aviation Safety, Aircraft, Safety.

PART 39—[AMENDED]

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By correcting the following AD:

In FR Doc. 82-9667 (47 FR 15569), appearing on page 15569 in the Federal Register of April 12, 1982, make the following corrections:

1. Correct the applicability statement to include the basic model MU-2B, by changing the statement to read as follows:

Mitsubishi Heavy Industries, Ltd. (MHI). Applies to MHI Models MU-2B, -10, -15, -20, -25, -26 (S/N 005 thru 347, except 313 and 321) and MU-2B-30, -35, -36 (S/N 501 thru 696, except S/N 652 and 661) airplanes certificated in any category.

2. Change Paragraph (C) to read as follows:

(C) An alternative means of compliance with this AD may be used when approved by the Manager, Western Aircraft Certification Office, FAA, Northwest Mountain Region, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009-2007.

Issued in Kansas City, Missouri, on August 6, 1985.

Edwin S. Harris,

Director, Central Region.

[FR Doc. 85-19664 Filed 8-16-85; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 73

[Airspace Docket No. 85-AWA-33]

Establishment of Restricted Area R-4009, Thurmont, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Restricted Area R-4009 in the state of Maryland to enhance security and safety at the Naval Support Facility, Thurmont, MD.

EFFECTIVE DATE: 0901 G.m.t., August 29, 1985.

FOR FURTHER INFORMATION CONTACT:

Gene Falsetti, Airspace and Air Traffic Rules Branch (ATO-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW.,

Washington, DC 20591; telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

History

On June 27, 1985, the FAA proposed to amend Part 73 of the Federal Aviation Regulations (14 CFR Part 73) to supplement the special use airspace of Prohibited Area P-40 which is currently in effect at the Naval Support Facility in Thurmont, MD (50 FR 26583). The additional airspace was proposed to have the same lateral dimensions as P-40, i.e., a radius of 3 miles, and vertical limits from 5,000 feet above mean sea level (MSL) (the ceiling of P-40) up to 12,500 feet MSL. The proposal was intended to provide adequate safeguards for aeronautical activity at the Naval Support Facility and to separate nonparticipating traffic from that activity as well as to supplement the security purposes of P-40. The Aircraft Owners and Pilots Association (AOPA) submitted comments suggesting that the proposed special use airspace be reconfigured as follows: AOPA suggested that Prohibited Area P-40 be reduced in lateral size from a 3 to 2-mile radius and that its vertical limit remain the same. Under AOPA's proposal, the new Restricted Area would be established between the 2 and 3-mile radius around P-40 and would extend from the surface up to the vertical limit of P-40. Additionally, the new Restricted Area would lie over P-40 with a lateral limit of 3 NM and extend from 5,000 to 12,500 feet MSL. AOPA's proposal was based on the contention first that their proposed Restricted Area would provide an adequate security buffer, and second, that the charting of the Restricted Area proposed by the FAA, with the same lateral dimensions for P-40 and the overlying Restricted Area, would lead to pilot misunderstanding and confusion. AOPA believed the pilot would not be able to distinguish between the boundaries of the Prohibited and Restricted Area having the exact same lateral dimensions. The FAA does not concur with the AOPA suggestion. A reduction in the lateral limits of the Prohibited Area would be counter to the national security needs associated with P-40. In addition, the establishment of a 1-mile wide Restricted Area around the Prohibited Area provides neither air traffic control nor airspace users any practical or additional degree of access to usable airspace. With respect to charting, P-40 and R-4009 will be distinguished clearly on the chart by the designated numbers and a note indicating that R-4009 overlies P-40 from 5,000 feet MSL up to and including

12,500 feet MSL. Section 73.40 of Part 73 of the Federal Aviation Regulations was republished in Handbook 7400.6A dated January 2, 1985.

The Rule

This amendment to Part 73 of the Federal Aviation Regulations establishes Restricted Area R-4009 in the state of Maryland to enhance security and safety at the Naval Support Facility, Thurmont, MD, and to segregate nonparticipating aircraft from potentially hazardous air operations at the facility. The boundaries of R-4009 will encompass that airspace within a 3 NM radius of the Naval Support Facility. The designated altitudes are from 5,000 feet MSL to 12,500 feet MSL. Operations through or within R-4009 would be subject to prior ATC authorization. Authorizations may be requested from the Washington Air Route Traffic Control Center which serves as both the using and controlling agency.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

In consideration of the national security interest in implementing this rule, I find that good cause exists for making this rule effective on the next charting date.

List of Subjects in 14 CFR Part 73

Aviation safety, Restricted areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is amended, as follows:

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510, 1522; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. Section 73.40 is amended as follows:

R-4009 Thurmont, MD

Boundaries. That airspace within a 3 NM radius of the Naval Support Facility (lat. 39°38'53" N., long. 77°28'01" W.).

Designated altitudes. 5,000 feet MSL to 12,500 feet MSL.

Time of designation. Continuous; Transit may be authorized by Washington ARTCC when conditions permit.

Controlling agency. FAA, Washington ARTCC.

Using agency. FAA, Washington ARTCC.

Issued in Washington, D.C., on August 13, 1985.

James Burns, Jr.,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 85-19695 Filed 8-16-85; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 84C-0098]

Poly(Hydroxyethyl Methacrylate)-Dye Copolymers; Listing of Color Additives for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of the colored polymeric reaction product formed by chemically bonding Reactive Blue No. 4 with poly(hydroxyethyl methacrylate) to produce tinted contact lenses. This action responds to a petition filed by Bausch & Lomb, Inc.

DATES: Effective September 19, 1985, except as to any provisions that may be stayed by the filing of proper objections; objections by September 18, 1985.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5600.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of April 19, 1984 (49 FR 15624), FDA announced that a color additive petition (CAP 4C0179) had been filed by Bausch & Lomb, Inc., Optics Center, P.O.

Box 450, Rochester, NY 14692, proposing that § 73.3121 *Poly(hydroxyethyl methacrylate)-dye copolymers* (21 CFR 73.3121) of the color additive regulations be amended to provide for the safe use of Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-[3-[[4,6-dichloro-s-triazin-2-yl]amino]-4-sulfoanilino]-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499-01-8) chemically bonded to the lens polymer for coloring contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

The colored polymeric reaction product that is the subject of this petition is formed when the dye is bonded with poly(hydroxyethyl methacrylate) on the front surface of a contact lens to form a thin layer of colored polymeric material on that surface. This polymeric material colors the contact lens.

Under the Medical Device Amendments of 1976 (Pub. L. 94-295), a color additive for use in a medical device must be listed when the color additive comes in direct contact with the body for a significant period of time (section 706(a) of the act).

The polymeric reaction product of the reactive dye and poly(hydroxyethyl methacrylate), identified as "poly(hydroxyethyl methacrylate)-dye copolymer" in § 73.3121, is a color additive within the meaning of section 201(t) of the act (21 U.S.C. 321(t)) because it is a substance made by a process of synthesis or similar artifice, and because it is capable of imparting color to food, drugs, cosmetics, or the human body if added or applied thereto. In the use considered here, the reactive dye is merely a starting material and not a color additive subject to section 706 of the act. In the reaction process that occurs in bonding the reactive dye to the poly(hydroxyethyl methacrylate), the reactive dye ceases to exist as a separate entity.

The use of the poly(hydroxyethyl methacrylate)-dye copolymer as a color additive in contact lenses is subject to regulation under section 706(a) of the act. The lenses that have this colored polymeric material on their front surfaces are intended to be placed on the eye for several hours a day, each day, for 1 year or more. The color additive accordingly will come in direct contact with the body for a significant period of time. Consequently, the use of the color additive presented in the petition now before the agency is subject to the statutory listing requirements.

III. Analysis of Data

To establish that the color additive is safe for use in contact lenses, the petitioner submitted various toxicity data. In a primary ocular irritation study in rabbits with saline and cottonseed oil extracts of lens material containing the color additive, neither the saline nor the cottonseed oil extracts of the tinted lens material caused ocular irritation under the conditions of the test. The petitioner also conducted cytotoxicity studies of tinted lens material and of saline and cottonseed oil extracts of the tinted lens material, using L-929 mouse fibroblast cells. In these tests, neither the tinted lens material nor the extracts were cytotoxic.

FDA has concluded, that as a worst case, any material migrating from the color additive in the lens would not pose a greater safety concern than if the estimated maximum amount of reactive dye was placed in the lens unbound, and all of the reactive dye was to migrate into the eye over a 1-year period. The maximum amount of reactive dye available for migration would be equivalent to 50 micrograms of reactive dye starting materials per lens or a total of 270 nanograms per day for both eyes. The petitioner conducted a cytotoxicity study in which serial dilutions of the reactive dye were applied directly to L-929 mouse fibroblast cells. No toxic effect was seen at a concentration approximately 2,500 times the concentration in the eyes if 270 nanograms migrated into the eyes per day.

IV. Conclusion

On the basis of data contained in the petition, and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the proposed use of the reaction product formed by bonding poly(hydroxyethyl methacrylate) with Reactive Blue No. 4 for coloring contact lenses. On this basis also, the agency concludes that this color additive is suitable for its intended use. The agency, therefore, is amending § 73.3121 by adding Reactive Blue No. 4 to this list of reactive dyes in paragraph (a).

In addition, based on relevant data, FDA concludes that the safety margin (difference between the potential exposure to the dye and its highest observed no adverse effect level) is large enough to rule out any need for imposing a limitation on the amount of the color additive that may be present in the lens, beyond the limitation that only that amount necessary to accomplish the intended technical effect may be used. This color additive will also be

subject to the requirement in § 73.3121(b) that the manufacturer wash the lens to remove any unbound reactive dye. On the basis of factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive is not necessary for the protection of the public health.

V. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Assessment

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the *Federal Register* of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(5).

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 18, 1985 file with the Dockets Management Branch (address above) written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objection shall state the issues for the hearing and shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual

information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulations may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Notice of the filing of objections or lack thereof will be published in the Federal Register.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

PART 73—[AMENDED]

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 73 is amended as follows:

1. The authority citation for 21 CFR Part 73 continues to read as follows:

Authority: Secs. 701, 703, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. In § 73.3121 by revising the introductory text of paragraph (a), by removing the word "and" before, and the period after, paragraph (a)(5), and by adding new paragraph (a)(6), to read as follows:

§ 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.

(a) *Identity.* The color additives are formed by reacting one or more of the reactive dyes listed in this paragraph with poly(hydroxyethyl methacrylate), so that the sulfate group (or groups) or chlorine substituent of the dye is replaced by an ether linkage to poly(hydroxyethyl methacrylate). The dyes that may be used along or in combination are

(6) Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-[(4,6-dichloro-s-triazin-2-yl)amino]-4-sulfoanilino]-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499-01-8).

Dated: August 12, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-19672 Filed 8-16-85; 8:45 am]

BILLING CODE 4150-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Hubbard Milling Co., providing for the manufacture of 5-, 10-, and 20-gram-per-pound tylosin premixes used to make completed feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: August 19, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-433-1414.

SUPPLEMENTARY INFORMATION: Hubbard Milling Co., 424 North Front St., Mankato, MN 56001, is the sponsor of a supplement to NADA 48-645 submitted on its behalf by Elanco Products Co. The supplemental NADA provides for the manufacture of new 5- and 20-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1) (i) through (vi). The use of the currently approved 10-gram-per-pound premix is revised to include additional uses in swine, beef cattle, and chickens. The supplemental NADA is approved and the regulations are amended to reflect the approval.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. Section 558.625 is amended by revising paragraph (b)(72) to read as follows:

§ 558.625 Tylosin.

(b) * * *

(72) To 012190: 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

Dated: August 13, 1985.

Marvin A. Norcross,
Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-19675 Filed 8-16-85; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[OW-FRL-2882-3]

Ocean Dumping; Extension of Interim Site Designations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: EPA today extends the interim designation of several existing dredged material disposal sites to allow completion of final rulemaking with full public participation. The interim designations of the following sites are extended until July 31, 1988, or until final rulemaking is completed, whichever is sooner: Portland, ME; San Juan, PR; Wilmington Harbor, NC; Charleston Harbor, SC; Savannah River, GA; Sabine-Neches, TX; Mouth of Columbia River, OR. This action is necessary to provide acceptable ocean dumping sites for the disposal of dredged material essential to maintain navigation until formal rulemaking is completed.

DATES: This action will become effective on August 19, 1985. Comments must be received on or before September 18, 1985.

ADDRESS: Send comments to: Paul Pan, Chief, Environmental Analysis Branch (WH-556M), EPA, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Paul Pan, 202/755-9231.

SUPPLEMENTARY INFORMATION: Section 102(c) of the Marine Protection, Research, and Sanctuaries Act of 1972, as amended, 33 U.S.C. 1401 et seq. ("the Act"), gives the Administrator of EPA the authority to designate sites where ocean dumping may be permitted. On September 19, 1980, the Administrator delegated the authority to designate ocean dumping sites to the Assistant Administrator for Water and Waste Management, now the Assistant Administrator for Water.

The EPA Ocean Dumping Regulations (40 CFR Chapter I, Subchapter H, § 228.4) state that ocean dumping sites will be designated by promulgation in this Part 228. A list of "Approved Interim and Final Ocean Dumping Sites" was published on January 11, 1977 (42 FR 2461 et seq.), was extended on January 16, 1980 (45 FR 3053 et seq.) and December 9, 1980 (45 FR 81042 et seq.), and was subsequently extended on February 7, 1983 (48 FR 5557 et seq.) and August 24, 1984 (49 FR 33647). That list established the Portland, ME; San Juan, PR; Wilmington Harbor, NC; Charleston Harbor, SC; Savannah River, GA; Sabine-Neches, TX; and Mouth of Columbia River, OR, sites as interim sites. The latest notice extended their period of use until July 31, 1985. Today's extension will continue the interim designations for these sites until July 31, 1988, or until final rulemaking is completed, whichever is sooner.

Preparation of Environmental Impact Statements (EIS's) for rulemaking has been completed on all of these sites. Designation of all consent decree sites ["National Wildlife Federation v. Costle," 629 F.2d 118 (D.C. Cir. 1980)] will proceed as expeditiously as possible. EPA cannot promulgate final designations for these sites and allow opportunity for full public participation within the existing deadline of July 31, 1985. The extensive opportunities for public participation are described in greater detail in the February 7, 1983, extension notice. Thirty-six months is a more realistic estimate of the amount of time EPA will need to complete the designation process for all of these sites. EPA expects to finish the designation process earlier for those sites where work is more advanced.

The Corps of Engineers has stated that they know of no adverse environmental impacts or substantive public opposition which would result from continued use of any of these historically used sites.

Continued designation of these interim dredged material disposal sites is necessary to assure the uninterrupted availability of the adjacent harbors to interstate and foreign commerce. These

site designations expired on July 31, 1985. Accordingly, pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), the Agency has determined that notice and public procedure on the interim designations, prior to their extension, is impracticable and contrary to the public interest. However, the Agency solicits public comment on the extension of the interim designations and will address any comments received in the final rulemakings designating these sites. For the same reasons, EPA has determined, pursuant to the Administrative Procedure Act, 5 U.S.C. 553(d)(3), that there is good cause to make this extension effective immediately.

It should be emphasized that, if an ocean dumping site is designated, such a site designation does not constitute or imply EPA's approval of actual disposal of materials at sea. Before ocean dumping of dredged material at the site may commence, the Corps of Engineers must evaluate a permit application according to EPA's ocean dumping criteria. If a Federal project is involved, the Corps must also evaluate the proposed dumping in accordance with those criteria. In either case, EPA has the right to disapprove the actual dumping, if it determines that environmental concerns under the Act have not been met.

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules which may have a significant impact on a substantial number of small entities. EPA has determined that this action will not have a significant impact on small entities since the site designation will only have the effect of providing a disposal option for dredged material. Consequently, this action does not necessitate preparation of a Regulatory Flexibility Analysis.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of \$100 million or more or cause any of the other effects which would result in its being classified by the Executive Order as a "major" rule. Consequently, this action does not necessitate preparation of a Regulatory Impact Analysis.

This action does not contain any information collection requirements subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 228

Water pollution control.

Dated: August 7, 1985.

Henry Longest II,

Acting Assistant Administrator for Water.

In consideration of the foregoing, Subchapter H of Chapter I of Title 40 is amended as set forth below.

PART 228—[AMENDED]

1. The authority citation for Part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

§ 228.12 [Amended]

2. In Part 228, paragraph (a)(1)(ii) of § 228.12 is amended by revising the introductory text and adding paragraphs (K) to (O) to read as follows:

(a) * * *

(1) * * *

(ii) Until such time as formal rulemaking is completed or until July 31, 1988, whichever is sooner:

(K) Portland, ME.

(L) San Juan, PR.

(M) Charleston/Savannah/Wilmington (3 sites): Wilmington Harbor, NC; Charleston Harbor, SC; and Savannah River, GA.

(N) Sabine-Neches, TX (4 sites)

(O) Mouth of Columbia River, OR (5 sites).

[FR Doc. 85-19423 Filed 8-16-85; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 90

[OST Docket No. 43344]

Audits of State and Local Governments

AGENCY: Department of Transportation.

ACTION: Final rule and request for comments.

SUMMARY: This final rule establishes a requirement for all recipients of Department of Transportation (DOT) assistance funds to comply with the requirements of the Single Audit Act of 1984, Pub. L. 98-502, and Office of Management and Budget (OMB) Circular A-128, Audits of State and Local Governments. The OMB Circular A-128 directs agencies to publish regulations implementing it. OMB Circular A-128 is included as an appendix to the basic regulation.

DATES: This rule is effective September 18, 1985. Comments must be received on or before October 18, 1985.